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Presidential Documents

Title 3—

The President

Proclamation 6520 of December 23, 1992

National Good Teen Day, 1993

By the President of the United States of America

A Proclamation

The passage between childhood and adulthood constitutes one of the most eventful stages of our life's journey. The teen years are as challenging as they are exciting, and at a time when young Americans are facing more serious pressures than ever before—from substance abuse and violence to sexual promiscuity and dropping out of school—it is fitting that we set aside this day to reaffirm the unique, God-given potential of every teenager.

Today millions of American teenagers are setting examples for others by demonstrating love and respect for their parents, by meeting their responsibilities at home and in school, by participating in their places of worship, and by showing consideration and concern for their classmates and neighbors. They are also enjoying the rewards of voluntary service to others, thereby contributing to our communities and Nation as Points of Light. These teens are making the most of their talents and opportunities and, through their determination and hard work, are building the foundation for a bright future.

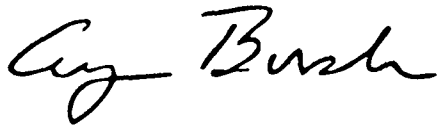
It is vital that we recognize and reinforce good behavior among teens and instill in every child a positive sense of responsibility, self-control, and self-worth. The pursuit of freedom and independence is characteristic of adolescence. Yet, while most adolescents demand increasing autonomy, they also continue to need and seek their parents' reassurance, guidance, and support. For teenagers who are struggling to cope with the many physical and emotional changes of adolescence, as well as the external pressures that weigh so heavily on young people today, such encouragement and guidance are essential. We must provide our teens with opportunity and hope, with firm yet loving moral guidance and discipline, and—most important—with clear, consistent examples of personal responsibility and virtue.

No child is destined to become a "bad teen." Through loving, responsible parenting and through the support of schools, churches, and communities that set high standards of character and conduct for people of all ages, we can help every young American to recognize and attain his or her fullest potential. On this occasion, let us resolve to do exactly that.

The Congress, by House Joint Resolution 409, has designated January 16, 1993, as "National Good Teen Day" and has authorized and requested the President to issue a proclamation in observance of this day.

NOW, THEREFORE, I, GEORGE BUSH, President of the United States of America, do hereby proclaim January 16, 1993, as National Good Teen Day. I invite all Americans to observe this day with appropriate programs and activities in honor of America's teenaged citizens.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-third day of December, in the year of our Lord nineteen hundred and ninety-two, and of the Independence of the United States of America the two hundred and seventeenth.



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Presidential Documents

Proclamation 6521 of January 4, 1993

National Sanctity of Human Life Day, 1993

By the President of the United States of America

A Proclamation

Americans have demonstrated their commitment to the belief "that all men are created equal, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty and the pursuit of Happiness." This tradition of generosity and reverence for human life stands in marked contrast with the prevalence of abortion in America today—some 1.5 million children lost each year; more than 4,000 each day. This is shocking evidence of just how far we have strayed from our Nation's most cherished values and beliefs. Thus we pause on this National Sanctity of Human Life Day to call attention to the tragedy of abortion and to recognize the many individuals who are working to restore respect for human life in our Nation.

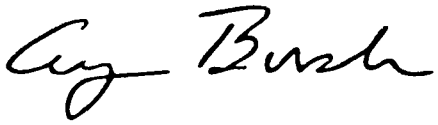
Advances in science and technology have offered us tremendous new insight on life in the womb: parents can now hear their unborn child's heartbeat as early as 8 weeks of age; physicians can monitor the baby's development using high-resolution sonography; and they may even diagnose and treat abnormalities before birth. How terribly ironic it is that, at one hospital or clinic, an unborn child may be carefully treated as a patient, while at another facility—perhaps just a few blocks away—another innocent child may become a victim of abortion.

Recognizing the tragedy of abortion and the feelings of desperation that lead some women to make such a painful, devastating choice, concerned individuals throughout the United States are working to help women choose life for their unborn children. On this occasion we recognize the many generous Americans who—with nothing to gain for themselves—reach out to women in need through crisis pregnancy centers, residential facilities, mentoring programs, and a host of other support services. We also recognize the many social services professionals, attorneys, and counselors who assist in promoting the adoption option, and we salute each of the courageous women who make this unselfish choice for their children. Such works of generosity and compassion are saving lives and, yes, slowly but surely turning hearts—one woman, one couple, one community at a time.

The struggle to overcome abortion in the United States—to educate individuals about life in the womb, to restore reverence for the miracle of creation, and to expand alternatives for women in need—is far from ended. While the struggle may be a long and difficult one, many Americans know that it is a cause from which we cannot retreat. And because it is a cause that appeals directly to the conscience of the Nation—a Nation that has, time and again, demonstrated its capacity to rediscover its highest ideals, ideals rooted in our belief in the God-given rights and dignity of every human being—it is a cause that cannot fail.

NOW, THEREFORE, I, GEORGE BUSH, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim Sunday, January 17, 1993, as National Sanctity of Human Life Day. I call on all Americans to reflect on the sanctity of human life in all its stages and to gather in homes and places of worship to give thanks for the gift of life and to reaffirm our commitment to respect the life and dignity of every human being.

IN WITNESS WHEREOF, I have hereunto set my hand this fourth day of January, in the year of our Lord nineteen hundred and ninety-three, and of the Independence of the United States of America the two hundred and seventeenth.



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Rules and Regulations

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Part 100

[INS No. 1511-92]

RIN 1115-AC95

Statement of Organization; Name Change for Border Patrol Stations in Sector Number 2

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Final rule.

SUMMARY: This final rule amends 8 CFR 100.4 by revising the names of stations located in Border Patrol sector headquarter's number 2 from "Malone, New York" to "Burke, New York", from "Rouses Point, New York" to "Champlain, New York", and from "Derby Line, Vermont" to "Newport, Vermont". These changes are necessary to show the actual city in which these Border Patrol stations are physically located.

EFFECTIVE DATE: January 6, 1993.

FOR FURTHER INFORMATION CONTACT: Marion E. Moody, Assistant Chief Patrol Agent, Border Patrol, Immigration and Naturalization Service, 425 I Street, NW., room 7227, Washington, DC 20536, telephone (202) 514-1109.

SUPPLEMENTARY INFORMATION: 8 CFR 100.4 is being amended to change the names of three Border Patrol stations located in sector headquarters number 2 from "Malone, New York" to "Burke, New York", from "Rouses Point, New York" to "Champlain, New York", and from "Derby Line, Vermont" to "Newport, Vermont", to show the actual city in which these Border Patrol stations are located.

The Service's implementation of this rule as a final rule is based upon 5 U.S.C. 553 (b)(A) as it is a rule of agency organization. The immediate implementation of this final rule is based upon the "good cause" exception found at 5 U.S.C. 553 (d) in that the usual notice provisions are unnecessary because the rule will benefit the public by showing the actual city in which these Border Patrol stations are physically located.

In accordance with 5 U.S.C. 605(b), the Commissioner of the Immigration and Naturalization Service certifies that this rule does not have a significant adverse economic impact on a substantial number of small entities. This rule is not considered to be a major rule within the meaning of section 1(b) of E.O. 12291, nor does this rule have Federalism implications warranting the preparation of a Federalism Assessment in accordance with E.O. 12612.

List of Subjects in 8 CFR Part 100

Authority delegation (Government agencies), Organization and functions (Government agencies).

Accordingly, part 100 of chapter I of title 8 of the Code of Federal Regulations is amended as follows:

PART 100—STATEMENT OF ORGANIZATION

1. The authority citation for part 100 continues to read as follows:

Authority: 8 U.S.C. 1103; 8 CFR part 2.

§ 100.4 [Amended]

2. In § 100.4, paragraph (d) is amended by revising the border patrol station names in Sector No. 2:

a. From "Derby Line, VT" to read: "Newport, VT";

b. From "Malone, NY" to read: "Burke, NY"; and

c. From "Rouses Point, NY" to read: "Champlain, NY".

Dated: December 21, 1992.

Gene McNary,

Commissioner, Immigration and Naturalization Service.

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FEDERAL RESERVE SYSTEM

12 CFR Part 225

[Regulation Y; Docket No. R-0755]

Review Criteria for Bank Holding Company Applications

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board is amending its Regulation Y to implement certain regulatory improvements contained in sections 202(d) and 210 of the Federal Deposit Insurance Corporation Improvement Act of 1991 (FDICIA). The final rule specifies additional factors that the Federal Reserve System must consider in acting on applications by bank holding companies to acquire banks under section 3 of the Bank Holding Company Act. The intended effect of the amendment is to conform the Board's regulations to the statutory changes.

EFFECTIVE DATE: February 4, 1993.

FOR FURTHER INFORMATION CONTACT: Scott G. Alvarez, Associate General Counsel (202-452-3583), or Brian E.J. Lam, Attorney (202-452-2067), Legal Division; or Sidney M. Sussan, Assistant Director (202-452-2638), Division of Banking Supervision and Regulation, Board of Governors of the Federal Reserve System. For the hearing impaired only, Telecommunications Device for the Deaf (TDD), Dorothea Thompson (202-452-3544), Board of Governors of the Federal Reserve System, 20th and C Street, NW., Washington, DC 20551.

SUPPLEMENTARY INFORMATION: The Board is adopting a final rule that revises its Regulation Y to include new supervisory factors that FDICIA requires the Board to consider in reviewing and acting on applications by bank holding companies to acquire banks under section 3 of the Bank Holding Company Act (BHC Act). These changes are required by sections 202(d) and 210 of FDICIA, Public Law 102-242, 105 Stat. 2237, 2290, 2298. On April 15, 1992, the Board adopted an interim rule that implemented sections 202(d) and 210 of FDICIA, and requested public comment on the revision to Regulation Y. 57 FR 13002, April 15, 1992. The public comment period expired on June 15, 1992.

Section 202(d) of FDICIA provides that the Board must disapprove an application under section 3 of the BHC Act if;

(1) The bank holding company fails to provide the Board with adequate assurances that it will make available to the Board such information on its operations or activities, and the operations or activities of any affiliates, as the Board deems appropriate to determine and enforce compliance with BHC Act; or

(2) In the case of an application involving a foreign bank, the foreign bank is not subject to comprehensive supervision or regulation on a consolidated basis by the appropriate authorities in the bank's home country. Public Law 102-242, 105 Stat. 2237, 2290. Section 210 of FDICIA also provides that the Board's consideration of the managerial resources of a bank holding company or bank shall include consideration of the competence, experience and integrity of the officers, directors and principal shareholders of the bank holding company or bank. Public Law 102-242, 105 Stat. 2237, 2298.

The Board is adopting a final rule substantially as proposed. The final rule adopts the statutory language contained in sections 202(d) and 210 of FDICIA, specifying that, in deciding applications under section 3 of the BHC Act, the Board will consider the competence, experience, and integrity of the officers, directors, and principal shareholders of the applicant, and of the banks and bank holding companies concerned, their record of compliance with applicable laws and regulations, and the record of the applicant and its affiliates of fulfilling any commitments to, and any conditions imposed by, the Board in connection with prior applications.[1] In addition, the final rule adopts a definition of "principal shareholder."[2]

The Board will also consider whether the applicant has provided the Board with adequate assurances that it will make available such information on its operations or activities, and the operations or activities of any affiliate of the applicant, that the Board deems appropriate to determine and enforce compliance with the BHC Act and other applicable federal banking statutes, and any regulations thereunder. Moreover, in the case of an application involving a foreign banking organization, the Board will consider whether the organization is subject to comprehensive supervision or regulation on a consolidated basis by the appropriate authorities in the organization's home country.

The final rule is being adopted in conjunction with the Board's implementation of the Foreign Bank Supervision Enhancement Act of 1991 (FBSEA), subtitle A of title II of FDICIA, which changed the authority of the Board under the International Banking Act of 1978. FBSEA provided the Board with new authority to approve the establishment of U.S. offices by a foreign bank, and to regulate and supervise the operations of a foreign bank with U.S. offices.

The Board anticipates that the final rule will not impose any significant additional burdens on domestic banking organizations or financial institutions because the Board currently seeks, and has generally been able to obtain, from domestic applicants all of the information needed to consider section 3 applications. The Board is not proposing to seek any additional types or quantities of information from domestic applicants by virtue of the final rule. The final rule ensures that the Board is able to obtain from all applicants, especially foreign applicants operating in jurisdictions that limit or prohibit the disclosure of financial information outside of the jurisdiction, the same type of information that the Board now seeks and typically obtains from domestic applicants.

Comments

In response to its request, the Board received four comments. Two commenters, a Federal Reserve Bank and a banking organization, favor the adoption of the interim rule as a final rule. Another commenter, a foreign bank, supports the goal of strengthening the applications process under the BHC Act, and agrees that the competence, experience and integrity of the officers and directors of banks and bank holding companies should be considered, as required by section 210 of FDICIA. This commenter, however, suggests that the Board should not consider the competence and experience of shareholders where such shareholders are passive investors that do not anticipate any significant involvement in the management of the bank or the bank holding company.

Section 210 expressly provides that the Board's consideration of the managerial resources of a bank or bank holding company include consideration of the competence, experience, and integrity of the officers, directors, and principal shareholders of the company or bank. Thus, the text of section 210 directs the Board to consider all three managerial factors with respect to all three groups of individuals.

However, the Board believes that the statutory language does not prevent the Board from considering the extent of the role a principal shareholder may play in the management of a bank or a bank holding company when evaluating the competence or experience of the shareholder. An underlying purpose of section 210 is to permit the Board to consider the abilities of the principal shareholders of banks and bank holding companies in appropriate situations, including situations where a principal shareholder has or could have a significant effect on the financial and managerial resources, future prospects, or safety and soundness of a bank or bank holding company. Thus, the Board could consider whether a shareholder proposes to be a passive investor in weighing the shareholder's banking experience and competence.

The final commenter, a banking association, suggests that, in reviewing applications submitted by domestic bank holding companies, the Board not

[1] The Board's regulations currently provide that, in considering applications under section 3 of the BHC Act, the Board will consider the records of the applicant, its subsidiaries, any banks related to the applicant through common ownership or management, and the bank or banks to be acquired, of complying with applicable laws and regulations, and their record of fulfilling any commitments to, and any conditions imposed by, the Board in connection with prior applications. *See* 12 CFR 225.13(b)(2). These provisions will remain unchanged in the final rule.

[2] Regulation Y currently includes a definition of "principal shareholder" that is used in determining the Board's presumption of control of a financial institution or banking organization, and in the Board's Capital Adequacy Guidelines. In order to avoid confusion and to maintain consistency between the statutory language of FDICIA and the implementing provisions of Regulation Y, the Board has redesignated the current term "principal shareholder" as "controlling shareholder", and has added a new definition of the term "principal shareholder" that applies strictly to the standards the Board must review under the FDICIA amendments to the BHC Act. Thus, in the final rule, the term "controlling shareholder" means any person that owns or controls, directly or indirectly, 25 percent or more of any class of voting securities of a bank or other company. Corresponding changes have been made in the Board's regulations regarding presumptions of control, and in the Board's Capital Adequacy Guidelines. The term "principal shareholder" has been redefined for purposes of implementing the FDICIA provisions to mean any person that owns or controls, directly or indirectly, 10 percent or more of any class of voting securities of a bank or other company, or any person that the Board determines has the power to exercise, directly or indirectly, a controlling influence over the management or policies of a bank or other company. The Board believes that the managerial qualities of all major shareholders (*i.e.*, shareholders controlling 10 percent or more of any class of voting securities) should be considered in appropriate situations. This is the level of ownership at which shareholder review is conducted under the Change in Bank Control Act, 12 U.S.C. 1817(j). As discussed in the preamble, the Board will consider the actual or anticipated role of a principal shareholder in the management of a bank in evaluating the competence, experience and integrity of that individual.

require domestic applicants to provide information on their respective operations and activities, and the operations and activities of their affiliates. This commenter asserts that the text and placement of section 202(d) of FDICIA, its legislative history, and other legal and practical considerations all support exempting domestic banks and bank holding companies from this requirement.

The Board has considered these comments and concluded that domestic bank holding companies should not be exempted from the requirement that, when submitting section 3 applications, they provide the Board with adequate assurances that they will make available appropriate information to the Board. By its express terms, section 202(d) requires the Board to disapprove *any* application by *any* bank holding company under section 3 of the BHC Act if the company fails to provide adequate assurances that the company will make available to the Board such information on the operations or activities of the company or any affiliate of the company. In drafting section 202(d), Congress expressly limited the application of certain other provisions of that section to foreign banks, without imposing a similar limitation on the "availability of information" provision. Moreover, the legislative history of section 202(d) expressly indicates that this requirement is applicable to domestic bank holding companies.[3] Thus, in light of the statutory language and the legislative history of section 202(d), the Board has concluded that the availability of information provision should apply to domestic bank holding companies.

[S]ection 202(d) amends the BHC Act to permit the Board to disapprove *any application* to acquire a U.S. bank unless the Board is given adequate assurances that it will have access to information on the operations or activities of a company or companies, or any affiliates, making application to acquire a U.S. bank that the Board deems necessary to fulfill the requirements of the [International Banking Act], the BHC Act, or the [Financial Institutions Supervisory Act of 1966]. *This requirement applies to applications by both foreign banking organizations and domestic bank holding companies.*

H.R. Rep. No. 157, 102nd Cong., 1st Sess. 159 (1991) (emphasis added); *see also* Section-By-Section Analysis Of S. 543 As Reported By The Senate Banking Committee, *reprinted in* 138 Cong. Rec. 2059, 2094 (February 21, 1992) (noting that the availability of information provision "applies to applications by both foreign banking organizations and domestic bank holding companies").

The Board does not believe, however, that the final rule will impose a significant additional burden on domestic applicants because the Board currently seeks and typically is able to obtain from such applicants all of the information needed to consider section 3 applications. The Board does not expect or propose, following adoption of this final rule, to seek additional types or quantities of information from domestic applicants than the Board currently seeks from these applicants.

The commenter also suggests that the Board should require domestic banks and bank holding companies to provide information on an affiliate only if the affiliate either transacts business with the bank that goes beyond ordinary deposit or loan services, or exposes the bank to substantial risk. Based on the express language and legislative history of section 202(d), which both refer to "any affiliates" of the applicant, the Board also has concluded that applicants should provide the necessary assurances with regard to all affiliates, not just affiliates that transact business with a bank that goes beyond ordinary deposit or loan services or that exposes a bank to substantial risk.

However, under section 202(d) and the final rule, the Board retains discretion to determine on a case-by-case basis the extent that assurances are needed for affiliates under common control of individuals. The Board does not believe that, in light of the language and purpose of section 202(d) of FDICIA, it is appropriate to provide a general regulatory exemption for all or most companies affiliated through individual owners.

Finally, the commenter urges the Board not to require banks, bank holding companies and their affiliates to provide information that is deemed to be privileged or confidential under applicable federal or state laws. No such exception appears to have been contemplated by section 202(d). The Board believes that, in certain circumstances, it may be appropriate for the Board to request, and for applicants to provide, information which may be deemed privileged or confidential. The Board can and will, however, afford this information confidential treatment as provided in the Freedom of Information Act. Accordingly, the Board believes that it is not appropriate to adopt a regulatory provision limiting the Board's ability to request or obtain relevant confidential or privileged information.

For all of the foregoing reasons, the Board has concluded that the availability of information provision of the interim rule should remain unchanged in the final rule.

Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act, the Board hereby certifies that the final rule will not have a significant impact on a substantial number of small entities.

The final rule imposes the minimum burdens necessary to implement the provisions of sections 202(d) and 210 of FDICIA for all banks and bank holding companies subject to the regulation, regardless of size. The regulation specifies additional factors which the Board must consider in acting on applications by bank holding companies to acquire banks under section 3 of the BHC Act. The final rule does not impose any additional regular recordkeeping, reporting or other similar requirements on banks.

List of Subjects in 12 CFR Part 225

Administrative practice and procedure, Banks, Banking, Federal Reserve System, Holding companies, Reporting and recordkeeping requirements, Securities.

For the reasons set forth in the preamble, and pursuant to the Board's authority under section 5(b) of the Bank Holding Company Act of 1956, 12 U.S.C. 1844(b), the Board amends part 225 of Chapter II of Title 12 of the Code of Federal Regulations as follows:

PART 225—BANK HOLDING COMPANIES AND CHANGE IN BANK CONTROL

1. Section 225.2 is amended by revising the text of paragraph (k) as follows:

§ 225.2 Definitions.

* * * * *

(k)(1) *Controlling shareholder* means a person that owns or controls, directly or indirectly, 25 percent or more of any class of voting securities of a bank or other company.

(2) *Principal shareholder* means a person that owns or controls, directly or indirectly, 10 percent or more of any class of voting securities of a bank or other company, or any person that the Board determines has the power, directly or indirectly, to exercise a controlling influence over the management or policies of a bank or other company.

* * * * *

[3] For example, the Report of the House Committee on Banking, Finance and Urban Affairs states:

2. Section 225.13 is amended by revising paragraphs (a) and (b)(2) to read as follows:

§ 225.13 Factors considered in acting on bank applications.

(a) *Prohibited anticompetitive transactions.* As specified in section 3(c) of the BHC Act, the Board may not approve any application under this subpart if:

(1) The transaction would result in a monopoly or would further any combination or conspiracy to monopolize, or to attempt to monopolize, the business of banking in any part of the United States;

(2) The effect of the transaction may be substantially to lessen competition in any section of the country, tend to create a monopoly, or in any other manner be in restraint of trade, unless the Board finds that the transaction's anticompetitive effects are clearly outweighed by its probable effect in meeting the convenience and needs of the community;

(3) The applicant has failed to provide the Board with adequate assurances that it will make available such information on its operations or activities, and the operations or activities of any affiliate of the applicant, that the Board deems appropriate to determine and enforce compliance with the BHC Act and other applicable federal banking statutes, and any regulations thereunder; or

(4) In the case of an application involving a foreign bank, the foreign bank is not subject to comprehensive supervision or regulation on a consolidated basis by the appropriate authorities in its home country, as provided in § 211.24(c)(1)(ii) of the Board's Regulation K (12 CFR 211.24(c)(1)(ii)).

(b) * * *

(2) *Managerial Resources.* The competence, experience, and integrity of the officers, directors, and principal shareholders of the applicant, its subsidiaries, and the banks and bank holding companies concerned; their record of compliance with laws and regulations; and the record of the applicant and its affiliates of fulfilling any commitments to, and any conditions imposed by, the Board in connection with prior applications.

* * * * *

3. Section 225.31 is amended by revising paragraph (d)(2)(ii) to read as follows:

§ 225.31 Control proceedings.

(d) * * *

(2) * * *

(ii) *Shares controlled by company and associated individuals.* A company that, together with its management officials or controlling shareholders (including members of the immediate families of either as defined in 12 CFR 206.2(k)), owns, controls, or holds with power to vote 25 percent or more of the outstanding shares of any class of voting securities of a bank or other company controls the bank or other company, if the first company owns, controls, or holds with power to vote more than 5 percent of the outstanding shares of any class of voting securities of the bank or other company.

* * * * *

4. Appendix B is amended by revising footnote 1 to read as follows:

Appendix B to Part 225—Capital Adequacy Guidelines for Bank Holding Companies and State Member Banks: Leverage Measure

* * * * *

[1] The guidelines will apply to bank holding companies with less than $150 million in consolidated assets on a bank-only basis unless:

(1) The holding company or any nonbank subsidiary is engaged directly or indirectly in any nonbank activity involving significant leverage or

(2) The holding company or any nonbank subsidiary has outstanding significant debt held by the general public. Debt held by the general public is defined to mean debt held by parties other than financial institutions, officers, directors, and controlling shareholders of the banking organization or their related interests.

* * * * *

By order of the Board of Governors of the Federal Reserve System, December 29, 1992.

William W. Wiles,

Secretary of the Board.

[FR Doc. 92-32 Filed 1-5-93; 8:45 am]

BILLING CODE 6210-01-F

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

12 CFR Part 567

[No. 92-539]

RIN 1550-AA50

Valuation and Regulatory Capital Treatment of Foreclosed Assets

AGENCY: Office of Thrift Supervision, Treasury.

ACTION: Final rule.

SUMMARY: The Office of Thrift Supervision (OTS) is revising its policy guidance to require savings associations to use fair value rather than net realizable value (NRV) for valuing foreclosed assets subsequent to acquisition. The OTS is also amending its capital regulation to place all assets previously assigned to the 200 percent risk-weight category, including foreclosed assets, into the 100 percent risk-weight category. The accounting change will make the accounting treatment of foreclosed assets consistent with generally accepted accounting principles as applied by the other Federal banking agencies. The capital rule change will make the capital treatment of certain items, including foreclosed assets, consistent with the new accounting treatment and with the treatment accorded these assets by the other Federal banking agencies.

EFFECTIVE DATE: December 31, 1992.

FOR FURTHER INFORMATION CONTACT: Robert J. Fishman, Program Manager, (202) 906-5672, Deidre G. Kvartunas, Program Analyst, (202) 906-7933, Timothy J. Stier, Deputy Chief Accountant (202) 906-5699, Policy; Catherine A. Shepard, Senior Attorney, Regulations and Legislation Division, Office of Chief Counsel (202) 906-7275; Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION:

I. Background and Summary of Proposal

On October 7, 1992, the OTS published a proposal to modify its classification, valuation, and regulatory capital treatment of troubled, collateral-dependent loans and foreclosed assets.[1] The OTS proposed three new policies:

(a) The use of fair value instead of net realizable value for the valuation of troubled, collateral-dependent loans and foreclosed assets;

(b) A requirement to use charge-offs instead of specific valuation allowances (SVAs) for amounts classified "loss"; and

(c) The removal of the 200 percent risk-weight category, and the reassignment of items formerly in that category to the 100 percent risk-weight category for capital purposes.[2]

The purposes of the proposal were to conform OTS's accounting treatment for troubled, collateral-dependent loans and foreclosed assets with that of the other Federal banking agencies and to amend its capital regulations to be consistent with the change in valuation

[1] 57 FR 46,096 (Oct. 7, 1992).

[2] Three types of assets are currently placed in the 200 percent risk-weight category under the OTS's risk-based capital rule: (1) Repossessed (or foreclosed) assets; (2) assets that are more than 90 days past due (except 1-4 family residential real estate that is more than 90 days past due, which is placed in the 100 percent risk-weight category); and (3) equity investments that OTS determines to have the same risk characteristics as real estate owned. 12 CFR 567.6(a)(1)(v).

methodology. The OTS intended that the proposed changes in valuation methodology would be reflected in agency guidance such as a Thrift Bulletin or instructions to the Thrift Financial Report. The requirement that charge-offs be used instead of SVAs and the removal of the 200 percent risk-weight category were to be accomplished through amendment of the agency's regulations.

II. Summary of Comments

The OTS received thirty-one comment letters on its proposal. Commenters included twenty-three savings associations, five financial institution trade associations, a bank holding company with a savings bank subsidiary, an accounting trade association, and an individual. As discussed in Section III below, today's final action addresses only the accounting treatment for foreclosed assets and the accompanying amendment to the capital rule. Comments addressing the use of fair value for troubled, collateral-dependent loans will be summarized and discussed when the agency issues its final guidance on that issue. Similarly, comments addressing the use of charge-offs instead of SVAs will be summarized and discussed in any final regulation on that issue.

Only ten commenters addressed whether the OTS should revise its guidance on foreclosed assets to require savings associations to value such assets at their fair value. All ten commenters supported the proposed change. Twenty of the commenters discussed the OTS's proposal to amend the risk-based capital rules by eliminating the 200 percent risk-weight category and placing foreclosed assets in the 100 percent risk-weight category. In light of the proposed changes in valuation for these assets, all twenty commenters supported this portion of the proposal without modification.

III. Description of Final Guidance and Regulation

The OTS has decided to finalize only part of its October proposal. First, the OTS is requiring that, as of December 31, 1992, savings associations use fair value for the valuation of all foreclosed assets. Second, today's final rule removes the 200 percent risk-weight category and reassigns all assets in that category to the 100 percent risk-weight category. The OTS is postponing to a later date final action on the application of fair value to troubled collateral-dependent loans and on revising its regulations on the use of charge-offs instead of SVAs. Final guidance will address both troubled collateral-dependent loans and foreclosed assets.[3]

A. Foreclosed Assets

The OTS is revising its policy on foreclosed assets, including repossessed real estate. Under the new policy, after foreclosure, foreclosed assets must be carried at the lower of cost or fair value,[4] based on the presumption that such assets are held for sale. The cost of such assets at the time of foreclosure is the fair value of the assets foreclosed. This policy also applies to in-substance foreclosures.

This policy accords with the Statement of Position (SOP) 92–3, "Accounting for Foreclosed Assets," issued by the American Institute of Certified Public Accountants. Under the SOP, there is a rebuttable presumption that foreclosed assets are held for sale. The SOP recommends that foreclosed assets held for sale be carried at the lower of: (a) Fair value minus estimated costs to sell, or (b) cost. While the SOP mandates the use of fair value for foreclosed assets in annual financial statements for periods ending on or after December 15, 1992, all savings associations, regardless of when their fiscal years end, must use the fair value method in all regulatory reports prepared for periods ending on or after December 31, 1992.

B. Removal of 200 Percent Risk-Weight Category

The OTS is also amending its risk-based capital rule, 12 CFR 567.6(a)(1)(v), to lower from 200 percent to 100 percent the risk-weight on all assets currently assigned to the 200 percent category. This amendment is consistent with the fair value accounting treatment adopted today. When the capital rules were promulgated in 1989, repossessed assets were assigned a 200 percent risk-weight because a savings association could carry such assets at the lower of cost or NRV.[5] Since the OTS is today eliminating the use of NRV in favor of fair value, it is appropriate to remove foreclosed assets from the 200 percent risk-weight category. Accordingly, foreclosed assets will be assigned a risk-weight of 100 percent.

The OTS's current capital rule also places all loans that are 90 days or more past due in the 200 percent risk-weight category except for 1 to 4 family residential mortgages, which are in the 100 percent risk-weight category. This risk-weighting treatment was intended to minimize any disincentive under the capital rules for thrifts to foreclose on properties. In recognition of the change in the risk-weight category for foreclosed assets, the OTS is also revising its capital rule to place loans 90 days or more past due in the 100 percent risk-weight category.[6]

C. Effective Date

Both of the actions taken today—the risk-weighting change to the OTS's capital regulations and the revision to OTS guidance on the valuation of foreclosed assets—are effective as of December 31, 1992. Regulatory reports prepared for periods ending on or after December 31, 1992, must, accordingly, reflect both changes. Neither of these actions is subject to the delayed effective date provision of the Administrative Procedure Act (APA).

The APA permits a regulation that relieves a restriction to become effective without a 30-day delay in its effective date. 5 U.S.C. 553(d)(1). The placement of assets formerly in the 200 percent risk-weight category into the 100 percent category falls within this exception. Accordingly, its effective date will not be delayed.

The OTS's revisions to its policy governing the valuation of foreclosed assets are subject to the APA provision authorizing interpretive rules and statements of policy to become effective without delay. 5 U.S.C. 553(d)(2). In addition, the OTS finds that good cause exists for its guidance on the valuation of foreclosed assets to take immediate effect.[7] SOP 92–3, "Accounting for Foreclosed Assets," must be applied by savings associations in preparing their annual financial statements for periods ending on or after December 15, 1992. The majority of, but not all, savings associations have calendar year-end fiscal years and, thus, will be required by GAAP to follow this SOP in

[3] The Financial Accounting Standards Board (FASB) has issued an exposure draft on accounting for impaired loans. "Proposed Statement of Financial Accounting Standards: Accounting by Creditors for Impairment of a Loan", File Reference No. 116–B, June 30, 1992. The OTS will address any final FASB action on this issue when it issues final guidance of the regulation of troubled, collateral-dependent loans.

[4] Fair value is to include a reduction for the seller's disposition costs.

[5] *See* 54 FR 48845, 48853 (Nov. 8, 1989).

[6] Given its decision to lower the risk-weight for the first two types of assets currently placed in the 200 percent category, that is, repossessed (or foreclosed) assets and assets more than 90 days past due, OTS has concluded that it is inappropriate to retain a 200 percent risk-weighting for the third type of asset—equity investments with the same risk characteristics as REO. If REO is risk-weighted at 100 percent, then assets having similar risk characteristics should carry the same risk-weight. Since no other assets are risk-weighted at 200 percent, it is appropriate to remove that risk-weighting category.

[7] *See* 5 U.S.C. 553(d)(3) (an agency may dispense with a delay in effective date for "good cause").

preparing their December 31, 1992 financial statements. An immediate effective date for the implementation of the fair value policy will cause the regulatory reports filed with the OTS by all savings associations to be consistent both with GAAP and with the treatment of these assets by the other federal banking regulatory agencies. A lack of uniformity would impede OTS's supervision of savings associations.

IV. Executive Order 12291

The OTS has determined that this regulation does not constitute a "major rule" and, therefore, the preparation of a regulatory impact analysis is not required. The impact on affected savings associations that results from the more stringent valuation methodology required for foreclosed assets will be substantially offset by removal of the 200 percent risk-weight category.

V. Regulatory Flexibility Analysis

Pursuant to section 605(b) of the Regulatory Flexibility Act, it is certified that this regulation will not have a significant impact on a substantial number of small savings associations. Any impact on small associations that results from the more stringent valuation methodology required for foreclosed assets will be substantially offset by removal of the 200 percent risk-weight category. Any impact on small savings associations will, accordingly, not be significant.

List of Subjects in 12 CFR Part 567

Capital, Reporting and recordkeeping requirements, Savings associations.

Accordingly, the Office of Thrift Supervision hereby amends part 567, chapter V, title 12, Code of Federal Regulations as set forth below.

SUBCHAPTER D—REGULATIONS APPLICABLE TO ALL SAVINGS ASSOCIATIONS

PART 567—CAPITAL

1. The authority citation for part 567 continues to read as follows:

Authority: 12 U.S.C. 1462, 1462a, 1463, 1464, 1476a.

2. Section 567.6 is amended by revising the section heading; by removing the period located at the end of paragraph (a)(1)(iv)(Q) and by adding in lieu thereof a semicolon; by adding new paragraphs (a)(1)(iv)(R) and (a)(1)(iv)(S); and by removing and reserving paragraph (a)(1)(v) to read as follows:

§ 567.6 Risk-based capital credit risk-weight categories.

(a) *Risk-weighted Assets.* * * *

(1) *On-balance Sheet Assets:* * * *

(iv) *100 percent Risk Weight (Category 4).* * *

(R) All repossessed assets or assets that are more than 90 days past due; and

(S) Equity investments that the Office determines have the same risk characteristics as foreclosed real estate by the savings association.

* * * * *

Dated: December 28, 1992.

By the Office of Thrift Supervision.

John F. Robinson,

Acting Director.

[FR Doc. 92-31948 Filed 12-31-92; 11:42 am]

BILLING CODE 6720-01-M

RESOLUTION TRUST CORPORATION

12 CFR Part 1616

RIN 3205-AA14

Privacy Act Regulations

AGENCY: Resolution Trust Corporation.

ACTION: Final rule.

SUMMARY: The Resolution Trust Corporation (RTC or Corporation) is adopting a rule for the processing of requests for access to or amendment of records, other than the records of the RTC Inspector General, pursuant to the Privacy Act of 1974 (5 U.S.C. 552a). An interim rule with request for comments was published on September 22, 1992 (57 FR 43607).

EFFECTIVE DATES: This final rule is effective December 21, 1992.

FOR FURTHER INFORMATION CONTACT: Richard White, Privacy Act Program Officer, Office of the Secretary, FOIA/PA Branch, (703) 908-6137. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: This rule governs release of all Corporate records, with the exception of the Office of Inspector General of the RTC, pursuant to the Privacy Act of 1974, as amended. This rule sets forth the procedures to be used in requesting records from the RTC, appealing the decision to deny, in whole or in part, access to Corporate records, the procedures for contesting the content of Corporate records, and the identification of systems of records that are exempt from the access, amendment, and disclosure accounting provisions of the Privacy Act. It also establishes a fee schedule for the duplication of Corporate records, and establishes a minimum amount under which fees will not be charged. No comments from members of the public were received. Appendix A of the rule has been amended to reflect the most current addresses of RTC field office locations.

List of Subjects in 12 CFR Part 1616

Privacy.

Accordingly, the interim rule adding part 1616 to title 12, chapter XVI, of the Code of Federal Regulations is amended and adopted as a final rule to read as follows:

PART 1616—PRIVACY ACT REGULATIONS

Sec.
1616.1 Purpose and scope.
1616.2 Definitions.
1616.3 Procedures for requests pertaining to individual records in a system of records.
1616.4 Times, places and requirements for identification of individuals making requests.
1616.5 Disclosure of requested information to individuals.
1616.6 Special procedures for medical records.
1616.7 Requests for amendment of records.
1616.8 Agency reviews of requests for amendment of records.
1616.9 Appeals of adverse initial agency determinations of access or amendment of records and Statements of Disagreement.
1616.10 Preservation of records.
1616.11 Disclosure of a record to a person other than the individual to whom the record pertains.
1616.12 Fees.
1616.13 Penalties.
1616.14 Exemptions.

Appendix A—RTC Field Offices

Authority: 5 U.S.C. 552a.

§ 1616.1 Purpose and scope.

This part sets forth the basic policies of the Resolution Trust Corporation (RTC or Corporation), with the exception of the Office of Inspector General of the RTC, that implement the provisions of the Privacy Act of 1974 (5 U.S.C. 552a) regarding the protection of the privacy of individuals on whom the Corporation maintains information which is retrieved by reference to an individual's name or an identifying particular assigned to the individual. This part also sets forth the procedures by which an individual may seek access under the Privacy Act to records pertaining to him/her, may request amendment of such records, or may seek an accounting of disclosures of such records maintained by the Corporation.

§ 1616.2 Definitions.

For the purposes of this part:

(a) *Corporation* means the Resolution Trust Corporation operating in its Corporate capacity.

(b) *Individual* means a natural person who is either a citizen of the United States of America or an alien lawfully admitted for permanent residence.

(c) *Maintain* includes maintain, collect, use, disseminate, or control.

(d) *Record* means any item, collection or grouping of information about an individual that is maintained by the RTC in its Corporate capacity and contains his/her name, or an identifying number, symbol, or other identifying particular assigned to the individual.

(e) *System of records* means a group of any records under the control of the Corporation from which information is retrieved by the name of the individual or some identifying number, symbol or other identifying particular assigned to the individual.

(f) *Designated system of records* means a system of records which has been listed and summarized in the **Federal Register** pursuant to the requirements of 5 U.S.C. 552a(e).

(g) *Routine use* means, with respect to disclosure of a record, the use of such record for a purpose which is compatible with the purpose for which it was created.

(h) *Amend* and *amendment* mean any correction of, addition to or deletion from a record.

(i) *System manager* means the agency official responsible for a designated system of records, as denominated in the **Federal Register** publication of "Systems of Records Maintained by the Resolution Trust Corporation."

§ 1616.3 Procedures for requests pertaining to individual records in a system of records.

(a) Any present or former employee of the Federal Deposit Insurance Corporation (FDIC) who is working for or has worked for the RTC and who is seeking access to his/her official personnel folder or other U.S. Office of Personnel Management government-wide personnel-type record, including compensation, training, medical information, time and attendance and performance, maintained by the RTC in Corporation offices should submit his/her request in such a manner as prescribed by the U.S. Office of Personnel Management in part 297 of its rules and regulations (5 CFR 297.101 through 297.501). Such requests should be submitted to the Office of the Secretary, RTC, FOIA/PA Branch, International Place, 1735 North Lynn Street, Rosslyn, VA 22209. An FDIC employee who is presently working for the RTC may also gain access to his/her unofficial personnel folder, and other personnel-type record, by visiting, either in person or with an authorized representative, the RTC Corporate office in which the folder is maintained.

(b) Written requests by individuals for access to records pertaining to them, other than official personnel folders, and maintained within one of the Corporation's designated system of records should be submitted to the Office of the Secretary, FOIA/PA Branch, RTC, International Place, 1735 North Lynn Street, Rosslyn, VA 22209. Each such request should contain a reasonable description of the record(s) sought, identify the system or systems in which such records may be contained, and any additional identifying information, as specified in the Corporation's **Federal Register** "Notice of Systems of Records" for that particular system, copies of which are available upon request from the FOIA/PA Branch, Office of the Secretary.

§ 1616.4 Times, places and requirements for identification of individuals making requests.

(a) Individuals may request access to records pertaining to themselves as provided in § 1616.3 by submitting a written request by mail or in person to the office in which the records are maintained or the Office of the Secretary, FOIA/PA Branch, RTC, International Place, 1735 North Lynn Street, Rosslyn, VA 22209. Before access to records is granted, pursuant to this part, reasonable identification, as specified in § 1616.4(b), of the person making the request is required to ensure that information is given and records are disclosed only to the proper individual.

(b) Employees appearing in person at RTC offices seeking access to or amendment of personnel records pertaining to themselves shall present two forms of reasonable identification, such as employment identification cards, driver's licenses, passports, or credit cards. One piece of identification shall contain the individual's photograph and signature.

(c) Individuals submitting written requests seeking access to or amendment of records pertaining to themselves shall include copies of two forms of identification which contain the signatures of the individuals. Except for records that must be publicly disclosed pursuant to the Freedom of Information Act (5 U.S.C. 552), where the Corporation determines it to be necessary for the individual's protection, a certification of a duly commissioned notary public, of any state or territory, attesting to the requesting individual's identity may be required before a written request seeking access to or amendment of a record will be honored. Identification, as described in this section, will be required of any individuals visiting RTC offices to inspect records after submission of written requests.

§ 1616.5 Disclosure of requested information to individuals.

(a) Except to the extent that Corporation records in a system of records pertaining to an individual:

(1) Are exempt from disclosure under § 1616.14, or

(2) May require special procedures for medical records under § 1616.6, or

(3) Were compiled in reasonable anticipation of a civil action or proceeding, the Corporation will make such records available upon request for purposes of inspection and copying by the individual about whom the information is maintained or, upon the individual's request and written authorization, by another person of the individual's own choosing (after proper identity verification as provided in § 1616.4).

(b) The Secretary, or designee, will acknowledge receipt of a request submitted under this rule within ten (10) working days, and notify, in writing, the individual making a request, whenever practicable within ten business days following receipt of the request, whether any specified, designated system of records maintained by the Corporation contains a record pertaining to the individual. Where such a record does exist, the Secretary, or designee, with the advice of the System Manager, will inform the individual of the decision whether to grant or deny, in whole or in part, the request for access. In the event existing records are determined not to be disclosable, the notification will inform the individual of the reason(s) for which disclosure will not be made and will provide a description of the individual's right to appeal the denial, as more fully set forth in § 1616.9.

(c) Individuals will be granted access to records disclosable under this part 1616 as soon as is practicable. The Secretary, or designee, will give written notification of a reasonable period within which individuals may inspect disclosable records pertaining to themselves at the Office of the Secretary (FOIA/PA Branch) or the appropriate Headquarters, or field offices during normal business hours. Alternatively, the Corporation may mail copies of requested records to the individual. Fees for copying such records will be assessed as provided in § 1616.12.

§ 1616.6 Special procedures for medical records.

Medical records in a system of records shall be disclosed on request to individuals to whom they pertain, except, if in the judgment of the Corporation, the transmission of the medical information directly to the requesting individual could have an adverse effect upon such individual. In the event medical information is withheld from a requesting individual because of any possible adverse effect such information may have upon the individual, the Corporation shall transmit such information to a licensed medical doctor named by the requesting individual.

§ 1616.7 Requests for amendment of records.

The Corporation will maintain all records it uses in making any determination about any individual with such accuracy, relevance, timeliness, and completeness as is reasonably necessary to assure fairness to the individual in the determination. An individual may request that the Corporation amend any portion of a record pertaining to that individual which the Corporation maintains in a designated system of records. Such a request should be submitted in writing to the Office of the Secretary, FOIA/PA Branch, RTC, International Place, 1735 North Lynn Street, Rosslyn, VA 22209, and should contain the individual's reason for requesting the amendment and a description of the record (including the name of the appropriate designated system of records) sufficient to enable the Corporation to identify the particular record or portion thereof with respect to which amendment is sought. If an individual has a copy of the record he/she wishes to have amended, it should be attached to the request for amendment and the specific portion of the record sought to be amended should be clearly identified. The individual making the request may be required to provide the information specified in § 1616.4 to permit verification of the identify of the individual making the request for amendment.

§ 1616.8 Agency reviews of requests for amendment of records.

(a) Requests by individuals for the amendment of records will be acknowledged by the Secretary, or designee, within ten (10) business days following receipt of such requests and referred to the System Manager of the system of records in which the record is contained for an analysis of the request to amend. Promptly thereafter, the Secretary, or designee, with the advice of the System Manager, will notify the individual of the decision to grant or deny the request to amend. If the request to amend is granted in whole or in part, the Secretary, or designee, will effect the appropriate amendment.

(b) If the Secretary, or designee, denies a request to amend a record, the notification of such denial shall contain the reason(s) for the denial, a description of the individual's right to appeal the denial as more fully set forth in § 1616.9, and the address of the Corporation officer to whom the appeal should be sent.

§ 1616.9 Appeals of adverse initial agency determinations of access or amendment of records and Statements of Disagreement.

(a) For RTC records contained within a system of records, the initial denial of an individual's request for access to or amendment of a record pertaining to him/her may be appealed to the RTC's General Counsel within 30 business days following receipt of notification of the denial. Such appeals should be mailed to the Office of the Secretary, FOIA/PA Branch, RTC, International Place, 1735 North Lynn Street, Rosslyn, VA 22209, and contain all the information specified for requests for access in § 1616.3 or for initial requests to amend in § 1616.7, as well as any other additional information the individual deems relevant for the consideration by the General Counsel, or designee, of the appeal. Both the envelope and the appeal letter should have written on them "Privacy Act Appeal." The appeal letter should also enclose a copy of the initial denial letter.

(b) The General Counsel, or designee, will normally make a final determination with respect to an appeal made under this part within 30 business days following receipt of the appeal by the Office of the Secretary. The General Counsel, or designee may, however, extend this 30-day time period for good cause shown. When such an extension is required, the individual making the appeal will be notified of the reason for the extension and the expected date upon which a final decision will be given.

(c) If the General Counsel, or designee, affirms the initial denial of a request for access or amendment, he/she will inform the individual affected by the decision, the reason(s) therefore and the right of judicial review of the decision. With respect to a decision to sustain the initial refusal to amend a record, the General Counsel, or designee, will also inform the individual of the right to submit a Statement of Disagreement under paragraph (d) of this section.

(d) Upon receipt of a determination to affirm the initial denial of a request to amend a record, the individual may submit to the Corporation a concise statement (Statement of Disagreement) setting forth his or reasons for disagreeing with the Corporation's determination not to amend. Such a Statement of Disagreement will be attached to the record which was the subject of the request to amend. The General Counsel, or designee may, if deemed appropriate, prepare a concise statement (Statement of Explanation) of the reason(s) why the requested amendment was not made. Any RTC Statement of Explanation will be included in the system of records in the same manner as the Statement of Disagreement. A copy of the Statement of Explanation and the notation of the dispute as marked on the original record will be provided to the individual who requested an amendment of the record.

(e) When a record has been amended or when a Statement of Disagreement has been filed, the Secretary, or designee, will provide all prior recipients of the affected record, whose identities may be determined pursuant to the disclosure accountings required by the Privacy Act (5 U.S.C. 552a(c)) or any other accounting previously made, a copy of the amended or corrected record or the Statement of Disagreement. Any disclosure of disputed information occurring after a Statement of Disagreement has been filed will clearly identify the specific information disputed and be accompanied by a copy of the Statement of Disagreement and a copy of any RTC Statement of Explanation.

§ 1616.10 Preservation of records.

The Corporation will preserve all correspondence relating to the written requests it receives under this part, and all records processed pursuant to such requests, in accordance with the records retention provisions of General Records Schedule 14, Informational Services Records. Under no circumstances will records be destroyed while they are subject to a pending request for access, amendment, appeal, or lawsuit pursuant to the Privacy Act.

§ 1616.11 Disclosure of a record to a person other than the individual to whom the record pertains.

(a) Except as provided in paragraph (b) of this section, the Corporation will not disclose any record contained in a designated system of records to any person or agency except without the

prior written consent of the individual to whom the record pertains.

(b) The restrictions on disclosure in paragraph (a) of this section do not apply to any disclosures:

(1) To those officers and employees of the Corporation who have a need for the record in the performance of their duties;

(2) Required under the Freedom of Information Act (5 U.S.C. 552);

(3) For a routine use, as defined in § 1616.2(g), listed with respect to a designated system of records and described in the **Federal Register** notice of the system;

(4) To the Bureau of the Census for purposes of planning or carrying out a census or survey or related activity pursuant to the provisions of title 13 of the United States Code;

(5) To a recipient who has provided the Corporation with advance adequate written assurance that the record will be used solely as a statistical research or reporting record, and the record is to be transferred in a form that is not individually identifiable;

(6) To the National Archives and Records Administration as a record which has sufficient historical or other value to warrant its continued preservation by the United States Government, or for evaluation by the Archivist of the United States, or designee, to determine whether the record has such value;

(7) To another agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if the head of the agency or instrumentality has made a written request to the Corporation specifying the particular portion desired and the law enforcement activity for which the record is sought;

(8) To a person pursuant to a showing of compelling circumstances affecting the health or safety of an individual if, upon such disclosure, notification is transmitted to the last known address of the individual to whom the record pertains;

(9) To either House of Congress, or, to the extent of matter within its jurisdiction, any committee or subcommittee thereof, any joint committee of Congress or subcommittee of any such joint committee;

(10) To the Comptroller General, or any of his/her authorized representatives, in the course of the performance of the duties of the General Accounting Office;

(11) Pursuant to the order of a court of competent jurisdiction; or

(12) To a consumer reporting agency in accordance with 31 U.S.C 3711(f)

(c) Any Statement of Disagreement with the Corporation's determination not to amend a record, filed with the Corporation by an individual pursuant to § 1616.9(d) will be included in the disclosure of the record under authority of paragraph (b) of this section. The Corporation may, in its discretion, also include a copy of the Corporation's Statement of Explanation.

(d) The Corporation, with respect to each system of records under its control shall:

(1) Except for disclosures made under paragraphs (b)(1) or (b)(2) of this section, keep an accurate accounting of:

(i) The date, nature, and purpose of each disclosure of a record to any person or to another agency made under paragraph (b) of this section; and

(ii) The name and address of the person or agency to whom the disclosure is made; and

(2) Retain the accounting made under paragraph (d)(1) of this section for at least five years or the life of the record, whichever is longer, after the disclosure for which the accounting is made;

(3) Except for disclosures made under paragraph (b)(7) of this section, make the accounting made under paragraph (d)(1) of this section available to the individual named in the record at his/her request; and

(4) Inform any person or other agency about any correction or Statement of Dispute made by an individual in accordance with § 1616.9(d), of any record that has been disclosed to the person or agency if an accounting of the disclosure was made.

§ 1616.12 Fees.

The Corporation, upon a request for records disclosable pursuant to the Privacy Act of 1974 (5 U.S.C. 552a), shall charge a fee of $0.20 per page for duplicating, except as follows:

(a) If the Corporation determines that it can grant access to a record only by providing a copy of the record, no fee will be charged for providing the first copy of the record or any portion thereof; and

(b) Whenever the aggregate fees computed under this section do not exceed $25.00 for any one request, the fee will be deemed waived by the Corporation.

§ 1616.13 Penalties.

Any person who knowingly and willfully requests or obtains any record concerning an individual from the RTC under false pretenses shall be guilty of a misdemeanor and fined not more than $5,000.

§ 1616.14 Exemptions.

The following information is exempt from disclosure: (a) Investigatory material compiled for law enforcement purposes is exempt from §§ 1616.3 through 1616.9 and § 1616.11(d)(3), *Provided, however,* that if any individual is denied any right, privilege, or benefit to which he/she would otherwise be entitled under Federal law, or for which he/she would otherwise be eligible, as a result of the maintenance of such material, such material shall be disclosed to such individual, except to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence;

(b) Investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for Corporation employment to the extent that disclosure of such material would reveal the identity of a source who furnished information to the Corporation under an express promise that the identity of the source would be held in confidence, is exempt from §§ 1616.3 through 1616.9 and § 1616.11(d)(3); and

(c) Testing or examination material used solely to determine or assess individual qualifications for appointment or promotion in the Corporation's service, the disclosure of which would compromise the objectivity or fairness of the testing, evaluation, or examination process is exempt from §§ 1616.3 through 1616.9 and § 1616.11(d)(3).

Appendix A—RTC Field Offices

1. Atlanta Office, 100 Colony Square, Atlanta, GA 30361;
2. Kansas City Office, 4900 Main Street, Kansas City, MO 64112;
3. Dallas Office, 3500 Maple Avenue, Dallas, TX 75219;
4. Denver Office, 1225 17th Street, Denver, CO 80202;
5. Costa Mesa Office, 4000 MacArthur Boulevard, Newport Beach, CA 92660;
6. Valley Forge Office, 1000 Adams Avenue, Norristown, PA 19403.

By order of the Chief Executive Officer.

Dated at Washington, D.C., this 30th day of December, 1992.

Resolution Trust Corporation

William J. Tricarico,

Assistant Secretary.

[FR Doc. 93-100 Filed 1-5-93; 8:45 am]

BILLING CODE 6714-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 92-NM-235-AD; Amendment 39-8459; AD 93-01-05]

Airworthiness Directives; Boeing Model 747 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment supersedes two existing airworthiness directives (AD), applicable to certain Boeing Model 747 series airplanes, that currently require repetitive inspections to detect cracks in forward and aft bottle bore fuse pins in the diagonal braces of the inboard engine struts, and replacement of cracked pins. Those AD's also provided for installation of forward 15-5 steel fuse pins or aft bulkhead fuse pins as optional terminating actions for the repetitive inspections. This amendment adds repetitive inspections of forward and aft bottle bore fuse pins in the outboard engine strut, and aft bulkhead fuse pins in the inboard and outboard engine struts. This AD also provides optional terminating action for certain repetitive inspections and adds airplanes to the applicability statement of the AD. This amendment is prompted by numerous reports of cracks and corrosion in certain fuse pins in the diagonal braces of the inboard and outboard engine struts. The actions specified in this AD are intended to prevent failure of the engine support structure and the inability of the strut to carry required engine operational loads.

DATES: Effective February 5, 1993.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of February 5, 1993.

Comments for inclusion in the Rules Docket must be received on or before March 8, 1993.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 92-NM-235-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

The service information referenced in this AD may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. Tim Backman, Aerospace Engineer, Seattle Aircraft Certification Office, Airframe Branch, ANM-120S, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (206) 227-2776; fax (206) 227-1181.

SUPPLEMENTARY INFORMATION: On August 5, 1981, the FAA issued AD 79-22-03 R3, Amendment 39-4176 (46 FR 38343, July 27, 1981), applicable to certain Model 747 series airplanes, to require:

1. Repetitive visual inspections at intervals of 350 landings, or ultrasonic inspections at intervals of 1,200 landings, to detect cracks and corrosion in forward bottle bore fuse pins in the diagonal braces of the inboard engine struts, and replacement of cracked pins; and

2. Application of corrosion preventive compound, and removal of any corrosion found.

That action also provided for installation of forward 15-5 steel fuse pins as an optional terminating action for the requirements of that AD. That action was prompted by a report of a completely fractured forward bottle bore fuse pin. The actions required by that AD are intended to prevent failure of the forward bottle bore fuse pins in the diagonal braces of the inboard engine struts.

Since the issuance of AD 79-22-03 R3, the FAA has received a total of 39 reports of cracking and two reports of complete fractures of forward bottle bore fuse pins. Boeing's analysis of several cracked forward bottle bore fuse pins indicates that cracking initiated at a sharp, circumferential machining groove in the fuse pin bore internal recess and was propagated by fatigue. The FAA notes that the same forward bottle bore fuse pin design is used on both inboard and outboard struts. In addition, these fuse pins operate in similar loads environments. Therefore, the FAA concludes that forward bottle bore fuse pins on the outboard struts, as well as the inboard struts, are subject to the same fatigue cracking.

One of the cracks discussed previously was found in a forward bottle bore fuse pin on an airplane that had accumulated only 192 landings since its last visual inspection. Critical crack length in these fuse pins is short; therefore, cracks cannot be detected using visual techniques before the pins would become fractured. Consequently, the FAA has determined that the option of performing visual inspections that is specified in the existing AD must be deleted, and repetitive ultrasonic inspections of these pins must be required.

On January 9, 1984, the FAA issued AD 83-24-05, Amendment 39-4775 (48 FR 54476, December 5, 1983), applicable to certain Model 747 series airplanes, to require repetitive visual inspections at intervals of 350 landings, or ultrasonic inspections at intervals of 1,200 landings, to detect cracks in aft bottle bore fuse pins in the diagonal braces of the inboard engine struts, and replacement of cracked pins. That AD also provided for installation of aft bulkhead fuse pins as an optional terminating action for the repetitive inspections. That AD was prompted by two reports of cracked aft bottle bore fuse pins. The actions required by that AD are intended to prevent failure of the aft bottle bore fuse pins in the diagonal braces of the inboard engine struts.

Since the issuance of AD 83-24-05, the FAA has received additional reports of cracks in aft fuse pins on the inboard and outboard engine struts. These reports involve both bottle bore and bulkhead fuse pins. Additionally, the FAA has received four reports of completely fractured aft bulkhead fuse pins.

Since cracks have been found on aft bulkhead fuse pins, as well as on aft bottle bore fuse pins, the FAA has determined that the installation of bulkhead fuse pins does not provide terminating action for the repetitive inspection requirements of AD 83-24-05. In addition, the FAA concludes that aft bulkhead fuse pins must be inspected to detect cracks and corrosion. Further, for reasons explained previously regarding AD 79-22-03 R3, both forward and aft bottle bore fuse pins must be inspected using ultrasonic, rather than visual, techniques. The applicability statement of this AD is expanded to include those airplanes equipped with bulkhead fuse pins. Additionally, since cracks in aft bottle bore fuse pins located in the outboard engine strut have been reported, inspections of both inboard and outboard struts are included in this AD.

The FAA has also determined that the repetitive ultrasonic inspection interval of 1,200 landings that is specified currently in both existing AD's must be reduced to 1,000 landings. This finding is based on an evaluation of additional crack growth data supplied by the manufacturer.

Cracks in these fuse pins could result in failure of the engine support structure

and the inability of the strut to carry required engine operational loads.

The FAA has reviewed and approved Boeing Alert Service Bulletin 747-54A2153, dated December 23, 1992, that describes procedures for repetitive inspections to detect cracks and corrosion in the forward and aft bottle bore fuse pins and the aft bulkhead fuse pins in the inboard and outboard engine struts; and replacement, if necessary. The service bulletin also describes procedures for installing a forward 15-5 steel fuse pin, which, if accomplished, eliminates the need for the repetitive inspections of the forward bottle bore fuse pins.

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of this same type design, this AD supersedes AD 79-22-03 R3 and AD 83-24-05 to require repetitive inspections to detect cracks and corrosion in (1) forward and aft bottle bore fuse pins, and (2) aft bulkhead fuse pins in the diagonal braces of the inboard and outboard engine struts; and replacement of pins, if necessary. This AD also provides terminating action for the repetitive inspections of forward bottle bore fuse pins in the diagonal braces of the inboard and outboard engine struts. The actions are required to be accomplished in accordance with the service bulletin described previously.

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified under the caption "ADDRESSES." All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 92-NM-235-AD." The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation and that it is not considered to be major under Executive Order 12291. It is impracticable for the agency to follow the procedures of Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption "ADDRESSES."

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39-4176 (46 FR 38343, July 27, 1981) and amendment 39-4775 (48 FR 54476, December 5, 1983), and by adding a new airworthiness directive (AD), amendment 39-8459, to read as follows:

93-01-05 Boeing: Amendment 39-8459. Docket 92-NM-235-AD. Supersedes AD 79-22-03 R3, Amendment 39-4176; and AD 83-24-05, Amendment 39-4775.

Applicability: All Model 747 series airplanes, certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent failure of the engine support structure and the inability of the strut to carry required engine operational loads, accomplish the following:

(a) For all Model 747 series airplanes, except JT9D-70-equipped airplanes: Inspect the forward bottle bore fuse pins in the rear diagonal brace of the inboard nacelle struts in accordance with paragraph (a)(1) or (a)(2) of this AD.

(1) Within 100 landings after August 5, 1981 (the effective date of AD 79-22-03 R3, Amendment 39-4176), unless accomplished already within the last 250 landings, but not to exceed 1,200 landings from the previous inspection: Remove the retainer bolt and end caps from the fuse pins, part numbers 65B94182-3, 69B904010-1, -3, -4, -600, and 69B89612-3, and perform a visual inspection of the fuse pins to detect cracks in the machined shear section, in accordance with Boeing Service Bulletin 747-54-2066, dated November 7, 1979; Revision 1, dated October 10, 1980; or Revision 2, dated July 16, 1982. Repeat that inspection thereafter at intervals not to exceed 350 landings until the inspection required by paragraph (e) of this AD is accomplished.

(2) Within 100 landings after August 5, 1981 (the effective date of AD 79-22-03 R3, Amendment 39-4176), unless accomplished already within the last 1,100 landings, but not to exceed 1,200 landings from the previous inspection: Remove the retainer bolt and end caps from the fuse pins, part numbers 65B94182-3, 69B904010-1, -3, -4, -600, and 69B89612-3, and perform an ultrasonic inspection of the fuse pins to detect cracks in the machined shear section, in accordance with Boeing Service Bulletin 747-54-2066, dated November 7, 1979; Revision 1, dated October 10, 1980; or Revision 2, dated July 16, 1982. Repeat that inspection thereafter at intervals not to exceed 1,200 landings until the inspection required by paragraph (e) of this AD is accomplished.

(b) After the effective date of this AD, perform the repetitive inspections required

by paragraph (a) of this AD only in accordance with the ultrasonic inspection method referenced in paragraph (a) of this AD.

(c) For Model 747 series airplanes listed in Boeing Service Bulletin 747-54-2101, dated April 11, 1983: Prior to the accumulation of 5,000 landings, or within 350 landings after January 9, 1984 (the effective date of AD 83-24-05, Amendment 39-4775), whichever occurs later, perform a visual or an ultrasonic inspection for cracks in the aft bottle bore fuse pin bore in recessed shear plane areas, in accordance with Boeing Service Bulletin 747-54-2101, dated April 11, 1983; or Revision 1, dated June 1, 1984. Repeat that inspection thereafter at intervals not to exceed 350 landings (if the previous inspection was visual) or 1,200 landings (if the previous inspection was ultrasonic) until the inspection required by paragraph (f) of this AD is accomplished.

(d) After the effective date of this AD, perform the repetitive inspections required by paragraph (b) of this AD only in accordance with the ultrasonic inspection method referenced in paragraph (b).

(e) For diagonal brace forward bottle bore fuse pins: Perform an ultrasonic inspection to detect cracks and a detailed visual inspection to detect corrosion in the forward bottle bore fuse pins located in the diagonal braces on the inboard and outboard engine struts from each end of the pin, in accordance with Boeing Alert Service Bulletin 747-54A2153, dated December 23, 1992, at the time specified in paragraph (e)(1) of this AD. Accomplishment of this inspection terminates the repetitive inspection requirements of paragraph (a) of this AD. Thereafter, repeat these inspections at intervals not to exceed 1,000 landings.

(1) Inspect all engine positions at the later of the times specified in paragraphs (e)(1)(i) and (e)(1)(ii) of this AD:

(i) Prior to the accumulation of 3,000 landings after the effective date of this AD, or within 3 years since pin installation, whichever occurs first, or

(ii) Within 90 days after the effective date of this AD.

Note: This AD does not require that these inspections be performed on forward 15-5 steel fuse pins or forward H-11 steel bolts in the diagonal brace.

(2) If any crack or corrosion is found as a result of the inspections required by paragraph (e) of this AD, prior to further flight, replace the cracked or corroded pin with a forward 15-5 steel fuse pin, in accordance with Boeing Alert Service Bulletin 747-54A2153, dated December 23, 1992. Installation of a forward 15-5 steel fuse pin constitutes terminating action for the repetitive inspections required by paragraph (e) of this AD.

(f) For diagonal brace aft bottle bore fuse pins and aft bulkhead fuse pins: Perform an ultrasonic inspection to detect cracks, and a detailed visual inspection to detect corrosion, in the aft bottle bore and aft bulkhead fuse pins in the diagonal brace on the inboard and outboard engine struts from each end of the pin, in accordance with Boeing Alert Service Bulletin 747-54A2153, dated December 23, 1992, at the time specified in paragraph (f)(1) of this AD. Accomplishment of this inspection terminates the repetitive inspection requirements of paragraph (c) of this AD.

(1) Inspect all engine positions at the later of the times specified in paragraphs (f)(1)(i) and (f)(1)(ii) of this AD:

(i) Prior to the accumulation of 3,000 landings after the effective date of this AD, or within 3 years since pin installation, whichever occurs first, or

(ii) Within 90 days after the effective date of this AD.

(2) If any crack is found as a result of the inspections required by paragraph (f) of this AD, prior to further flight, replace the cracked pin with an aft bulkhead fuse pin, in accordance with Boeing Alert Service Bulletin 747-54A2153, dated December 23, 1992. Thereafter, accomplish the initial inspection required by paragraph (f) of this AD on the newly installed aft bulkhead fuse pin.

(3) If any corrosion is found as a result of the inspections required by paragraph (f) of this AD, prior to further flight, accomplish paragraph (f)(3)(i) or (f)(3)(ii) of this AD, as applicable.

(i) If corrosion is found in any aft bottle bore fuse pin: Replace with an aft bulkhead fuse pin, in accordance with Boeing Alert Service Bulletin 747-54A2153, dated December 23, 1992.

(ii) If corrosion is found in any aft bulkhead fuse pin: Accomplish paragraph (f)(3)(ii)(A), (f)(3)(ii)(B), or (f)(3)(ii)(C) of this AD, as applicable.

(A) If the amount of corroded material that must be removed exceeds the limit specified in Figure 8 of the service bulletin, replace the corroded fuse pin with an aft bulkhead fuse pin, in accordance with the service bulletin. Thereafter, accomplish the initial inspection required by paragraph (f) of this AD on the newly-installed aft bulkhead fuse pin.

(B) If the amount of corroded material that must be removed is more than light, and equal to or less than the limit specified in Figure 8 of the service bulletin, rework the corroded fuse pin, or replace the corroded fuse pin with an aft bulkhead fuse pin, in accordance with the service bulletin. "Light" corrosion is characterized by discoloration or pitting to a depth of not more than 0.001-inch maximum. This type of corrosion can be removed normally by light hand sanding. A fuse pin that has been reworked in accordance with Figure 6 of the service bulletin must be replaced with an aft bulkhead fuse pin prior to the accumulation of 3,000 landings on the pin, or 3 years since the pin was reworked and reinstalled, whichever occurs first.

(C) If the corrosion is light, remove the corroded material from the fuse pin in accordance with the service bulletin. Thereafter, accomplish the repetitive inspections required by paragraph (f)(4) of this AD.

(4) Repeat the inspections required by paragraph (f) of this AD at the intervals specified in paragraph (f)(4)(i) or (f)(4)(ii) of this AD, as applicable:

(i) For aft bottle bore fuse pins: Repeat at intervals not to exceed 1,000 landings.

(ii) For aft bulkhead fuse pins: Repeat at intervals not to exceed 2,000 landings.

(g) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(h) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate the airplane to a location where the requirements of this AD can be accomplished.

(i) The inspections, replacement, and repair shall be done in accordance with the following Boeing service bulletins, as applicable, which contain the specified effective pages:

Service bulletin referenced and date	Page No.	Revision level shown on page	Date shown on page
747-54-2066, November 7, 1979	1-7	Original	November 7, 1979.
747-54-2066, Revision 1, October 10, 1980	1-27	1	October 10, 1980.
747-54-2066, Revision 2, July 16, 1982	1-17, 20, 27	2	July 16, 1982.
	18-19, 21-16	1	October 10, 1980.
747-54-2101, April 11, 1983	1-27	Original	April 11, 1983.
747-54-2101, Revision 1, June 1, 1984	1-23	1	June 1, 1984.
747-54A2153, December 23, 1992	1-56	Original	December 23, 1992.

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the

Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(j) This amendment becomes effective on February 5, 1993.

Issued in Renton, Washington, on December 24, 1992.

James V. Devany,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 93-175 Filed 1-5-93; 8:45 am]

BILLING CODE 4910-13-U

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14 CFR Part 39

[Docket No. 92-NM-234-AD; Amendment 39-8458; AD 93-01-04]

Airworthiness Directives; Boeing Model 747 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to certain Boeing Model 747 series airplanes, that currently requires repetitive ultrasonic inspections to detect cracks in the inboard and outboard midspar fitting lugs or spring beam aft lugs of each strut, and replacement of midspar fittings or spring beams, if necessary. This amendment reduces certain inspection intervals, removes the optional terminating action for repetitive inspections of the lugs, and adds airplanes to the applicability of the AD. This amendment is prompted by seven reports of fatigue cracking on lugs and numerous reports of lug bushing migration. The actions specified in this AD are intended to prevent failure of the engine support structure and the inability of the strut to carry required engine support loads.

DATES: Effective February 5, 1993.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of February 5, 1993.

Comments for inclusion in the Rules Docket must be received on or before March 8, 1993.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 92-NM-234-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

The service information referenced in this AD may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. Tim Backman, Aerospace Engineer, Seattle Aircraft Certification Office, Airframe Branch, ANM-120S, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (206) 227-2776; fax (206) 227-1181.

SUPPLEMENTARY INFORMATION: On October 10, 1985, the FAA issued AD 85-22-07, Amendment 39-5153 (50 FR 42146, October 18, 1985), to require repetitive ultrasonic inspections to detect cracks in the inboard and outboard midspar fitting lugs or spring beam aft lugs of each strut, and replacement of midspar fittings or spring beams, if necessary. That action was prompted by a report of the failure of both lugs on the inboard midspar fitting of an inboard strut on a Boeing Model 747 series airplane that had accumulated approximately 44,000 flight hours and 11,300 landings. The actions required by that AD are intended to prevent failure of the strut midspar fitting lugs or spring beam aft lugs.

Since the issuance of that AD, the FAA has received seven reports of fatigue cracking on lugs. One of these reports involved a failed lug that was found on the inboard midspar fitting of an inboard strut on a Model 747 series airplane that had accumulated 1,724 landings since its last ultrasonic inspection accomplished in accordance with AD 85-22-07. The FAA concludes that the repetitive inspection interval must be reduced from the currently required 3,000 landings to 1,000 landings in order to adequately address cracking of the midspar fitting lugs.

Although the operational loads environment of the spring beam aft lugs is similar to that of the midspar fitting lugs, there have been no reports of cracks in the spring beam aft lugs. Therefore, the FAA concludes that the existing inspection interval of 3,000 landings is adequate to address cracking of these spring beam aft lugs.

Two types of bushings are installed currently on Model 747 series airplanes: (1) Press-fit bushings, and (2) roller-swaged, shrink-fitted bushings. Recently, the FAA has received numerous reports of migration of press-fit and roller-swaged, shrink-fitted bushings. The FAA has determined that migration of the bushings could result in moisture ingression and subsequent corrosion of the lugs. Operator reports indicate that lug cracking initiated from corrosion pits. Cracking of the lugs, if not detected and corrected, could result in failure of the engine support structure and the inability of the strut to carry required engine support loads.

The FAA has reviewed and approved Boeing Alert Service Bulletin 747-54A2152, dated December 23, 1992, which describes procedures for repetitive ultrasonic inspections to detect cracks on the inboard and outboard midspar fitting lugs or spring beam aft lugs of each strut, and replacement of midspar fittings or spring beams, if necessary. The service bulletin also describes repetitive detailed visual inspections of the inboard and outboard struts to detect bushing migration and corrosion, and repair, if necessary.

In light of the recent reports discussed previously, the FAA has determined that the initial and repetitive inspection intervals for ultrasonic inspections of the midspar fitting lugs, as specified currently in AD 85-22-07, must be reduced.

That AD also specifies that installation of roller-swaged, shrink-fitted bushings constitutes terminating action for repetitive ultrasonic inspections of the lugs. However, since reports of the migration of roller-swaged, shrink-fitted bushings have been received, the FAA has determined that a detailed visual inspection to detect migration of these bushings is necessary.

Roller-swaged, shrink-fitted bushings that have migrated are susceptible to the addressed unsafe condition and are subject to the requirements of this AD. Therefore, those airplanes equipped with roller-swaged, shrink-fitted bushings are included in the applicability statement of this AD.

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of this same type design, this AD supersedes AD 85-22-07 to require repetitive ultrasonic inspections to detect cracks on the inboard and outboard midspar fitting lugs or spring beam aft lugs of each strut, and replacement of midspar fittings or spring beams, if necessary. This AD also requires repetitive detailed visual inspections of the inboard and outboard struts to detect bushing migration and corrosion, and repair, if necessary.

Currently, the FAA is conducting a review of the wing-to-strut attachment structure on Boeing Model 747 series airplanes and may consider further rulemaking as additional data becomes available.

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified under the caption "ADDRESSES." All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 92-NM-234-AD." The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation and that it is not considered to be major under Executive Order 12291. It is impracticable for the agency to follow the procedures of Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption "ADDRESSES."

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39-5153 (50 FR 42146, October 10, 1985), and by adding a new airworthiness directive (AD), amendment 39-8458, to read as follows:

93-01-04 Boeing: Amendment 39-8458. Docket 92-NM-234-AD. Supersedes AD 85-22-07, Amendment 39-5153.

Applicability: All Model 747 series airplanes, certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

Note: Paragraph (a) of this AD restates the inspection requirements of AD 85-22-07, Amendment 39-5153. As allowed by the phrase, "unless accomplished previously," if the initial inspection requirements of AD 85-22-07 have been accomplished previously, paragraph (a) of this AD does not require the initial inspection to be repeated.

To prevent failure of the engine support structure and the inability of the strut to carry required engine support loads, accomplish the following:

(a) For Model 747 series airplanes listed in Boeing Service Bulletin 747-54-2100, dated June 20, 1983: Perform an ultrasonic inspection of the inboard and outboard midspar fitting lugs or spring beam aft lugs of each strut for cracks, in accordance with Boeing Service Bulletin 747-54-2100, dated June 20, 1983; Revision 1, dated August 25, 1988; Revision 2, dated July 20, 1989; or Revision 3, dated November 16, 1989; at the time specified in paragraph (a)(1), (a)(2), (a)(3), or (a)(4) of this AD. Repeat that inspection thereafter at intervals not to exceed 3,000 landings until the inspection required by paragraph (b) of this AD is accomplished.

(1) For airplanes that have accumulated less than 30,000 flight hours as of November 24, 1985 (the effective date of AD 85-22-07, Amendment 39-5153), inspect within 18 months after November 24, 1985, or prior to the accumulation of 25,000 flight hours, whichever occurs later.

(2) For airplanes that have accumulated 30,000 or more flight hours, but less than 40,000 flight hours, as of November 24, 1985 (the effective date of AD 85-22-07, Amendment 39-5153), inspect within 12 months after November 24, 1985.

(3) For airplanes that have accumulated 40,000 or more flight hours as of November 24, 1985 (the effective date of AD 85-22-07, Amendment 39-5153), inspect within 6 months after November 24, 1985.

(4) For airplanes on which the midspar fitting or its lug bushings have been replaced, or on which the spring beam or its aft lug bushings have been replaced, inspect those lugs within 18 months after November 24, 1985 (the effective date of AD 85-22-07, Amendment 39-5153), or within 25,000 flight hours after such replacement, whichever occurs later.

(b) For airplanes equipped with midspar fittings with press-fit bushings; and for airplanes equipped with spring beam lugs with press-fit bushings, as listed in Boeing Alert Service Bulletin 747-54A2152, dated December 23, 1992: Perform an ultrasonic inspection of the midspar fitting lugs or spring beam aft lugs of each strut for cracks, and a detailed visual inspection for corrosion of the lugs and bushing migration, in accordance with Boeing Alert Service Bulletin 747-54A2152, dated December 23, 1992, at the applicable times specified in paragraphs (b)(1) and (b)(2) of this AD. Accomplishment of this inspection terminates the repetitive inspection requirement of paragraph (a) of this AD.

(1) Inspect inboard engine positions 2 and 3 at the later of the times specified in paragraph (b)(1)(i) or (b)(1)(ii) of this AD:

(i) Prior to the accumulation of 5,000 landings on the midspar fitting lugs or spring beam, or within 5 years since installation, whichever occurs first. Or

(ii) Within 60 days after the effective date of this AD.

(2) Inspect outboard engine positions 1 and 4 at the later of the times specified in paragraph (b)(2)(i) or (b)(2)(ii) of this AD:

(i) Prior to the accumulation of 5,000 landings on the midspar fitting lugs or spring beam, or within 5 years since installation, whichever occurs first. Or

(ii) Within 90 days after the effective date of this AD.

(c) For airplanes having midspar fittings or spring beam lugs delivered with roller-

swaged, shrink-fitted bushings, as listed in Boeing Alert Service Bulletin 747-54A2152, dated December 23, 1992, or installed in accordance with Boeing Service Bulletin 747-54-2100, dated June 20, 1983; Revision 1, dated August 25, 1988; Revision 2, dated July 20, 1989; or Revision 3, dated November 16, 1989: Perform a detailed visual inspection of the midspar fitting lugs or spring beam aft lugs of each strut for corrosion of the lugs and bushing migration, in accordance with Boeing Alert Service Bulletin 747-54A2152, dated December 23, 1992, at the later of the times specified in paragraphs (c)(1) and (c)(2) of this AD.

(1) Prior to the accumulation of 5,000 landings on the midspar fitting lugs or spring beam, or within 5 years since installation, whichever occurs first. Or

(2) Within 90 days after the effective date of this AD.

(d) If any migrated bushing is found as a result of the inspection of lugs with roller-swaged, shrink-fitted bushings required by paragraph (c) of this AD, prior to further flight, perform an ultrasonic inspection of the midspar fitting lugs or spring beam aft lugs for cracks, in accordance with Boeing Alert Service Bulletin 747-54A2152, dated December 23, 1992.

(e) If any crack is found in the lugs as a result of any inspection required by paragraph (b), (c), or (d) of this AD, prior to further flight, replace the affected midspar fitting or spring beam in accordance with Boeing Service Bulletin 747-54-2100, dated June 20, 1983; Revision 1, dated August 25, 1988; Revision 2, dated July 20, 1989; or Revision 3, dated November 16, 1989.

(f) If any migrated bushing is found as a result of any inspection required by paragraph (b) or (c) of this AD, prior to further flight, re-seal the bushing in accordance with Boeing Alert Service Bulletin 747-54A2152, dated December 23, 1992. Prior to the accumulation of 1,000 additional landings after detecting the migrated bushing, re-work the fitting in accordance with Figure 5 of the service bulletin.

(g) If any corrosion is found as a result of any inspection required by paragraph (b) or (c) of this AD, prior to further flight, remove the corrosion in accordance with Boeing Alert Service Bulletin 747-54A2152, dated December 23, 1992.

(h) Repeat the inspections required by paragraphs (b) and (c) of this AD at the applicable time specified in paragraph (h)(1) or (h)(2) of this AD.

(1) For midspar fitting lugs, as listed in Boeing Alert Service Bulletin 747-54A2152, dated December 23, 1992: At intervals not to exceed 1,000 landings. Or

(2) For spring beam aft lugs, as listed in Boeing Alert Service Bulletin 747-54A2152, dated December 23, 1992: At intervals not to exceed 3,000 landings.

(i) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(j) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate the airplane to a location where the requirements of this AD can be accomplished.

(k) The inspections, replacement, and repair shall be done in accordance with the following Boeing service bulletins, as applicable, which contain the specified effective pages:

Service bulletin referenced and date	Page No.	Revision level shown on page	Date shown on page
747-54-2100, June 20, 1983	1-153	Original	June 20, 1983.
747-54-2100, Revision 1, August 25, 1988	1-6, 8-9, 24, 27, 33, 70	1	August 25, 1988.
	7, 10-23, 25-26, 28-32, 34-69, 71-153.	Original	June 20, 1983.
747-54-2100, Revision 2, July 20, 1989	1-6, 8-11, 16, 21	2	July 20, 1989.
	24, 27, 33, 70	1	August 25, 1988.
	7, 12-15, 17-20, 22-23, 25-26, 28-32, 34-69, 71-153.	Original	June 20, 1983.
747-54-2100, Revision 3, November 16, 1989	1-6, 8-11, 16, 26-27, 32	3	November 16, 1989.
	21	2	July 20, 1989.
	24, 33, 70	1	August 25, 1988.
	7, 12-15, 17-20, 22-23, 25, 28-31, 34-69, 71-153.	Original	June 20, 1983.
747-54A2152, December 23, 1992	1-49	Original	December 23, 1992.

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(l) This amendment becomes effective on February 5, 1993.

Issued in Renton, Washington, on December 24, 1992.

James V. Devany,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 93-176 Filed 1-5-93; 8:45 am]

BILLING CODE 4910-13-U

DEPARTMENT OF COMMERCE

Bureau of Export Administration

15 CFR Parts 771, 773, 774, 776, 779, and 785

[Docket No. 921082-2282]

Exports to Afghanistan; Special Country Policies

AGENCY: Bureau of Export Administration, Commerce.

ACTION: Final rule.

SUMMARY: On June 3, 1980, the Department of Commerce announced that in response to the Soviet invasion of Afghanistan, applications for licenses to export to Afghanistan were being reviewed on the assumption that commodities and technical data sent to that country would be available to the U.S.S.R. (45 FR 37415). Validated licensing requirements for Afghanistan were therefore made virtually identical to those in force for the U.S.S.R. However, since that time the Soviet military withdrew from Afghanistan, and the Department of State has determined that there is no longer a need for this special treatment of Afghanistan. The Bureau of Export Administration is therefore amending the Export Administration Regulations (EAR) to correctly reflect this change in policy.

EFFECTIVE DATE: This rule is effective on January 6, 1993.

FOR FURTHER INFORMATION CONTACT:

David Schlechty, Foreign Policy Branch, Office of Technology and Policy Analysis, Bureau of Export Administration, Telephone: (202) 482-4252.

SUPPLEMENTARY INFORMATION:

Rulemaking Requirements

1. This rule is consistent with Executive Orders 12291 and 12661.

2. This rule involves collections of information subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). These collections have been approved by the Office of Management and Budget under control numbers 0694-0005 and 0694-0010. This rule may slightly increase the number of export license applications.

3. This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.

4. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by section 553 of the Administrative Procedure Act (5 U.S.C. 553) or by any other law, under section 3(a) of the Regulatory Flexibility Act (5 U.S.C. 603(a) and 604(a)) no initial or final Regulatory Flexibility Analysis has to be or will be prepared.

5. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military or foreign affairs function of the United States. No other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule.

Therefore, this regulation is issued in final form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis. Comments should be submitted to Nancy Crowe, Office of Technology and Policy Analysis, Bureau of Export Administration, Department of Commerce, room 4054, 14th Street and Pennsylvania Ave., NW., Washington, DC 20230.

List of Subjects

15 CFR Parts 771, 773, 774, 776

Exports, Reporting and recordkeeping requirements.

15 CFR Part 779

Computer technology, Exports, Reporting and recordkeeping requirements, Science and technology.

15 CFR Part 785

Exports.

PARTS 771, 773, 774, 776, 779, and 785—[AMENDED]

Accordingly, parts 771, 773, 774, 776, 779, and 785 of the Export Administration Regulations (15 CFR parts 730-799) are amended as follows:

1. The authority citation for 15 CFR parts 771 and 774 continues to read as follows:

Authority: Public Law 90-351, 82 Stat. 197 (18 U.S.C. 2510 *et seq.*), as amended; sec. 101, Public Law 93-153, 87 Stat. 576 (30 U.S.C. 185), as amended; sec. 103, Public Law 94-163, 89 Stat. 877 (42 U.S.C. 6212), as amended; secs. 201 and 201(11)(e), Public Law 94-258, 90 Stat. 309 (10 U.S.C. 7420 and 7430(e)), as amended; Public Law 95-223, 91 Stat. 1626 (50 U.S.C. 1701 *et seq.*); Public Law 95-242, 92 Stat. 120 (22 U.S.C. 3201 *et seq.* and 42 U.S.C. 2139a); sec. 208, Public Law 95-372, 92 Stat. 668 (43 U.S.C. 1354); Public Law 96-72, 93 Stat. 503 (50 U.S.C. App. 2401 *et seq.*), as amended; sec. 125, Public Law 99-64, 99 Stat. 156 (46 U.S.C. 466c); E.O. 11912 of April 13, 1976 (41 FR 15825, April 15, 1976); E.O. 12002 of July 7, 1977 (42 FR 35623, July 7, 1977), as amended; E.O. 12058 of May 11, 1978 (43 FR 20947, May 16, 1978); E.O. 12214 of May 2, 1980 (45 FR 29783, May 6, 1980); E.O. 12730 of September 30, 1990 (55 FR 40373, October 2, 1990), as continued by Notice of September 25, 1992 (57 FR 44649, September 28, 1992); and E.O. 12735 of November 16, 1990 (55 FR 48587, November 20, 1990), as continued by Notice of November 14, 1991 (56 FR 58171, November 15, 1991).

2. The authority citation for 15 CFR parts 773, 779 and 785 continues to read as follows:

Authority: Public Law 90-351, 82 Stat. 197 (18 U.S.C. 2510 *et seq.*), as amended; Public Law 95-223, 91 Stat. 1626 (50 U.S.C. 1701 *et seq.*); Public Law 95-242, 92 Stat. 120 (22 U.S.C. 3201 *et seq.* and 42 U.S.C. 2139a); Public Law 96-72, 93 Stat. 503 (50 U.S.C. App. 2401 *et seq.*), as amended; E.O. 12002 of July 7, 1977 (42 FR 35623, July 7, 1977), as amended; E.O. 12058 of May 11, 1978 (43 FR 20947, May 16, 1978); E.O. 12214 of May 2, 1980 (45 FR 29783, May 6, 1980); E.O. 12730 of September 30, 1990 (55 FR 40373, October 2, 1990), as continued by Notice of September 25, 1992 (57 FR 44649, September 2, 1992); and E.O. 12735 of November 16, 1990 (55 FR 48587, November 20, 1990), as continued by Notice of November 14, 1991 (56 FR 58171, November 15, 1991).

3. The authority citation for 15 CFR part 776 continues to read as follows:

Authority: Public Law 90-351, 82 Stat. 197 (18 U.S.C. 2510 *et seq.*), as amended; Public Law 95-223, 91 Stat. 1626 (50 U.S.C. 1701 *et seq.*); Public Law 95-242, 92 Stat. 120 (22 U.S.C. 3201 *et seq.* and 42 U.S.C. 2139a); Public Law 96-72, 93 Stat. 503 (50 U.S.C. App. 2401 *et seq.*), as amended; sec. 125, Public Law 99-64, 99 Stat. 156 (46 U.S.C. 466c); E.O. 12002 of July 7, 1977 (42 FR 35623, July 7, 1977), as amended; E.O. 12058 of May 11, 1978 (43 FR 20947, May 16, 1978); E.O. 12214 of May 2, 1980 (45 FR 29783, May 6, 1980); E.O. 12730 of September 30, 1990 (55 FR 40373, October 2, 1990), as continued by Notice of September 25, 1992 (57 FR 44649, September 28, 1992); and E.O. 12735 of November 16, 1990 (55 FR 48587, November 20, 1990), as continued by Notice of November 14, 1991 (56 FR 58171, November 15, 1991).

4. The term "Afghanistan" is removed from the following places:

Sec.
773.7(d)(2)(ii) heading and introductory text
773.7(d)(2)(ii)(A)
773.7(d)(2)(ii)(C)
773.7(h)(1)(ii)
773.7(i) heading and introductory text
773.7(i)(2)
773.7(i)(6)
773.7(k) introductory text
773.7(k) concluding text

5. The phrase "Afghanistan," is removed from the following places:

Sec.
771.23(b)
773.3(a)(1)(ii)
773.3(d)(3)(iii)(D)
776.8(b)(1)(ii)
776.8(b)(1)(iii)
776.10(a)(1)

6. The phrase "or Afghanistan" is removed from the following places:

Sec.
773.7(i)(1)
774.5(a)
779.4(f)(1)(i)
779.4(f)(1)(iii)
779.4(f)(2)(i)
779.4(f)(2)(iii)
779.5(e)(1)(vii)

7. The phrase "Afghanistan, Iran, and" is revised to read "Iran and" in the following places:

Sec.
773.7(d)(1) introductory text
773.7(d)(2)(i) [three references]
773.7(d)(2)(ii) introductory text
773.7(d)(3) introductory text [two references]
773.7(h)(1)(ii)

PART 773—[AMENDED]

8. Section 773.3 is amended by removing the phrase ", Afghanistan" from paragraph (e)(1)(ix)(I).

§ 773.7 [Amended]

9. Section 773.7 is amended:

a. By removing the phrase "Afghanistan and" from paragraph (c)(2) heading and text [two references];

b. By removing the phrase ", and Afghanistan" from paragraph (d)(1), introductory text;

c. By removing the phrase "and Afghanistan" from paragraph from footnote no. 2 to paragraph (h)(1)(i); and

d. By removing the phrase ", or to Afghanistan" from paragraph (i)(4).

§ 773.8 [Amended]

10. Section 773.8 is amended by removing the phrase "or Afghanistan," from paragraph (a)(2), introductory text.

§ 773.8 [Amended]

11. Section 773.8 is amended by removing the phrase ", Afghanistan" from paragraph (c)(1).

PART 779—[AMENDED]

12. Section 779.5 is amended:

a. By revising the phrase "the People's Republic of China, or Afghanistan" in paragraph (e)(2) the first place it appears to read "or the People's Republic of China"; and

b. By removing the phrase ", or Afghanistan" from the end of the first sentence in paragraph (e)(2).

PART 785—[AMENDED]

13. Section 785.4 is amended:

a. By removing paragraph (f); and

b. By redesignating paragraph (g) as paragraph (f).

Dated: December 31, 1992.

James M. LeMunyon,

Acting Assistant Secretary for Export Administration.

[FR Doc. 93-161 Filed 1-5-93; 8:45 am]

BILLING CODE 3510-DT-M

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15 CFR Parts 771 and 777

[Docket No. 910480-2266]

Western Red Cedar

AGENCY: Bureau of Export Administration, Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Export Administration (BXA) is amending the Export Administration Regulations (EAR) by adding a new General License GLOG, which authorizes exports of unprocessed western red cedar, and by revising the short supply provisions of the EAR to remove the individual validated licensing requirements for exports of unprocessed western red cedar harvested from: Federal, State, and other public lands in Alaska, lands held in trust by any Federal or State official or agency for a recognized Indian tribe, or private lands. In addition, this rule amends the short supply provisions of the EAR by revising the licensing procedures and recordkeeping requirements for exports of unprocessed western red cedar.

Unprocessed western red cedar harvested from Federal or State lands (except lands in the State of Alaska and lands held in trust for recognized Indian tribes by Federal or State agencies) continues to require a validated license. Applications to export unprocessed western red cedar harvested from these public lands will be reviewed with a presumption of denial.

This rule also revises the definition of processed western red cedar to exclude any individual piece of western red cedar having a cross section that exceeds 2,000 square centimeters (310 square inches), regardless of grade.

BXA expects the new General License GLOG to eliminate individual validated licensing for approximately $78 million of annual exports.

EFFECTIVE DATE: This rule is effective January 6, 1993.

FOR FURTHER INFORMATION CONTACT: Bernard Kritzer, Office of Foreign Availability (OFA), Bureau of Export Administration, Telephone: (202) 482-0074.

SUPPLEMENTARY INFORMATION:

Background

The Department of Commerce administers export controls, under section 7(i) of the Export Administration Act[1] (EAA), as amended, on western red cedar. Section 777.7 of the Export Administration Regulations (EAR) formerly required an individual validated license to export all unprocessed western red cedar (WRC) timber, with a presumption of denial for WRC timber harvested from public lands located outside the state of Alaska. This final rule amends the EAR:

(1) By revising § 777.7 to remove the individual validated licensing requirements for exports of unprocessed western red cedar harvested from private lands, Indian lands, or Federal, State, and other public lands in Alaska;

(2) By adding § 771.7, which authorizes exports of this unprocessed western red cedar under a new General License GLOG; and

(3) By revising, in § 777.7, certain licensing procedures and recordkeeping requirements for exports of unprocessed red cedar.

These changes are consistent with those contained in the proposed rule on western red cedar that BXA published in the **Federal Register** on June 3, 1991 (56 FR 25054).

Exports of unprocessed western red cedar harvested from Federal and State lands (except lands in the State of Alaska and lands held in trust for recognized Indian tribes by Federal or State agencies) continue to require a validated license. A presumption of denial exists for such timber if it was harvested under harvest contracts entered into after September 30, 1979.

This rule also revises the definition of processed western red cedar. Previously, the licensing requirements of § 777.7 did not apply to WRC timber that had been processed into lumber of American Lumber Standards, Grades of Number 3 or better, or Pacific Lumber Inspection Bureau of Export R-List Grades of Number 3 dimension common or better. This rule revises the definition of processed western red cedar in § 777.7 to limit the maximum cross section for any individual piece of western red cedar that may be exported as processed lumber to 2,000 square centimeters (310 square inches), regardless of grade.

This clarification conforms with the comments submitted by the U.S. Department of Agriculture's Forest Service Pacific Northwest Region (Forest Service) on the June 3, 1991, proposed rule. The Forest Service comments, which were the only comments received on the proposed rule, supported the establishment of a limit, based on product size (2,000 square centimeter or 310 square inch cross section), to distinguish between processed and unprocessed western red cedar, but indicated that the proposed rule was unclear as to whether the 310 square-inch cross section limitation applied to "Number 3 Common or Better" lumber as a single grade, or "Number 3 Common" and all higher (or better) grades of lumber. The Forest Service suggested that the size limitation apply to any piece of timber, regardless of grade. BXA agrees with this interpretation and believes that it is consistent with the intent of the statute to restrict the maximum size, with or without wane, that can be considered to be processed western red cedar lumber and, therefor, not subject to the licensing requirements described in § 777.7.

Rulemaking Requirements

1. This rule is consistent with Executive Orders 12291 and 12661.

2. This rule involves a collection of information subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). This collection has been approved by the Office of Management and Budget under control number 0694-0005. This rule also contains a collection of information that has been approved by OMB under control number 0694-0025 and new recordkeeping requirements for

[1] Although the Export Administration Act of 1979 (EAA), as amended, expired on September 30, 1990, the President invoked the International Emergency Economic Powers Act and continued in effect, to the extent permitted by law, the provisions of the EAA and the Export Administration Regulations in Executive Order 12730 of September 30, 1990.

exporters using the General License GLOG that have been approved by OMB under control number 0694–0065. Public burden hours for these information collection and recordkeeping requirements is estimated to average 30 minutes for the collection of information under 0694–0025 and 1 hour for the new recordkeeping requirement 0694–0065. This includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding these burden estimates or any other aspect of the data requirements, including suggestions for reducing these burdens, to the Office of Security and Management Support, Bureau of Export Administration, U.S. Department of Commerce, Washington, DC 20230; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503 (ATTN: Paperwork Reduction Project—0694–0025 and/or 0694–0065).

3. This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.

4. The General Counsel of the Department of Commerce has certified to the Chief Counsel for Advocacy of the Small Business Administration that this rule will not have a significant economic impact on a substantial number of small entities. The establishment of General License GLOG is expected to result in the export licensing decontrol of approximately $75 million to $80 million (extrapolated from 1989 data) of unprocessed western red cedar harvested from private lands and Indian lands, as well as Federal, State, and other public lands in Alaska. This amount represents approximately one to one and one-half percent of the $6 billion dollar value of United States exports of forest products during 1990. As a result, no initial or final Regulatory Flexibility Analysis has to be or will be prepared.

5. The provisions of the Administrative Procedure Act, 5 U.S.C. 553, requiring notice of proposed rulemaking and the opportunity for public participation have been satisfied because this rule was issued in proposed form and comments were considered in the development of this final rule. Moreover, because this rule relieves certain licensing burdens on exporters, there is good cause for making it effective immediately.

Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis. Comments should be submitted to Willard Fisher, Office of Technology and Policy Analysis, Bureau of Export Administration, Department of Commerce, P.O. Box 273, Washington, DC 20044.

List of Subjects

15 CFR Part 771

Exports, Reporting and recordkeeping requirements.

15 CFR Part 777

Administrative practice and procedure, Exports, Forest and forest products, Petroleum, Reporting and recordkeeping requirements.

Accordingly, parts 771 and 777 of the Export Administration Regulations (15 CFR parts 730–799) are amended as follows:

1. The authority citation for 15 CFR part 771 is revised to read as follows:

Authority: Pub. L. 90–351, 82 Stat. 197 (18 U.S.C. 2510 *et seq.*), as amended; sec. 101, Pub. L. 93–153, 87 Stat. 576 (30 U.S.C. 185), as amended; sec. 103, Pub. L. 94–163, 89 Stat. 877 (42 U.S.C. 6212), as amended; secs. 201 and 201(11)(e), Pub. L. 94–258, 90 Stat. 309 (10 U.S.C. 7420 and 7430(e)), as amended; Pub. L. 95–223, 91 Stat. 1626 (50 U.S.C. 1701 *et seq.*); Pub. L. 95–242, 92 Stat. 120 (22 U.S.C. 3201 *et seq.* and 42 U.S.C. 2139a); sec. 208, Pub. L. 95–372, 92 Stat. 668 (43 U.S.C. 1354); Pub. L. 96–72, 93 Stat. 503 (50 U.S.C. App. 2401 *et seq.*), as amended; sec. 125, Pub. L. 99–64, 99 Stat. 156 (46 U.S.C. 466c); E.O. 11912 of April 13, 1976 (41 FR 15825, April 15, 1976); E.O. 12002 of July 7, 1977 (42 FR 35623, July 7, 1977), as amended; E.O. 12058 of May 11, 1978 (43 FR 20947, May 16, 1978; E.O. 12214 of May 2, 1980 (45 FR 29783, May 6, 1980); E.O. 12730 of September 30, 1990 (55 FR 40373, October 2, 1990), as continued by Notice of September 25, 1992 (57 FR 44649, September 28, 1992); and E.O. 12735 of November 16, 1990 (55 FR 48587, November 20, 1990), as continued by Notice of November 14, 1991 (56 FR 58171, November 15, 1991).

2. The authority citation for 15 CFR part 777 is revised to read as follows:

Authority: Pub. 90–351, 82 Stat. 197 (18 U.S.C. 2510 *et seq.*), as amended; sec. 101, Pub. L. 93–153, 87 Stat. 576 (30 U.S.C. 185), as amended; sec. 103, Pub. L. 94–163, 89 Stat. 877 (42 U.S.C. 6212), as amended; secs. 201 and 201(11)(e), Pub. L. 94–258, 90 Stat. 309 (10 U.S.C. 7420 and 7430(e)), as amended; Pub. L. 95–223, 91 Stat. 1626 (50 U.S.C. 1701 *et seq.*); Pub. L. 95–242, 92 Stat. 120 (22 U.S.C. 3201 *et seq.* and 42 U.S.C. 2139a); sec. 208, Pub. L. 95–372, 92 Stat. 668 (43 U.S.C. 1354); Pub. L. 96–72, 93 Stat. 503 (50 U.S.C. App. 2401 *et seq.*), as amended; E.O. 11912 of April 13, 1976 (41 FR 15825, April 15, 1976); E.O. 12002 of July 7, 1977 (42 FR 35623, July 7, 1977), as amended; E.O. 12058 of May 11, 1978 (43 FR 20947, May 16, 1978); E.O. 12214 of May 2, 1980 (45 FR 29783, May 6, 1980); E.O. 12730 of September 30, 1990 (55 FR 40373, October 2, 1990), as continued by Notice of September 25, 1992 (57 FR 44649, September 28, 1992); and E.O. 12735 of November 16, 1990 (55 FR 48587, November 20, 1990), as continued by Notice of November 14, 1991 (56 FR 58171, November 15, 1991).

PART 771—[AMENDED]

3. Section 771.7 (formerly reserved) is added to read as follows:

§ 771.7 General License GLOG; Unprocessed western red cedar timber harvested from public lands in Alaska, private lands, and Indian lands.

(a) *Scope.* A General License GLOG is established, subject to the provisions of this section (including the recordkeeping requirements described in paragraph (b)), authorizing the export of unprocessed western red cedar timber harvested from Federal, State and other public lands in Alaska, all private lands, and lands held in trust for recognized Indian tribes by Federal or State agencies.

(b) *Recordkeeping requirements.* Exporters who use General License GLOG must obtain and retain on file the documents described in paragraphs (b)(1) and (b)(2) of this section. These documents must be maintained in accordance with the recordkeeping requirements of § 787.13 of this subchapter.

(1) A statement by the exporter (or other appropriate documentation) indicating that the unprocessed western red cedar timber exported under GLOG was not harvested from State or Federal lands outside the State of Alaska, and did not become available for export through substitution of commodities so harvested or produced. If the exporter did not harvest or produce the timber, the records or statement must identify the harvester or producer and must be accompanied by an identical statement from the harvester or producer. If any intermediate party or parties held title to the timber between harvesting and purchase, the exporter must also obtain such a statement, or equivalent documentation, from the intermediate party or parties and retain it on file. The exporter shall retain this documentation in the files for the period prescribed in § 787.13(e).

(2) A certificate of inspection issued by a third party log scaling and grading organization, approved by the United States Forest Service, that:

(i) Specifies the quantity in cubic meters or board feet, scribner rule, of unprocessed western red cedar timber to be exported; and

(ii) Lists each type of brand, tag, and/or paint marking that appears on any log

or unprocessed lumber in the export shipment or, alternatively, on the logs from which the unprocessed timber was produced.

Note: See § 777.7 for the definition of unprocessed red cedar.

PART 777—[AMENDED]

4. Section 777.7 is revised to read as follows:

§ 777.7 Unprocessed western red cedar.

(a) *General.* The export of unprocessed western red cedar timber, as defined in paragraph (b) of this section, from the United States to any destination, including Canada, is prohibited, except pursuant to a validated license issued by the Office of Export Licensing, unless the timber was harvested from public lands in the State of Alaska, private lands, or Indian lands, and otherwise meets the requirements for export under General License GLOG (see § 771.7 of this subchapter).

(b) *Licensing policy.* (1) The Office of Export Licensing will generally deny applications for individual validated licenses to export unprocessed western red cedar harvested from Federal or State lands under harvest contracts entered into after September 30, 1979.

(2) The Office of Export Licensing will consider, on a case-by-case basis, applications for individual validated licenses to export unprocessed western red cedar harvested from Federal or State lands under harvest contracts entered into prior to October 1, 1979.

(c) *Definitions.* When used in this section, the following terms have the meaning indicated:

(1) *Unprocessed western red cedar* means western red cedar (thuja plicata) timber, logs, cants, flitches, and processed lumber containing wane on one or more sides, as defined in ECCN 1C88D, that has not been processed into:

(i) Lumber of American Lumber Standards Grades of Number 3 dimension or better, or Pacific Lumber Inspection Bureau Export R-List Grades of Number 3 common or better grades, with a maximum cross section of 2,000 square centimeters (310 square inches) for any individual piece of processed western red cedar (WRC) being exported, regardless of grade;

(ii) Chips, pulp, and pulp products;

(iii) Veneer and plywood;

(iv) Poles, posts, or pilings cut or treated with preservative for use as such and not intended to be further processed; and

(v) Shakes and shingles.

(2) *Federal and State lands* means Federal and State lands, excluding lands in the State of Alaska and lands held in trust by any Federal or State official or agency for a recognized Indian tribe or for any member of such tribe.

(3) *Contract harvester* means any person who, on October 1, 1979, had an outstanding contractual commitment to harvest western red cedar timber from State and Federal lands and who can show by previous business practice or other means that the contractual commitment was made with the intent of exporting or selling for export in unprocessed form all or part of the commodities to be harvested.

(4) *Producer* means any person engaged in a process that transforms an unprocessed western red cedar commodity (e.g., western red cedar timber) into another unprocessed western red cedar commodity (e.g., cants) primarily through a saw mill.

(d) *Application for export license.* (1) Applicants to export unprocessed western red cedar must submit a properly completed Form BXA-622P, Application for Export License, other documents as may be required by the Office of Export Licensing, and a signed statement from an authorized representative of the exporter, reading as follows:

I, _____
(Name)

_____
(Title)

of _____
(Exporter)

Hereby Certify that to the best of my knowledge and belief the

_____
(Quantity)

(cubic meters or board feet scribner) of unprocessed western red cedar timber that

_____
(Exporter)

proposes to export was not harvested from State or Federal lands under contracts entered into after October 1, 1979.

_____
(Signature)

_____
(Date)

(2) For Items 6 and 7 on Form BXA-622P, "Various" may be entered when there is more that one purchaser or ultimate consignee.

(e) *Supporting documentation.* For each Form BXA-622P submitted, and for each export shipment made under the authority of a validated export license, the exporter must assemble and retain for the period prescribed in § 787.13(e) of this subchapter, and produce or make available for inspection as provided in § 787.13(f), the following:

(1) A signed statement(s) by the harvester or producer, and each subsequent party having held title to the commodities, that the commodities in question were harvested under a contract to harvest unprocessed western red cedar from State or Federal lands, entered into before October 1, 1979; and

(2) A copy of the Shipper's Export Declaration.

(f) *Shipping tolerance.* A shipping tolerance of 5 percent in cubic feet or board feet scribner is allowed on the unshipped balance of a commodity listed on an individual validated license. This tolerance applies only to the final quantity remaining unshipped on a license against which more than one shipment is made and not to the original quantity authorized by such license. (See § 786.7 of this subchapter.)

(g) *Communications.* Questions concerning applications to export unprocessed western red cedar under this section, and the specific documentation requirements, should be directed to the Bureau of Export Administration at the address provided in § 772.1(e) of this subchapter.

Dated: December 30, 1992.

James M. DeMunyon,

Acting Assistant Secretary for Export Administration.

[FR Doc. 93-231 Filed 1-5-93; 8:45 am]

BILLING CODE 3510-DT-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 2

[Docket No. FA88-62-001]

Order Denying Interlocutory Appeal and Amending Policy Statement Concerning Disclosure of Documents and Information Obtained in Staff Audits

Issued December 28, 1992.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Final rule; policy statement.

SUMMARY: The Federal Energy Regulatory Commission (Commission) is amending its regulations which authorized disclosure of information in cases under the Natural Gas Act scheduled for formal hearing if the information is relevant to the case. The Commission is extending the provisions of those regulations to Commission

proceedings under the Federal Power Act and under the Interstate Commerce Act as it applies to the regulation of oil pipelines. The Commission found that the authorization of the release of information specified in a prior policy statement for natural gas proceedings and the underlying rationale are equally applicable in other Commission proceedings.

EFFECTIVE DATE: This final rule is effective December 28, 1992.

FOR FURTHER INFORMATION CONTACT: Kasha Ciaglo, Office of General Counsel, Federal Energy Regulatory Commission, 825 North Capitol St., NE., Washington, DC 20426, Telephone: (202) 208–2165.

SUPPLEMENTARY INFORMATION: In addition to publishing the full text of this document in the **Federal Register**, the Commission also provides all interested persons an opportunity to inspect or copy the contents of this document during normal business hours in the Commission's Public Reference Room, room 3104, 941 North Capitol St., NE., Washington, DC 20426.

The Commission Issuance Posting System (CIPS), an electronic bulletin board service, provides access to the texts of formal documents issued by the Commission. CIPS is available at no charge to the user and may be accessed using a personal computer with a modem by dialing (202) 208–1397. To access CIPS, set your communications software to use 300, 1200 or 2400 baud, full duplex, no parity, 8 date bits, and 1 stop bit. The full text of this final rule will be available on CIPS for 30 days from the date of issuance. The complete text on diskette in WordPerfect format may also be purchased from the Commission's copy contractor, LaDorn Systems Corporation, also located in room 3104, 941 North Capitol St., NE., Washington, DC 20426.

I. Background

On November 16, 1992, Wisconsin Electric Power Company (Company) filed an interlocutory appeal of the presiding judge's denial of a motion to permit appeal rendered on November 9, 1992. On November 23, 1992, the Chairman, as the Motions Commissioner, determined, pursuant to Rule 715 of the Commission's Rules of Practice and Procedure, 18 CFR 385.715, that extraordinary circumstances existed which made prompt Commission review of the contested rulings necessary to prevent detrimant to the public interest or irreparable harm to any person, warranting referral to the Commission of the Company's interlocutory appeal.

A. The Case

On February 4, 1992, the Chief Accountant issued an audit report under delegated authority summarizing the results of an audit performed by the Office of Chief Accountant's Division of Audits. Wisconsin Electric Power Company, 58 FERC ¶ 62,121 (1992). The Chief Accountant noted the Company's disagreement with one item included in the report, regarding the accounting and fuel adjustment clause billings for coal mine reclamation costs. 58 FERC at 63,350, 63,357–60. In response to a request from the Chief Accountant regarding disposition of the question, the Company initially advised the Commission that it consented to the shortened procedures provided under section 41.3 of the Commission's regulations. 18 CFR 41.3. Accordingly, on March 30, 1992, the Commission issued an Order Instituting Proceedings under part 41 of the Commission's Regulations. Wisconsin Electric Power Company, 58 FERC ¶ 61,332 (1992). On April 22, 1992, the Company filed a motion for termination of the shortened procedures under part 41 and for a hearing under part 385. Accordingly, on May 14, 1992, the Commission set the accounting issue for evidentiary hearing. Wisconsin Electric Power Company, 59 FERC ¶ 61,184 (1992). On August 19, 1992, the Commission issued an order expanding the scope of the hearing to include prudence issues. Wisconsin Electric Power Company, 60 FERC ¶ 61,181 (1992).

1. The Legal Opinions at Issue

In October 1990, at the request of audit staff, the Company provided a copy of four opinions rendered by its in-house and outside legal counsel concerning the coal mine reclamation costs dispute. In a letter to the audit staff dated October 25, 1990, the Company asserted that the opinions involved factual and legal analysis by its attorneys and so constituted privileged working papers and attorney-client communications. Nonetheless, "in order to resolve the issue," the Company provided the opinions to audit staff, "on the condition that the opinions be kept confidential, not reproduced, and returned to the Company when [the] audit is closed." The Company requested privileged and confidential treatment of the documents under 18 CFR 388.112.[1]

When trial staff advised the Company that it proposed to use the documents in evidence and under seal, the Company asserted that trial staff had no right to use the documents.[2]

2. The Presiding Judge's Orders

On September 29, 1992, trial staff filed a motion requesting a conference to resolve the status of the four opinions. Trial staff argued that the Company's voluntary disclosure of the documents to the audit staff waived any attorney-client or work product privilege that might apply to the documents. On October 9, 1992, the Company filed an answer opposing trial staff's request to use the privileged documents, arguing that the Company waived neither the attorney-client nor work product privilege and that the documents should not be used in the trial staff's prudence evidence.

At a prehearing conference on October 15, 1992, the presiding judge granted the relief requested in the trial staff's motion. The judge adopted what he called the "majority view" that, once the documents were voluntarily disclosed, the privilege is waived, even if the third-party agrees not to disclose the information to anyone else. The judge cited as support cases from the District of Columbia and Third Circuits: *Permian Corporation* v. *United States*, 665 F.2d 1214 (D.C. Cir. 1981) (Permian) and *Westinghouse Electric Corporation* v. *Republic of the Philippines*, 951 F.2d 1414 (3d Cir. 1991) (*Westinghouse*). Tr. 20, 21. The judge considered the rejected the Eighth Circuit's limited waiver analysis relied upon by the Company: *Diversified Industries, Inc.* v. *Meredith*, 572 F.2d 596 (8th Cir. 1977) (Diversified). Tr. 21.[3]

The judge declined to follow Diversified for two reasons. First, in the case at bar, there was no agreement on the part of trial staff to keep the information confidential. The Company merely requested confidential treatment pursuant to section 388.112, which does not insure a document's confidentiality. Tr. 21. The judge added that, although section 388.112 provides that the Commission will place materials it receives under a request for privileged

[1] Section 388.112 provides that a party submitting a document to the Commission may request privileged treatment by claiming that all or part of the information is exempt from Freedom of Information Act (FOIA) requirements and should be withheld from public disclosure.

[2] The Company also objected to an intervenor's discovery requests seeking the legal opinions.

[3] In Diversified, the company voluntarily surrendered privileged material to the Securities and Exchange Commission (SEC). The court concluded that only a limited waiver of the attorney-client privilege had occurred, reasoning that to hold otherwise may have the effect of thwarting the developing procedure of corporations to employ independent outside counsel to investigate and advise them in order to protect stockholders, potential stockholders and customers. Diversified, 572 F.2d at 611.

treatment in a non-public file, it also provides that this is not a determination on any claim or privilege and that the "Commission retains the right to make determinations with regard to any claim or privilege, and the discretion to release information as necessary to carry out its jurisdictional responsibilities." *Id.*, discussing and quoting 18 CFR 388.112.

Second, the judge followed the Permian and Westinghouse line of cases which specifically reject Diversified's "limited" or "selective" waiver theory. Tr. 22. The judge noted that, the Permian court rejected Diversified's selective waiver because it has little to do with the purpose of the attorney-client privilege, and because voluntary cooperation with government investigations does not improve the attorney-client relationship. Permian, 665 F. 2d at 1220–21. Tr. 22. The judge found that, once the attorney-client privilege is waived, it is waived for all purposes. As a Permian, the Company may not pick and choose as to the issues to which the privilege still attaches. *Id.*

The presiding judge also rejected the Company's argument that section 301(b) of the Federal Power Act (FPA), 16 U.S.C. § 825(b) (1988), prohibits release of the documents. The judge explained that section 301(b) provides that information received by staff in the course of an audit shall be kept confidential unless ordered to be disclosed by a Commission or court order. Tr. 22–23. The judge reasoned that the Commission's two hearing orders in this case are sufficient to satisfy the requirements of section 301(b) and to authorize the use of the documents received by audit staff in this investigation. Tr. 22–24, 26. The judge relied on the Federal Power Commission decision in Availability of Information Acquired By Staff Investigation, Order No. 509–A, 52 FPC 389 (1974), involving a statement of policy that the Commission was not going to assume a case-by-case determination of when information garnered by staff in various investigations should be released, but was authorizing as a matter of policy that the information can be released and not kept confidential. The judge noted that, while this statement of policy was issued under the National Gas Act, in adopting this statement of policy the Commission has relied on the legislative history of section 301(b) of the Federal Power Act. Tr. 23–24.

The judge added that he was willing to proceed with use of the information pursuant to a protective order, but would retain his right to re-examine the question of whether the information should be protected once he had viewed the documents. TR 24–25.

On October 30, 1992, the Company filed a motion to permit an interlocutory appeal to the Commission, from the presiding judge's rulings, under 18 CFR 385.715. On November 5, 1992 trial staff filed an answer opposing the Company's motion. On November 9, 1992, the presiding judge issued an order which denied the Company's motion. The judge stated that, based on the applicable case law and the rationale in his October 15, 1992 ruling, the Company had not demonstrated the extraordinary circumstances which would warrant prompt Commission review.

B. The Company's Interlocutory Appeal

In its November 16, 1992 interlocutory appeal, the Company objected to the judge's interlocutory rulings that: (1) The Company has waived the attorney-client and work product privileges attached to legal opinions by providing them to audit staff under an express claim of privilege and on the condition that they be given confidential treatment; and (2) the Commission's hearing orders implicitly authorize the release of the opinions under section 301(b) of the FPA, which prohibits a Commission employee from divulging information required in an audit except as directed by the Commission or a court. The Company claims that the first ruling would discourage utilities from providing privileged documents to the audit staff in audits. According to the Company, the second ruling would violate the prohibition against disclosure; the documents cannot be released absent a Commission order without violating section 301(b).

With respect to the claim of privilege, the Company argues that there is well-reasoned precedent for a "limited waiver" theory under which disclosure of privileged documents to an agency for one purpose does not result in a waiver for other purposes, citing Diversified. The Company claims that Diversified applies here because legal opinions were disclosed to audit staff in a confidential audit and the presiding judge ruled that the confidential disclosure entitled trial staff and an intervenor access to documents on the separate prudence issue. The Company argues that requiring such disclosure here would thwart full disclosure in audits. The Company also argues that the "unlimited waiver" theory adopted by the D.C. Circuit was adopted without intending to deprive an agency of the power to adopt a "limited waiver" approach, citing In Re Sealed Case, 676 F.2d 793 (D.C. Cir. 1982). The Company believes that the Commission is free to adopt a "limited waiver" policy as best serving full disclosure in audits.

With regard to the claim that section 301(b) protects the confidentiality of information obtained by the audit staff, the Company criticizes the judge's finding that the hearing orders in this proceeding may be construed as lifting the requirement that the documents be kept confidential. The Company notes that the judge's finding was based on Order No. 509–A, which is a statement of policy under the Natural Gas Act. The Company contends that there is no comparable statement of policy under the FPA. In addition, the Company argues that Order No. 509–A did not provide that hearing orders implicitly authorize the release of documents. Consequently, the necessary legal authorization for release of the documents at issue here is missing.

II. Discussion

There are essentially two issues to be resolved in this proceeding: First, whether the Company waived the attorney-client and work product privileges for all purposes when it voluntarily disclosed certain documents to the audit staff; and second, whether the Commission's hearing orders authorized the release of the documents under section 301(b) of the FPA.

A. Waiver of Attorney-Client and Work Product Privileges

As an initial matter, the Commission notes that the Company requests privileged treatment of the documents under section 388.112 of the Commission's regulations, but argues that the staff would violate attorney-client and work product privileges by releasing these documents. Section 388.112 has nothing to do with attorney-client communications or work product Rather, it provides procedures under which a party may request that a document be exempt from FOIA requirements and be withheld from public disclosure. As noted above, and discussed further *infra*, the presiding judge agreed to use the documents under a protective order, which would be consistent with section 388.112. However, that provision also allows protected information to be released, subject to certain notice and comment procedures.

In addition, staff has, to this point, kept the documents confidential. Tr. 26–30. Trial staff has proposed a procedure that would ensure that the documents would be provided to the decisionmaker and at the same time would protect any rights that the

Company may have under FOIA. Trial staff would offer the documents in evidence in this proceeding by filing a sealed copy of trial staff's testimony with the presiding judge and placing only a redacted copy in the public files. Other parties to the case would be granted access to the sealed portion of staff's testimony if they executed a protective agreement preventing public disclosure. The Commission finds this proposal reasonable and in compliance with the Company's request for privileged treatment under § 388.112. We will leave to the presiding judge's sound discretion whether the documents should later be released or made public, pursuant to the requirements in § 388.112.

The Commission believes that the Company's appeal raises various issues regarding the Commission's policy regarding attorney-client communications and work product that should be addressed and clarified.

As noted above, there are two schools of thought regarding voluntary disclosure and subsequent waiver. One school, following Diversified, recognizes the "limited" or "selective" waiver theory under which disclosure of privileged documents for one purpose does not result in waiver for other purposes. The other school, following Permian and Westinghouse, recognizes the "unlimited" waiver theory that, once the attorney-client or work product privilege is voluntarily waived for any purpose, it is waived for all purposes. The Commission believes that the presiding judge ruled correctly in following the "unlimited" waiver theory in this proceeding and rejecting the "selective" waiver theory. In this regard, the Commission specifically adopts the presiding judge's rationale from the October 15, 1992 prehearing conference, discussed above, in support of the unlimited waiver theory.

The Commission believes that the better approach is to reject creating a special exception to the waiver doctrine for the purpose of encouraging voluntary disclosure to government agencies. Westinghouse, 951 F.2d at 1424.[4] The Commission disagrees that adopting the theory of unlimited waiver will discourage utilities from providing the audit staff with confidential information. The unlimited waiver rule does not affect a utility's right to protect legitimate attorney-client communications and work product. The utility may still assert the privileges, even in audits. However, once the utility has opted to surrender the privileges because the utility believes it to be in its interest to do so, the utility cannot reassert the privileges at a later date when it believes it better to conceal what it earlier revealed. Additionally, we have not seen natural gas companies refuse to provide confidential data to staff as a result of the statement of policy announced in Order No. 509–A, making information acquired by staff investigation available in contested cases.

The Commission also believes that the Company's voluntary disclosure waived the work product privilege that may apply to these documents. In contrast to the attorney-client privilege, the work product privilege exists not to protect a confidential relationship, but rather to promote the adversary system by safeguarding the fruits of an attorney's trial preparation from the discovery attempts of an opponent. Permian, 665 F.2d at 1219, *citing United States* v. *AT&T*, 642 F.2d 1285, 1299 (D.C. Cir. 1980). Hence, the work product privilege is not automatically waived by any disclosure to a third party. *Id.*[5]

The D.C. Circuit has identified three factors that lead to a waiver of work product privilege:[6] (1) "the party claiming the privilege seeks to use it in a way that is not consistent with the purpose of the privilege," citing In Re Sealed Case, 676 F.2d at 818; (2) the party had no reasonable basis for believing that the disclosed materials would be kept confidential by the agency; and (3) waiver of the privilege would not trench on any policy inherent in the privilege. In Re Subpoena Duces Tecum, 738 F.2d at 1372.

Concerning the first factor, the court reasoned that fairness and consistency require that the party not be allowed to gain substantial advantages resulting from voluntary disclosure of work product to one adversary—in that case, SEC—while being able to maintain another advantage in protecting the same work product from other adversaries. In Re Subpoena Duces Tecum, 738 F.2d at 1372, citing In Re Sealed Case, 676 F.2d at 818–21. The court added that, in that instance, it was unreasonable not to anticipate litigation with other adversaries at the time of disclosure to the SEC. *Id.* Here, the Company disclosed the documents to gain advantage with the audit staff and then asserted work product privilege for those documents in a later trial-type evidentiary hearing that resulted from that investigation. The Company cannot be allowed to disclose the documents selectively within the Commission.

With regard to the second factor, concerning confidentiality, the court found no common interest between the company and the regulatory agency in that case, and declined to find in the SEC's procedures any proper expectations of confidentiality that the company claimed. In Re Subpoena Duces Tecum, 738 F.2d at 1372–74. Similarly, the Company's request for confidentiality under FOIA and the Commission's FOIA regulations, given the circumstances of its disclosure, does not justify the expectation of confidentiality that the D.C. Circuit found necessary to maintain the privilege. The Company could have no reasonable expectations that its disclosure in an attempt to influence the audit staff could be limited so as to preclude disclosure to the parties, trial staff and presiding judge (and ultimately the Commission) later in the same case.[7]

With regard to the third factor, as to policy concerns, the court believed there was no policy inherent in the work product privilege that required a special exception for the SEC's voluntary disclosure program or similar governmental projects. The court stated that the privilege does not protect against the manipulation of selecting a particular opponent for selective disclosure, most probably for the discloser's own benefit. In Re Subpoena Duces Tecum, 738 F.2d at 1374–75. Here also there is no policy inherent in the work product privilege which calls for a special waiver exemption. The Company "voluntarily and deliberately made disclosures to" the Commission "undoubtedly in the hope and expectation of receiving a benefit * * *." *Id.* at 1375. While such disclosure is certainly not improper, it is inconsistent with a later assertion of a work product privilege.

[4] The Company's request that the documents be kept confidential under section 388.112 of the Commission's regulations does not reinstate the Company's waived privilege. Westinghouse, 951 F.2d at 1427. In Westinghouse, the Department of Justice (DOJ) had apparently agreed not to disclose the information and SEC regulations provided that the SEC would maintain confidentiality. *Id.* Nonetheless, the court found that voluntary disclosures to the SEC and the DOJ still waived the attorney-client privilege. *Id.*

[5] See also In Re Sealed Case, 676 F.2d at 809; In Re Subpoena Duces Tecum, 738 F.2d 1367, 1371 (D.C. Cir. 1984); and Westinghouse, 951 F.2d at 1428.

[6] In Westinghouse, the court stated: "Most courts hold that to waive the protection of the work-product doctrine, the disclosure must enable an *adversary* to gain access to the information [and] the purpose of the work-product doctrine requires [the court] to distinguish between disclosure to adversaries and disclosures to non-adversaries." Westinghouse, 951 F.2d at 1428 (emphasis added). When, as is the case here, the company is the target of an investigation conducted by the agency, the courts have found that the agency is the company's adversary. *Id.* *Subpoena* Duces Tecum, 738 F.2d at 1372.

[7] *Cf. infra* note 12.

The Company would also fail the Third Circuit's test in Westinghouse. Under the Third Circuit's standard, a party who discloses documents protected by the work product doctrine may continue to assert the doctrine's protection only when the disclosure furthers the doctrine's underlying goal. Westinghouse, 951 F.2d at 1429. According to the court:

> When a party discloses protected materials to a government agency investigating allegations against it, it uses those materials to forestall prosecution (if the charges are unfounded) or to obtain lenient treatment (in the case of well-founded allegations). These objectives, however rational, are foreign to the objectives underlying the work-product doctrine.

Id. Like Westinghouse, the Company disclosed the documents to the Commission's audit staff "to resolve the issue." Again, this objective is certainly not improper, but it is inconsistent with the objectives underlying the work product privilege.[8]

In summary, the Commission believes that the Company waived both the attorney-client and the work product privileges in this proceeding. The Company provided the documents in this case "in order to resolve the issue." However, the evidentiary hearing that the Commission ordered is likewise for the precise purpose of resolving the issue. The question here is whether, having provided the documents to audit staff early in the proceeding to help resolve the issue, the Company may later in the proceeding assert a privilege with regard to those documents. The answer is no.[9]

We also note that our position regarding disclosures of privileged materials here is consistent with our prior rulings: a disclosure of privileged material waives the privileges as to that material; once it is disclosed, the confidentiality is breached.[10]

B. Release of Documents Under Section 301(b) of the FPA

The second issue in this proceeding pertains to whether the two hearing orders issued by the Commission—one to initiate the audit investigation and the other to initiate the prudence inquiry—authority staff's release of the documents pursuant to section 301(b) of the FPA.

Under section 301(b),

> No member, officer, or employee of the Commission shall divulge any fact or information which may come to his knowledge during the course of examination of books or other accounts, as hereinbefore provided, except insofar as he may be directed by the Commission or by a court.

The Company argues that this provision protects the confidentiality of *any* information which the audit staff uncovers, unless the Commission or a court requires that it be divulged. As noted above, the presiding judge found that the two hearing orders issued in this case are sufficient to remove the requirements that the documents be kept confidential. Tr. 23. The judge based his finding on Order No. 509–A, announcing a statement of policy under the Natural Gas Act.[11] Order No. 509–A provides that the Natural Gas Act's section 8(b) restraint on disclosing information—the counterpart of the Federal Power Act's section 301(b)—did not prohibit the Commission's blanket authorization of disclosure of information in cases scheduled for formal hearings if the information is relevant to the case. order No. 509–A cites the legislative history of section 301(b) as the basis for a blanket authorization to disclose information. 52 FPC at 391. The presiding judge reasoned that because the Commission in Order No. 509–A found that section 8(b) of the Natural Gas Act originated in the legislative history of section 301(b), the statement of policy in Order No. 509–A regarding gas proceedings may also be applied to electric proceedings. He concluded that the Commission's issuance of the two orders in this proceeding authorizes use of the documents in this proceeding and their release from the confidential status they may previously have had, and thus, satisfies section 301(b). Tr. 24.

In Order No. 509–A, while the Commission cited the legislative history of section 301(b) as basis for its blanket authorization under the Natural Gas Act, the Commission did not specifically extend that statement of policy to proceedings under the FPA. However, the Commission believes that the authorization of the release of information specified in Order No. 509–A for natural gas proceedings and the underlying rationale are equally applicable in other Commission proceedings, *i.e.*, in proceedings under the FPA, and should be applied in this case.[12] Thus, section 301(b)'s restraint on disclosing information does not prohibit the Commission's authorization of disclosure of information in cases, such as this, which are set for formal hearing if the information is relevant to the case. Rather, section 301(b) merely provides that information cannot be released without authorization.

We believe that hearing orders, such as the hearing orders in this proceeding, should be read to authorize the release of information obtained during the course of an audit, such as the documents in question, in those cases set for formal hearing.[13] However, to the extent that an additional order under the FPA is necessary, this order authorizes the release of the information at issue in this proceeding.

In addition, to avoid any future misunderstandings, this order specifically extends the policy statement in Order No. 509–A to jurisdictional proceedings under the FPA, as well as to proceedings under the Interstate Commerce Act as it applies to the regulation of oil pipelines. Thus, we will amend 18 CFR 2.72, as set forth below. This revised statement of policy is effective December 28, 1992.

The Commission Orders:

The Company's interlocutory appeal is hereby denied, as discussed in the body of this order.

List of Subjects in 18 CFR Part 2

Administrative practice and procedure, Electric power, Natural gas, Pipelines, Reporting and recordkeeping requirements.

In consideration of the foregoing, the Commission is amending part 2, chapter I, title 18, Code of Federal Regulations, as set forth below.

[8] The Third Circuit specifically rejected the argument that the work product privilege was not waived because the company reasonably expected the agencies to keep the documents confidential. Westinghouse, 951 F.2d at 1430.

[9] Contrary to the Company's suggestion, ordering an evidentiary hearing does not make this a different proceeding.

[10] *See* Consolidated Gas Supply Corporation, 16 FERC ¶ 61,234 at 61,502 (1981) (citing and quoting from *Permian* approvingly). *Accord*, Tenneco, Inc., *et al.*, Opinion No. 41, 7 FERC ¶ 61,258 at 61,541–42 (1979). See *also* Pennzoil Louisiana and Texas Offshore Co., Inc., *et al.*, 3 FERC ¶ 61,133 at 61,382 & 61,396 n.1 (1988).

[11] This policy was codified in 18 CFR 2.72, which provides that: Pursuant to the Commission's authority under the Natural Gas Act, particularly subsection (b) of section 8 thereof, upon request by a party to the proceedings, or as required in conjunction with the presentation of a Commission staff case or staff's cross-examination of any other presentation therein, all relevant information acquired by Commission staff, including workpapers pursuant to any staff investigation conducted under sections 8, 10, or 14 of the Natural Gas Act shall, without further order of the Commission, be free from the restraints of said subsection (b) of section 8 regarding the divulgence of information, with respect to any matter hereafter set for formal hearing.

[12] See 52 FPC at 390, 391–92; Availability of Information Acquired by Staff Investigation, Order No. 509, 51 FPC 1439, 1439–40, *order on reh'q*, Order No. 509–A, 52 FPC 389 (1974). Accord, 7 FERC at 61,541–42 & 61,549 n.51; 3 FERC at 61,382.

[13] See 51 FPC at 1440; 52 FPC at 391–92. Accord, 7 FERC at 61,541–42 & 61,549 n.51; 3 FERC at 61,382.

By the Commission.

Lois D. Cashell,

Secretary.

PART 2—GENERAL POLICY AND INTERPRETATIONS

1. The authority citation for part 2 continues to read as follows:

Authority: 15 U.S.C. 717–717w, 3301–3432; 16 U.S.C. 792–825r, 2601–2545; 42 U.S.C. 4321–4361, 7101–7352.

2. Section 2.72 is redesignated as section 2.1b and is revised to read as follows:

§ 2.1b Availability in contested cases of information acquired by staff investigation.

Pursuant to the Commission's authority under the Natural Gas Act, particularly subsection (b) of section 8 thereof, under the Federal Power Act, particularly subsection (b) of section 301 thereof, and under the Interstate Commerce Act as it applies to regulation of oil pipelines, particularly subsection (7)(f) of section 20 thereof, upon request by a party to the proceedings, or as required in conjunction with the presentation of a Commission staff case or staff's cross-examination of any other presentation therein, all relevant information acquired by Commission staff, including workpapers pursuant to any staff investigation conducted under sections 8, 10, or 14 of the Natural Gas Act, sections 301, 304 or 307 of the Federal Power Act, and sections 12 and 20 of the Interstate Commerce Act as it applies to regulation of oil pipelines shall, without further order of the Commission, be free from the restraints of said subsection (b) of section 8 of the Natural Gas Act, subsection (b) of section 301 of the Federal Power Act, and subsection (7)(f) of section 20 of the Interstate Commerce Act as it applies to regulation of oil pipelines regarding the divulgence of information with respect to any matter hereafter set for formal hearing.

[FR Doc. 93–111 Filed 1–5–93; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization; Counterfeit Drugs Enforcement Activities

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority relating to enforcement activities concerning counterfeit drugs. The amendment clarifies the authority of FDA criminal investigators and the description of the official credentials issued to them.

EFFECTIVE DATE: January 6, 1993.

FOR FURTHER INFORMATION CONTACT: Ellen Rawlings, Division of Management Systems and Policy (HFA–340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4976.

SUPPLEMENTARY INFORMATION: In a May 24, 1991, **Federal Register** notice (56 FR 23788), FDA amended the regulations for delegations of authority for § 5.35 *Enforcement activities* (21 CFR 5.35). FDA added to the authorities delegated to officers and employees of FDA-issued official credentials by delegating authority to criminal investigators to conduct certain activities under section 702(e)(1) through (e)(5) of the Federal Food, Drug, and Cosmetic Act (the act), as amended (21 U.S.C. 372(e)(1) through (e)(5)). This amendment clarifies the authority of the criminal investigators to perform other functions under the act, or any other law, as the Commissioner of Food and Drugs may prescribe. This amendment also clarifies the description of the official credentials, consisting of a two part Form FDA–200D, Special Authority for Criminal Investigations, issued to the criminal investigators.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 21 U.S.C. 41–50, 61–63, 141–149, 467f, 679(b), 801–886, 1031–1309; secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 361, 362, 1701–1706, 2101 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11490, 11921, and 12591.

2. Section 5.35 is amended by revising the introductory text of paragraph (b), by redesignating paragraphs (b)(1) through (b)(5) as (b)(1)(i) through (b)(1)(v), by adding new paragraphs (b)(1) introductory text and (b)(2), and by revising paragraph (c)(3) to read as follows:

§ 5.35 Enforcement activities.

(a) * * *

(b) Any officer or employee of the Food and Drug Administration who has been designated by the Commissioner to conduct examinations, investigations, or inspections under the act relating to counterfeit drugs and issued the Food and Drug Administration Official Credential consisting of Form FDA–200D, Special Authority for Criminal Investigators, is authorized to do the following:

(1) As set forth under section 702(e)(1) through (e)(5) of the act:

* * * * *

(2) Perform such other functions under the act, or any other law, as the Commissioner of Food and Drugs may prescribe.

(c) * * *

(3) Form FDA–200D, entitled "Special Authority for Criminal Investigators," is in two parts and bears the holder's name, a color photograph, the signature of the holder, his or her special authority under 21 U.S.C. 334 and 372 and other duties as assigned by the Commissioner, an identification number, the Commissioner's or his designee's signature, the names of the Department of Health and Human Services, the Public Health Service, and the Food and Drug Administration. Part 1 of the form is superimposed with the symbol FDA with blue imprint, and part 2 is superimposed with the FDA criminal investigator's badge with blue imprint.

Dated: December 30, 1992.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 93–244 Filed 1–5–93; 8:45 am]

BILLING CODE 4160–01–F

Substance Abuse and Mental Health Services Administration

Food and Drug Administration

21 CFR Part 291

[Docket No. 88N-0444]

Methadone in Maintenance Treatment of Narcotic Addicts; Joint Revision of Conditions for Use; Interim Maintenance Treatment; Human Immunodeficiency Virus Disease Counseling

AGENCIES: Food and Drug Administration and Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) formerly the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) are revising the conditions for the use of methadone in the maintenance treatment of narcotic addicts. The final rule allows, contingent on FDA and State approval, public and nonprofit private narcotic treatment programs to provide interim maintenance treatment to patients awaiting placement in comprehensive maintenance treatment and to require all narcotic treatment programs to provide counseling on preventing exposure to, and the transmission of, human immunodeficiency virus (HIV) disease.

EFFECTIVE DATE: January 6, 1993.

FOR FURTHER INFORMATION CONTACT: Thomas C. Kuchenberg, Center for Drug Evaluation and Research (HFD-362), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-295-8046.

SUPPLEMENTARY INFORMATION:

I. Background

A. Summary of the Proposal

In the **Federal Register** of March 2, 1989 (54 FR 8973) (corrected in the **Federal Register** of March 27, 1989 (57 FR 12531)), FDA and the National Institute on Drug Abuse (NIDA) jointly published a proposed regulation to revise the conditions for the use of methadone in the maintenance treatment of narcotic addicts. The proposal would allow narcotic treatment programs to provide interim maintenance treatment to patients awaiting placement in comprehensive maintenance treatment and require such programs to provide counseling on avoidance and transmission of HIV disease. Prompted by the HIV epidemic in the intravenous (IV) drug abuser population and evidence that methadone treatment is an effective method of limiting the transmission of HIV among this population, the proposal was intended to allow narcotic treatment programs greater flexibility in admitting narcotic addicts into treatment. The proposal specifically solicited comments on several unresolved issues that are important to the successful implementation of interim maintenance treatment. Those issues included: (1) The elements of a policy for transferring patients from interim maintenance treatment to comprehensive maintenance treatment, (2) the question of requiring mandatory HIV testing in methadone treatment programs, (3) the utility of requiring random urine testing of interimcare patients, (4) the question of allowing "stand alone" interim maintenance clinics, and (5) other limitations (allowable number of interim patients, ratio of interim patients to comprehensive patients) on the interim maintenance treatment modality.

In the **Federal Register** of April 6, 1989 (54 FR 13897), FDA and NIDA extended the comment period on the proposal until May 3, 1989. This action was based on several requests for extension of the comment period.

B. Administrative Record

FDA and NIDA received over 80 comments on the proposal. These comments represented many interests—members of Congress; Federal, State, and local government authorities; narcotic treatment programs and counseling services; professional associations representing administrators, physicians, and treatment programs; and national organizations for HIV prevention and treatment research. Comments on the proposed interim maintenance provisions revealed large differences of opinion both on the desirability of adopting the interim maintenance provisions and on a number of related issues as well. Some comments were concerned with the possible detrimental effect proposed interim maintenance treatment would have on comprehensive maintenance treatment. Other comments questioned the existence of an extensive, nationwide, or regional waiting list problem associated with methadone maintenance programs. Because of these differing views and in light of comments urging that an expert meeting be convened to addressed the complex issues posed by the proposal, the agencies concluded that it was necessary to solicit additional information before making a final decision. Therefore, FDA and NIDA jointly published a notice in the **Federal Register** of December 4, 1989 (54 FR 50226), announcing a public hearing to be convened on February 28, 1990, to obtain further public comment and factual information on the unresolved issues. The December 4, 1989, notice specifically sought comments on the likely success of the interim maintenance treatment approach to decrease the spread of HIV infection among IV drug abusers. In addition, the agencies sought help in assessing the extent to which demand for methadone maintenance treatment exceeds current treatment resources, and the likely impact that interim maintenance treatment would have in shortening the waiting lists for entry into methadone treatment programs. Finally, the agencies sought help in developing standards for interim maintenance treatment should interim maintenance rules be adopted.

At the February 28, 1990, public hearing, 28 individuals representing 20 organizations made oral presentations on these and related issues before a panel composed of representatives from FDA, NIDA, and other Public Health Service organizations. A transcript of the hearing and additional written information were placed in the administrative record.

FDA and NIDA evaluated the data, evidence, and testimony submitted as part of the February 28, 1990, public hearing, together with the written comments submitted in response to the March 2, 1989, proposed rule. Several comments stressed the potential importance of interim maintenance in checking the spread of AIDS. Representatives of an interim program, operating under a § 291.505(d)(11) exemption (21 CFR 291.505(d)(11)), indicated that they had witnessed a substantial decline in high risk heroin use among those participating in the program. While submissions indicated some regional shortages of methadone treatment capacity, the administrative record does not disclose significant national shortages in the availability of methadone maintenance treatment slots. Several comments noted that the exemption process currently provided for in § 291.505(d)(11), and described in the preamble of the public hearing notice that was published December 4, 1989 (54 FR 50226 at 50227), would provide for treatment modifications similar to the proposed interim maintenance approach. The comments suggested that this exemption process could be applied on a case-by-case basis

to relieve regional or State overcrowding.

Extensive information was presented in the administrative record regarding the current "poly-drug abuse" profile of IV narcotic addicts and the concomitant need to focus counseling and other rehabilitative services available in comprehensive maintenance treatment on narcotic addicts with multiple addictions entering treatment. Many comments contended that the resources and funding that participating methadone treatment programs would have to provide to offer the proposed interim maintenance treatment would be at the expense of the current comprehensive maintenance treatment and would therefore diminish the role of comprehensive narcotic treatment programs in reducing IV drug abuse. In light of this concern, a considerable number of comments concluded that interim maintenance would fail to decrease the incidence of IV drug abuse and the transmission of HIV disease nationwide.

In addition, the agencies have also considered reports regarding the effectiveness of drug abuse treatment prepared in 1990 by the General Accounting Office (GAO) and the Office of Technology Assessment (OTA). The GAO report concluded that its research findings did not support the effectiveness of proposed interim maintenance in reducing IV drug use and in reducing the corresponding risk of Acquired Immunodeficiency Syndrome (AIDS). The OTA report stated that interim methadone maintenance programs may be more appropriate for certain geographical areas, such as those with large numbers of IV drug users and long waiting lists.

C. ADAMHA Reorganization Act

On July 10, 1992, the ADAMHA Reorganization Act (the Act) became law (Pub. L. 102–321). Pursuant to the reorganization provisions of Title I of the Act, ADAMHA has been restructured to transfer its substance abuse and mental health research institutes, including NIDA, to the National Institutes of Health and to establish SAMHSA to administer substance abuse and mental health prevention and treatment services programs. Thus, unless specifically provided otherwise by the Act, all service-related functions formerly exercised by ADAMHA or its entities, including NIDA, have been transferred to SAMHSA. The reorganization provisions under Title I of the Act were effective on October 1, 1992.

The Act amended the PHS Act and requires the Secretary of Health and Human Services (the Secretary), after consultation with the National Commission or Acquired Immunodeficiency Syndrome (NCAIDS), to issue a final rule establishing interim maintenance treatment regulations and the conditions for public and nonprofit private programs to obtain authorization from the Secretary to provide such treatment. Section 1976(b)(1) of the PHS Act, as amended by section 202 of the ADAMHA Reorganization Act, provides that interim maintenance treatment regulations do not need to be promulgated if the Secretary finds that one or more of three conditions exist. These conditions are that:

(1) "The preponderance of scientific research indicates that the risk of transmission of HIV disease pursuant to the intravenous abuse of drugs is minimal;" (2) "the preponderance of scientific research indicates that the medically supervised dispensing of methadone is not an effective method of reducing the extent of dependence on heroin and other morphine-like drugs;" or (3) "the preponderance of available data indicates that, of treatment programs that dispense methadone as part of comprehensive treatment, a substantial majority admit all individuals seeking services to the programs not later than 14 days after the individuals seek admission to the programs." Further, section 1976(b)(2) of the PHS Act requires the Secretary to consult with NCAIDS to determine one or more of those conditions have been met.

With the concurrence of NCAIDS, the Secretary has determined that none of these conditions has been met. First, the Secretary has determined that the preponderance of scientific research indicates that IV abuse of drugs is, in fact, a primary pathway for HIV disease transmission and as such constitutes a major public health problem. Second, the Secretary has determined that the preponderance of scientific research indicates that the medically supervised dispensing of methadone continues to be an effective method of reducing dependence on heroin and other morphine-like drugs.

Finally, the Secretary has determined that the preponderance of available data does not indicate that, of treatment programs that dispense methadone as part of comprehensive treatment, a substantial majority admit all individuals seeking services to the programs not later than 14 days after the individuals seek admission to the programs. Because waiting lists are currently not an accurate measure of the number of individuals seeking treatment services or in need of treatment services, the Secretary does not believe that the available data could support a finding of inapplicability for this condition. Therefore, the Secretary, after consultation with NCAIDS, has determined that the conditions for the use of methadone should be revised to allow public and nonprofit private narcotic treatment programs to provide interim maintenance treatment to patients awaiting placement in comprehensive maintenance treatment. Further, to provide HIV disease counseling to all individuals seeking treatment, the Secretary has decided the methadone regulations should be revised in § 291.505(d)(4)(i)(C) to require all narcotic treatment programs offering maintenance and detoxification treatment to provide counseling to each patient on exposure to, and the transmission of, HIV disease.

Current narcotic treatment regulations require a tuberculin skin test to be included in each patient's initial medical evaluation. In view of the recent increase in tuberculosis cases, the agencies emphasize the importance of the tuberculin skin test required under § 291.505(d)(3) as part of the medical evaluation given each patient at the time of admission. Programs are also encouraged to periodically retest patients who had negative tuberculin skin tests on admission. In addition, the agencies encourage programs to routinely perform tuberculin skin tests for all program personnel at the start of employment and all current employees who have not recently received a tuberculin skin test. Programs are encouraged to periodically retest all program employees with negative skin tests. Programs are encouraged to maintain records on the tuberculin skin testing results of both patients and staff. All tuberculin skin tests should be administered intradermally using the Mantoux technique, or, when available, a procedure of equal or better sensitivity.

Any patient or staff member with a positive skin test or clinical evidence of possible tuberculosis disease needs a prompt medical evaluation and appropriate treatment.

Methadone treatment programs should report all patients or staff who have tuberculosis disease to State and local health departments.

II. Interim Maintenance Treatment

Section 1976(c)(1) of the PHS Act requires the Secretary, after consultation with NCAIDS, to issue regulations containing the conditions for public and nonprofit private narcotic treatment programs to obtain authorization from

the Secretary and the chief public health officer of the State to provide interim maintenance treatment. Such conditions shall include conditions for preventing the unauthorized use of methadone. In addition, the Secretary expects that the State public health officer will consult with the State Alcohol and Drug Abuse Director. Section 1976(c)(4) of the PHS Act also requires the Secretary to issue a final rule providing for interim maintenance treatment not later than 180 days after enactment. If a final rule is not promulgated by that time, the proposed rule of March 2, 1989, and the mandated provisions of the Act will take effect as a final rule. Therefore, under section 1976(c)(4) of the PHS Act, FDA and SAMHSA are promulgating this final rule that is based on the proposed rule of March 2, 1989, and mandated provisions of the PHS Act.

Provisions of the ADAMHA Reorganization Act other than those requiring interim maintenance treatment, such as the substance abuse block grant provisions, also affect interim maintenance treatment. Consistent with the PHS Act, the interim maintenance treatment provisions proposed in 1989 are being finalized with changes to incorporate all of the requirements of the Act. These are as follows: First, § 291.505(b)(1)(v) the applicability of interim maintenance treatment regulations is limited to public and nonprofit private narcotic treatment programs that are approved in accordance with § 291.505(c). Secondly, § 291.505(d)(7) provides that a public or nonprofit private narcotic treatment program may place a patient, otherwise eligible for admission to comprehensive maintenance treatment, in interim maintenance only if the program is unable to place the patient in comprehensive treatment in a public or nonprofit private program within a reasonable geographic area within 14 days of seeking admission. Thirdly, § 291.505(b)(2)(vi) provides that a public or nonprofit private narcotic treatment program, to provide interim maintenance treatment, must obtain authorization from FDA and the chief public health officer of the State. Before such authorization is granted by FDA, the program must provide FDA with written certification from the chief public health officer of the State that he or she does not object to interim maintenance treatment in the State and that interim maintenance treatment programs will not reduce the capacity or fiscal support of comprehensive maintenance treatment programs to admit individuals (relative to the date on which such officer so certifies). The Secretary expects that the States will ensure that interim maintenance programs are given appropriate guidance in order to assure that, before admitting a patient, comprehensive treatment in a public or nonprofit private program was not available to the patient within a reasonable geographic area. The Secretary also expects that, as part of the certification process, a State's chief public health officer will consult with the State agency charged with oversight of substance abuse programs utilizing methadone. If a State certifies interim maintenance treatment the State must establish appropriate and reasonable criteria to ensure that interim care is provided in a manner consistent with Federal law and that no individual continues in such a program for more than a total of 120 days for a 12-month period.

Fourth, consistent with section 1923 of the PHS Act, a State must make comprehensive treatment available to any individual who requests and is in need of treatment for intravenous drug abuse within 120 days of the date of such request. Thus, patients may only be admitted to, and treated with, interim maintenance for a period up to and including 120 days per 12-month period. After 120 days, patients must be transferred to a comprehensive program if they are still in need of treatment. The program must notify the State health officer both when interim treatment begins and before the 120-day period expires and document these notifications.

Fifth, § 291.505(d)(7) provides that consistent with section 1927(a) of the PHS Act, a State must ensure that programs within the State providing interim maintenance services give preference in admission to interim care and transfer to comprehensive care to pregnant women who seek or are referred to and would benefit from such services. The Department of Health and Human Services (DHHS) will monitor closely interim maintenance treatment programs.

The final regulation does not require programs to maintain a specific counselor to patient ratio. However, programs are required to provide a number of services (e.g., referrals to such services as medical services, prenatal care, HIV counseling). Accordingly, programs should assure that sufficient counseling staff is available to provide these services. In addition, programs should assure that counseling staff is available to respond to patient emergency situations.

The Secretary advises that, in addition to the initial drug screening, interim programs should perform a minimum of two additional drug screenings. The Secretary recommends that programs perform more frequent tests to assist in assessing patient needs and priorities for transfer to comprehensive programs.

III. HIV Disease Counseling

Section 1976(c)(2) of the PHS Act requires that the Secretary not authorize the provision of interim maintenance unless the public and nonprofit private program provides patients with counseling on preventing exposure to, and the transmission of, HIV disease. Additionally, the March 2, 1989, interim maintenance treatment proposal included a provision requiring all narcotic treatment programs offering maintenance or detoxification treatment to provide counseling on avoiding the transmission of HIV disease. This requirement was uniformly supported by received comments. Therefore, FDA and SAMHSA, in § 291.505(d)(4)(i)(C) are also finalizing that portion of the March 2, 1989, proposal requiring all narcotic treatment programs to provide counseling to each patient on preventing exposure to, and transmission of, HIV disease. This counseling shall be provided upon entrance to all types of maintenance and detoxification treatment. Counseling should be repeated as necessary.

Although HIV testing is not required by this regulation, HIV testing is an important element in reducing the risk of HIV transmission. Accordingly, the agencies believe that HIV testing must be made accessible to patients who request it. If a program does not provide HIV testing on site, then the program shall counsel patients on other opportunities where availability of testing is assured through agreements with HIV testing facilities to make HIV testing accessible to patients who request it.

The final rule also amends the narcotic treatment regulations in § 291.505(a)(10) to include a definition for the term "HIV disease" as defined under section 1976(d)(2) of the PHS Act and a conforming amendment in § 291.505(d)(8)(i)(F) to include a requirement inadvertently omitted from the March 2, 1989, proposal requiring HIV disease counseling in the provisions for short-term detoxification.

IV. Environmental Impact

FDA has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment

nor an environmental impact statement is required.

V. Economic Impact

FDA and SAMHSA have examined the regulatory impact and regulatory flexibility implications of the final rule in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354). The final rule will allow methadone treatment programs to provide minimum service (interim) maintenance treatment to patients awaiting placement in comprehensive treatment. This will allow narcotic addicts into treatment more quickly, thereby decreasing the incidence of intravenous drug abuse and the transmission of HIV. The agencies find that the final rule is not a major rule inasmuch as these revisions will not result in any significant increase in cost to narcotic treatment programs or to State and local authorities. In fact, this final rule will allow maintenance treatment of narcotic drug addicts at a lower cost per patient. In addition, the final rule establishes a provision requiring treatment programs to provide counseling on preventing exposure to, and the transmission of, HIV disease for each patient seeking admission and readmission to a treatment program.

The agencies estimated the costs of providing HIV disease counseling for a range of patients because of varying estimates of the census of patients under treatment nationally. The GAO report, "Methadone Maintenance" (March 1990), and SAMHSA estimate 100,000 patients are under treatment nationally, while other experts offered a higher estimate of 350,000 patients. In response to the proposed rule, one comment suggested an incremental cost of 80 cents per patient per day, but did not present information on the components of this cost.

For its cost analysis, the agencies have assumed that counselors earn $13 per hour and that patients on average would receive 1 hour of counseling. Based on these assumptions, the annual cost of providing HIV-disease counseling would be between $1,300,000 ($13/hour × 100,000 patients) and $4,550,000 ($13/hour × 350,000 patients). This cost estimate assumes that no narcotic treatment programs currently offer HIV-disease counseling. However, because some narcotic treatment programs currently already provide disease counseling, the actual costs will be less than the agencies' estimates. The requirements for referrals for other services already exist for providers of comprehensive services; thus, minimum incremental costs will be incurred in the provision of these referrals. In areas where there is a shortage of drug treatment slots, interim methadone maintenance provides a bridge to comprehensive treatment, thus reducing both HIV transmission and continued use of opiates. Even if interim methadone maintenance changes the behavior of only a few addicts, the potential savings from reducing the spread of HIV and reducing illicit drug use by facilitating entrance to a proven treatment modality, thereby reducing illicit drug use, are substantial.

For these reasons, therefore, the agencies have determined that this rule is not a major rule as defined in Executive order 12291. Further, FDA and SAMHSA certify that the rule will not have a significant impact on a substantial number of small entities as defined by the Regulatory Flexibility Act.

VI. Paperwork Reduction Act of 1980

The final rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the paperwork reduction Act of 1980. The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Methadone, HIV Disease Counseling, Transfer Priority Criteria Evaluation Notation.

Description: FDA and SAMHSA are requiring this notation to ensure that a record exists of the transfer criteria evaluation, which is designed to help prevent interim maintenance treatment from becoming a long-term treatment modality for any patient.

Description of Respondents: State or local governments, businesses, or other organizations; nonprofit institutions.

Estimated Annual Reporting and Recordkeeping Burden:

Section 291.505(d)(7).
Annual number of respondents: 20.
Annual frequency: 200.
Average burden per response: 5 minutes.
Annual burden hours: 333.

The agencies received no public comments on the estimated public reporting burden, and it remains the same as that contained in the proposed rule.

VII. Effective Date

This final rule is effective on January 6, 1993. The ADAMHA Reorganization Act requires that a final rule be effective not later than 180 days after its enactment (by January 6, 1993) or the proposed rule issued on March 2, 1989 (54 FR 8973) is deemed to take effect. The final rule also relieves a restriction, in that it will provide conditions for interim maintenance treatment to patients awaiting placement in comprehensive maintenance treatment programs. Therefore, the agencies find that the final rule is within the exemption to the Administrative Procedure Act (5 U.S.C. 553d) so that it can be made effective in less than 30 days.

List of Subjects in 21 CFR Part 291

Health professions, Methadone, Reporting and recordkeeping requirements.

Therefore, under the Comprehensive Drug Abuse Prevention and Control Act of 1970, the Narcotic Addict Treatment Act of 1974, and applicable delegations of authority thereunder, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 291 is amended as follows:

PART 291—DRUGS USED FOR TREATMENT OF NARCOTIC ADDICTS

1. The authority citation for 21 CFR part 291 is revised to read as follows:

Authority: Secs. 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 371); 21 U.S.C. 823; secs. 301(d), 548, 1976 of the Public Health Service Act (42 U.S.C. 241(d), 290ee–3, 300y–11); 42 U.S.C. 257a.

2. Section 291.505 is amended by inserting the word "comprehensive" before the word "maintenance" everywhere it appears in paragraphs (d)(1)(i), (d)(1)(iii), (d)(1)(iv), (d)(2)(i), (d)(3)(v)(D), (d)(4)(i)(B)*2*), (d)(5)(ii), (d)(6)(iv)(B)(*6*), (d)(6)(v)(A)(*1*) and (d)(6)(v)(A)(*3*), (d)(6)(v)(C), (d)(8)(i) introductory text and (d)(8)(i)(E), (d)(9)(i) introductory text and (d)(9)(i)(F), and by revising paragraph (a)(2), by adding paragraphs (a)(10), (b)(1)(v), (b)(2)(vi), (d)(4)(i)(C), and (d)(7), and by revising paragraph (d)(8)(i)(F) to read as follows:

§ 291.505 Conditions for the use of narcotic drugs; appropriate methods of professional practice for medical treatment of the narcotic addiction of various classes of narcotic addicts under section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970.

(a) * * *

(2) *Maintenance treatment* means the dispensing of a narcotic drug, at relatively stable dosage levels, in the treatment of an individual for dependence on heroin or other morphine-like drug. There are two types of maintenance treatment:

comprehensive maintenance treatment and interim maintenance treatment.

(i) *Comprehenisve maintenance treatment* is maintenance treatment provided in conjunction with a comprehensive range of appropriate medical and rehabilitative services.

(ii) *Interim maintenance treatment* is maintenance treatment provided in conjunction with appropriate medical services while a patient is awaiting transfer to comprehensive maintenance treatment.

* * * * *

(10) The term *HIV disease* means infection with the etiologic agent for acquired immunodeficiency syndrome.

* * * * *

(b) * * *

(1) * * *

(v) *Interim maintenance treatment.* A public or nonprofit private narcotic treatment program may provide interim maintenance treatment only if the program also provides comprehensive maintenance treatment to which interim maintenance treatment patients may be transferred.

(2) * * *

(vi) *Interim maintenance treatment program approval.* Before a public or nonprofit private narcotic treatment program may provide interim maintenance treatment, the program must receive approval of both the Food and Drug Administration and the chief public health officer of the State. Before such approval is granted, the program must provide the Food and Drug Administration with certification from the chief public health officer of the State that:

(A) Such officer does not object to the authorization of programs providing interim maintenance treatment in the State and that programs seeking such authorization are unable to place patients in a public or nonprofit private comprehensive treatment program within a reasonable geographic area within 14 days of the time patients seek admission to such programs;

(B) The authorization of programs providing interim maintenance treatment in the State will not reduce the capacity of comprehensive programs in the State to admit individuals to these programs (relative to the date on which such officer so certifies);

(C) The State guarantees that individuals enrolled in interim maintenance treatment will be transferred to comprehensive programs not later than 120 days, as provided by section 1923 of the Public Health Service Act (the PHS Act) and applicable regulations; and

(D) Requests for authorization should be submitted to the address specified in § 291.505(k).

* * * * *

(d) * * *

(4) * * *

(i) * * *

(C) *Counseling on HIV disease.* A narcotic treatment program shall provide counseling on preventing exposure to, and the transmission of, HIV disease for each patient admitted or readmitted to maintenance or detoxification treatment. Although HIV testing is not required, an interim program shall inform patients of the availability of HIV testing. The program sponsor shall also ensure that HIV testing is accessible to patients who request such testing either on site or by the programs entering into agreements with HIV testing facilities to make HIV testing accessible to those patients who request it.

* * * * *

(7) *Minimum standards for interim maintenance treatment.* The person(s) responsible for a program may place an individual, who is eligible for admission to comprehensive maintenance treatment, in interim maintenance treatment if the individual cannot be placed in a public or nonprofit private comprehensive program within a reasonable geographic area and within 14 days of the individual's application for admission. An initial and at least two other urine screens shall be taken from interim patients during the maximum of 120 days permitted for such treatment. A program shall establish and follow reasonable criteria for establishing priorities for transferring patients from interim maintenance to comprehensive maintenance treatment. These transfer criteria shall be in writing and available for inspection and shall include, at a minimum, a preference for pregnant women in admitting patients to interim maintenance and in transferring patients from interim maintenance to comprehensive maintenance treatment. Interim maintenance shall be provided in a manner consistent with all applicable Federal and State laws including sections 1923 (mandatory transfer) and 1927(a) (pregnant patients) of the PHS Act. The program shall notify the State health officer when a patient begins interim treatment, when a patient leaves interim treatment, and before the date of mandatory transfer to a comprehensive program, and shall document such notifications. Programs in States not in compliance with provisions of this regulation risk loss of authorization for interim maintenance. All requirements for comprehensive maintenance treatment apply to interim maintenance treatment with the following exceptions:

(i) The narcotic drug is required to be administered daily under observation;

(ii) Take-home medication is not allowed;

(iii) The initial treatment plan and periodic treatment plan evaluation are not required;

(iv) A primary counselor is not required to be assigned to a patient;

(v) Interim maintenance cannot be provided for longer than 120 days in any 12 month-period; and

(vi) The requirements and exceptions in paragraphs (b)(2)(iii) (as apply to rehabilitative services), in paragraphs (b)(3)(iv)(B) and (d)(4)(i)(A) (as apply to rehabilitative services), and in paragraphs (d)(4)(ii)(E), (d)(4)(ii)(F), (d)(4)(iv), (d)(6)(iv), (d)(6)(v), (d)(6)(vi), and (d)(6)(vii) of this section do not apply.

* * * * *

(8) * * *

(i) * * *

(F) The requirements of paragraph (d)(4) of this section, except paragraphs (d)(4)(i)(C), (d)(4)(ii)(A) through (d)(4)(ii)(D), and (d)(4)(iii) of this section, do not apply to short-term detoxification treatment.

* * * * *

Elaine Johnson,

Acting Administrator, Substance Abuse and Mental Health Services Administration.

David A. Kessler,

Commissioner of Food and Drugs.

Dated: January 4, 1993.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 93-266 Filed 1-4-93; 12:33 pm]

BILLING CODE 4160-17-M

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Diazepam Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Hoffmann-La Roche Inc. The NADA provides for the use of diazepam injection as a preanesthetic agent to reduce the amount of barbiturate required for short duration anesthesia in dogs.

EFFECTIVE DATE: January 6, 1993.

FOR FURTHER INFORMATION CONTACT: Marcia K. Larkins, Center for Veterinary Medicine (HFV-112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-295-8614.

SUPPLEMENTARY INFORMATION: Hoffmann-La Roche, Inc., Nutley, NJ 07110, filed NADA 140-848 which provides for intravenous use of Veteeze® (diazepam) injection for dogs as a preanesthetic agent to reduce the amount of barbiturate required for short duration anesthesia. The NADA is approved as of December 17, 1992, and the regulations are amended by adding new § 522.575 (21 CFR 522.575) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning December 17, 1992, because no active ingredient (including any ester or salt thereof) has been approved previously in any other NADA.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. New § 522.575 is added to read as follows:

§ 522.575 Diazepam injection.

(a) *Specification.* Each milliliter of sterile solution contains 5 milligrams of diazepam.

(b) *Sponsor.* See 000004 in § 510.600(c) of this chapter.

(c) *Conditions of use. Dogs*—(1) *Indications for use.* As a preanesthetic agent to reduce the amount of barbiturate required for short duration anesthesia.

(2) *Dosage.* Intravenously, 0.2 milligram per kilogram of body weight 3-5 minutes before anesthesia is to be induced using a short acting barbiturate.

(3) *Limitations.* Not for use in dogs with known sensitivity to benzodiazepines. Safety in animals intended for breeding and pregnant animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: December 17, 1992.

Gerald B. Guest,

Director, Center for Veterinary Medicine.

[FR Doc. 93-99 Filed 1-5-93; 8:45 am]

BILLING CODE 4160-01-F

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21 CFR Part 526

Intramammary Dosage Forms; Penicillin G Procaine in Oil

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to remove that portion reflecting approval of new animal drug application (NADA) held by Boehringer Ingelheim Animal Health, Inc., for procaine penicillin G for treatment of bovine mastitis. In a notice published elsewhere in this issue of the **Federal Register**, FDA is withdrawing approval of the NADA.

EFFECTIVE DATE: January 19, 1993.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV-216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-295-8749.

SUPPLEMENTARY INFORMATION: In a notice published elsewhere in this issue of the **Federal Register**, FDA is withdrawing approval of NADA 65-466 held by Boehringer Ingelheim Animal Health, Inc., 2621 North Belt Hwy., St. Joseph, MO 64506, for procaine penicillin G bovine mastitis treatment. This final rule removes 21 CFR 526.1696a(f) to reflect the withdrawal of approval of the NADA.

List of Subjects in 21 CFR Part 526

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 526 is amended as follows:

PART 526—INTRAMAMMARY DOSAGE FORMS

1. The authority citation for 21 CFR part 526 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 526.1696a [Amended]

2. Section 526.1696a *Penicillin G procaine in oil* is amended by removing paragraph (f).

Dated: December 16, 1992.

Gerald B. Guest,

Director, Center for Veterinary Medicine.

[FR Doc. 93-95 Filed 1-5-93; 8:45 am]

BILLING CODE 4160-01-F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL-4552-5]

Minnesota: Schedule of Compliance for Modification of Minnesota's Hazardous Waste Program

AGENCY: Environmental Protection Agency.

ACTION: Notice of Minnesota's Compliance Schedule to adopt program modifications.

SUMMARY: On September 26, 1986, U.S. EPA promulgated amendments to the deadlines for State program modifications and published requirements for States to be placed on a compliance schedule to adopt necessary program modifications. U.S. EPA is today publishing a compliance schedule for Minnesota to modify its program, in accordance with § 271.21(g) to adopt Federal program modifications.

EFFECTIVE DATE: January 1, 1993.

FOR FURTHER INFORMATION CONTACT: Christine Klemme, Minnesota Regulatory Specialist, Office of RCRA, U.S. EPA, Region V, 77 W. Jackson, HRM-7J, Chicago, Illinois 60604, (312) 886-3715, [FTS (312) 886-3715].

SUPPLEMENTARY INFORMATION:

A. Background

Final authorization to implement the Federal hazardous waste program within the State is granted by U.S. EPA if the Agency finds that the State program: (1) Is "equivalent" to the Federal program, (2) is "consistent" with the Federal program and other State programs, and (3) provides for adequate enforcement (section 3006(b), 42 U.S.C. 6926(b)). U.S. EPA regulations for final authorization appear at 40 CFR 271.1-271.25. In order to retain authorization, a State must revise its program to adopt new Federal requirements by the cluster deadlines and procedures specified in 40 CFR 271.21. See 51 FR 33712, September 22, 1986, for a complete discussion of these procedures and deadlines.

B. Minnesota

Minnesota received final authorization of its base hazardous waste program on February 11, 1985 (see 49 FR 226). The State received authorization for program revisions effective on September 18, 1987, June 23, 1989, August 14, 1990, August 23, 1991, and May 18, 1992. Today U.S. EPA is publishing a compliance schedule for Minnesota to complete a program revision on two Federal regulations, the Burning of Hazardous Waste in Industrial Furnaces (56 FR 7134, February 21, 1991), and, the Petroleum Refinery Primary and Secondary Oil/Water/Solids Separation Sludge Listing (55 FR 46354, November 2, 1990). The adoption deadline under 40 CFR 271.21 for these Federal regulations was July 1,1992. Minnesota has been granted a six-month extension to address these rules.

Minnesota has determined that, due to resource constraints, a one year delay to address these rules is necessary. On September 23, 1992, a letter from the State was received requesting an extension. Therefore, U.S. EPA is granting a one year extension of time until January 1, 1994, to address these two rules.

Authority

This notice is issued under authority of sections 2002(a), 3006, and 7004(b) of the Solid Waste Disposal Act, as amended by the RCRA of 1976, as amended, 42 U.S.C. 6912(a), 6926, and 6974(b).

Dated: December 17, 1992.

David A. Ullrich,

Acting Regional Administrator.

[FR Doc. 93-195 Filed 1-5-93, 8:45 am]

BILLING CODE 6560-50-M

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 64

[Docket No. FEMA-7559]

Suspension of Community Eligibility

AGENCY: Federal Insurance Administration, FEMA.

ACTION: Final rule.

SUMMARY: This rule identifies communities, where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP), that are suspended on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If FEMA receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will be withdrawn by publication in the **Federal Register**.

EFFECTIVE DATES: The effective date of each community's suspension is the third date ("Susp.") listed in the fourth column of the following tables.

ADDRESSES: If you wish to determine whether a particular community was suspended on the suspension date, contact the appropriate FEMA Regional Office or the NFIP servicing contractor.

FOR FURTHER INFORMATION CONTACT: Frank H. Thomas, Assistant Administrator, Office of Loss Reduction, Federal Insurance Administration, 500 C Street, SW., room 417, Washington, DC 20472, (202) 646-2717.

SUPPLEMENTARY INFORMATION: The National Flood Insurance Program (NFIP), enables property owners to purchase flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage as authorized under the National Flood Insurance Program, 42 U.S.C. 4001 et seq., unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR Part 59 *et seq.* Accordingly, the communities will be suspended on the effective date in the fourth column. As of that date, flood insurance will no longer be available in the community. However, some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue their eligibility for the sale of insurance. A notice withdrawing the suspension of the communities will be published in the **Federal Register**.

In addition, the Federal Emergency Management Agency has identified the special flood hazard areas in these communities by publishing a Flood Insurance Rate Map (FIRM). The date of the FIRM if one has been published, is indicated in the fifth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may legally be provided for construction or acquisition of buildings in the identified special flood hazard area of communities not participating in the NFIP and identified for more than a year, on the Federal Emergency Management Agency's initial flood insurance map of the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column.

The Administrator finds that notice and public comment under 5 U.S.C. 553(b) are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives a 6-month, 90-day, and 30-day notification addressed to the Chief Executive Officer that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications have been made, this final rule may take effect within less than 30 days.

National Environmental Policy Act

This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act

The Federal Insurance Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and, after the effective date, flood insurance will no longer be available in the communities unless they take remedial action.

Regulatory Impact Analysis

This rule is not a major rule under Executive Order 12291, Federal Regulation, February 17, 1981, 3 CFR, 1981 Comp., p. 127. No regulatory impact analysis has been prepared.

Paperwork Reduction Act

This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq.

Executive Order 12612, Federalism

This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, October 26, 1987, 3 CFR, 1987 Comp., p. 252.

Executive Order 12778, Civil Justice Reform

This rule meets the applicable standards of section 2(b)(2) of Executive Order 12778, October 25, 1991, 56 FR 55195, 3 CFR, 1991 Comp., p. 309

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

1. The authority citation for Part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 et seq.; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 64.6 [Amended]

2. The tables published under the authority § 64.6 are amended as follows:

State and Location	Community No.	Effective date of authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in special flood hazard areas
Suspensions				
Region III				
Virginia.				
Clinchport, town of Scott County	510143	Mar. 11, 1974, Emerg; Sept. 29, 1978, Reg; Jan. 6, 1993, susp.	Sept. 29, 1978	Jan. 6, 1993
Region II				
New Jersey:				
Stow Creek, township of Cumberland County	340174	July 1, 1975, Emerg; June 15, 1979, Reg; Jan. 20, 1993, Susp.	Jan. 20, 1993	Jan. 20, 1993
New York:				
Busti, town of Chautauqua County	361106	Aug. 8, 1975, Emerg; Mar. 18, 1980, Reg; Jan. 20, 1993, Susp.	Jan. 20, 1993	Do
Elizabethtown, town of Essex County	361388	Apr. 30, 1976, Emerg; July 20, 1984, Reg; Jan. 20, 1993, Susp.	Jan. 20, 1993	Do
Morristown, town of St. Lawrence County	360706	July, 30, 1980, Emerg; Aug. 6, 1982, Reg; Jan. 20, 1993, Susp.	Aug. 6, 1982	Do
Region III				
West Virginia:				
Ranson, city of Jefferson County	540068	Apr. 2, 1975, Emerg; June 15, 1979, Reg; Jan. 20, 1993, Susp.	Jan. 20, 1993	Do

Code for reading fourth column: Emerg.—Emergency; Reg.—Regular; Susp.—Suspension.

(Catalog of Federal Domestic Assistance No. 83.100, "Flood Insurance.")

Issued: December 30, 1992.

C.M. "Bud" Schauerte,

Administrator, Federal Insurance Administration.

[FR Doc. 93-188 Filed 1-5-93; 8:45 am]

BILLING CODE 6718-21-M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 1

[OST Docket No. 1; Amdt. 1-252]

Organization and Delegation of Powers and Duties; Delegation of Authority to the Federal Highway Administrator

AGENCY: Office of the Secretary, DOT.

ACTION: Final rule.

SUMMARY: This document delegates to the Federal Highway Administrator the authority vested in the Secretary of Transportation by section 601 of the Pipeline Safety Act of 1992, Public Law 102-508, concerning the construction of the Page Avenue Extension Project in St. Charles and St. Louis Counties, Missouri. The purpose of this rulemaking is to amend 49 CFR part 1 to reflect this delegation.

EFFECTIVE DATE: January 6, 1993.

FOR FURTHER INFORMATION CONTACT: John Kraybill, Office of the Chief Counsel, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590 (202) 366-1367, or Steve Farbman, Office of the Assistant General Counsel for

Regulations and Enforcement, U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590 (202) 366–9306.

SUPPLEMENTARY INFORMATION: The Secretary has determined that the authority vested in the Secretary by section 601 of the Pipeline Safety Act of 1992, Pub. L. 102–508, concerning the authority to waive the requirements of section 138 of title 23, United States Code, and section 303 of title 49, United States Code, and other authority relating to construction of the Page Avenue Extension Project in the State of Missouri should be delegated to the Federal Highway Administrator. Since this rule relates to Departmental management, organization, procedure, and practice, notice and comment on it are unnecessary and it may be made effective in fewer than 30 days after publication in the **Federal Register**.

List of Subjects in 49 CFR Part 1

Authority delegations (government agencies), Organizations and functions (government agencies).

PART 1—[AMENDED]

In consideration of the foregoing, part 1 of title 49, Code of Federal Regulations, is amended as follows:

1. The authority citation for 49 CFR part 1 continues to read as follows:

Authority: 49 U.S.C. 322.

2. Section 1.48 is amended by adding a new paragraph (jj), and the introductory text of the section is reprinted for the convenience of the reader, to read as follows:

§ 1.48 Delegations to Federal Highway Administrator.

The Federal Highway Administrator is delegated authority to—

* * * * *

(jj) Carry out the functions vested in the Secretary of Transportation by section 601 of the Pipeline Safety Act of 1992, Public Law 102–508, relating to construction of the Page Avenue Extension Project in Missouri.

Issued on: December 30, 1992.

Andrew H. Card, Jr.,

Secretary.

[FR Doc. 93–224 Filed 1–5–93; 8:45 am]

BILLING CODE 4910–62–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 672

[Docket No. 921240–2340]

RIN 0648–AE90

Groundfish of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Final rule.

SUMMARY: NMFS announces a final rule to remove a provision from the regulations acting to define "pelagic trawl gear" for purposes of the time/area closures authorized by Amendment 18 to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP). Amendment 18 expires on December 31, 1992. New time/area closure authority is provided by Amendment 26 to the FMP, which uses the definition of "pelagic trawl gear" appearing in 50 CFR 672.2.

EFFECTIVE DATE: Effective January 1, 1993.

ADDRESSES: Copies of the environmental assessment/regulatory impact review (EA/RIR) may be obtained from the North Pacific Fishery Management Council, P.O. Box 103136, Anchorage, AK 99510 (telephone 907–271–2809).

FOR FURTHER INFORMATION CONTACT: Susan J. Salveson, Fisheries Management Division, Alaska Region, NMFS, 907–586–7230.

SUPPLEMENTARY INFORMATION:

Background

The domestic and foreign groundfish fisheries in the exclusive economic zone (EEZ) of the Gulf of Alaska (GOA) are managed by the Secretary of Commerce (Secretary) in accordance with the FMP. The FMP was prepared by the North Pacific Fishery Management Council (Council) under the Magnuson Fishery Conservation and Management Act (Magnuson Act). The FMP is implemented by regulations appearing at 50 CFR part 611 for the foreign fishery and at 50 CFR part 672 for the U.S. fishery. General regulations that also pertain to U.S. fisheries appear at 50 CFR part 620.

Amendment 18 to the FMP, which expires December 31, 1992, authorizes time/area closures around Kodiak Island. paragraph (d) of 50 CFR 672.24 implements that authority.

A notice of proposed rulemaking was published in the **Federal Register** on October 15, 1992 (57 FR 47321) that invited comment on the continuation of time/area closures around Kodiak Island to protect sensitive king and Tanner crab habitat areas from on-bottom trawl operations as recommended by the Council under Amendment 26 to the FMP. The intent of that notice was to propose to implement the time/area closure authority of Amendment 26 by maintaining, without change paragraphs (d) (1) and (2) of 50 CFR 672.24 and removing paragraphs (d) (3) and (4), which act to define pelagic trawl gear for the sole purpose of time/area closures authorized by Amendment 18. Paragraphs (d) (3) and (4) require that each person using pelagic trawl gear in the Kodiak Island time/area closures maintain a working net-sonde device on the trawl, retain all net-sonde recordings on board the vessel, and maintain contact between the footrope and the seabed 10 percent or less of the period of any tow as indicated by the net-sonde device. Amendment 26 provides authority for time/area closures but uses the definition of pelagic trawl gear appearing in § 672.2. This definition defines pelagic trawl gear based on gear configuration rather than net-sonde device recordings (56 FR 2700, January 24, 1991). Unfortunately, because of a drafting error, the proposed amendatory language failed to propose removal of paragraphs (d) (3) and (4).

Response to Comments

Two letters of comment were received during the comment period. Comments are summarized and responded to below.

Comment 1: Regulations implementing Amendment 26 and its predecessor, Amendment 18, exemplify a wise approach to the conservation of the crab resource without unnecessarily impacting commercial fishing operations.

Response: NMFS notes this comment.

Comment 2: NMFS invited comment on the enforcement concerns about aerial monitoring of the time/area closures to non-pelagic trawl gear when pelagic trawl gear could still be deployed in the closed areas. These concerns are unfounded in the Gulf of Alaska (GOA). Pollock is the only pelagic trawl fishery in the GOA. All other groundfish trawl fisheries are prosecuted with non-pelagic trawl gear. Additionally, all non-pelagic groundfish fisheries are restricted by a single halibut bycatch limit that is apportioned into seasonal allowances. When a seasonal allowance is reached, the GOA is closed to directed fishing for groundfish by vessels using trawl gear, except that fishing for pollock with pelagic trawl gear may continue when directed fishing for pollock is open. The only time pelagic and non-pelagic trawl

gear operations simultaneously occur in the GOA is when directed fisheries for pollock and other groundfish are both open. The trawl fleet normally fishes for pollock at the beginning of each quarterly reporting period when quarterly apportionments of the annual pollock quota become available. Quarterly apportionments are harvested within a short time period and the trawl fleet typically shifts to other groundfish species during the remainder of the quarter. Therefore, monitoring of the non-pelagic trawl gear closures around Kodiak Island may only be complicated during the seasonal openings of the pollock fishery. NMFS enforcement need not resort to aerial monitoring in this case, but could simply confirm a vessel's participation in the pelagic trawl pollock fishery by checking observer reports, landings documents, or vessel logbooks.

Response: NMFS concurs that enforcement of the Kodiak Island closures to trawl gear other than pelagic trawl gear is possible. However, aerial surveillance of areas closed to specified gear types is the most effective and least costly and intrusive means to monitor such closures. NMFS may pursue an FMP amendment in the future that would prohibit the deployment of all trawl gear in the Kodiak Island time/area closures implemented under Amendment 26.

Comment 3: Fisheries enforcement would be enhanced if the time/area closures implemented under Amendment 26 applied to all trawl operations. Allowing only pelagic trawls in the closed areas renders aerial enforcement ineffective. As a result, enforcement of these closures will continue to require air/sea coordination to board and verify whether pelagic or non-pelagic trawl gear activity is occurring. The U.S. Coast Guard does not object to the regulations implementing Amendment 26 because they continue current practices and minimize impacts on pelagic trawl fisheries in the Kodiak Island area.

Response: NMFS notes this comment. Also, see response to Comment 2.

Final Rule

For the reasons set forth above, the final rule maintains paragraphs (d) (1) and (2) of 50 CFR 672.24 but removes paragraphs (d) (3) and (4).

Classification

The Assistant Administrator for Fisheries, NOAA (Assistant Administrator), has determined that this action is necessary for conservation and management of the groundfish fishery in the Gulf of Alaska and that it is consistent with the Magnuson Act and other applicable laws.

This final rule deletes a more restrictive definition for a gear exemption from regulatory time/area closures around Kodiak Island. As a substantive rule that relieves a restriction, under 5 U.S.C. 553(d)(1) it can and is being made effective without a 30-day delay in effective date.

The Council prepared an EA for this rule and the Assistant Administrator concluded that no significant impact on the environment would result from its implementation. The public may obtain a copy of the EA (see ADDRESSES).

The Assistant Administrator determined that this rule is not a major rule requiring a regulatory impact analysis under E.O. 12291. This determination is based on the socioeconomic impact discussed in the EA/RIR prepared by the Council.

NMFS has determined that this rule will be implemented in a manner that is consistent to the maximum extent practicable with the approved coastal zone management program of the State of Alaska. This determination has been submitted for review by the responsible State agency under section 307 of the Coastal Zone Management Act. The State agency declined to comment on the consistency determination within the statutory time period and consistency is inferred.

This rule does not contain policies with federalism implications sufficient to warrant preparation of a federalism assessment under E.O. 12612, and does not contain a collection-of-information requirement for the purposes of the Paperwork Reduction Act.

List of Subjects in 50 CFR Part 672

Fisheries, Reporting and recordkeeping requirements.

Dated: December 30, 1992.

Samuel W. McKeen,

Acting Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 672 is amended as follows:

PART 672—GROUNDFISH OF THE GULF OF ALASKA

1. The authority citation for 50 CFR part 672 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

§ 672.24 [Amended]

2. In § 672.24, paragraphs (d)(3) and (d)(4) are removed.

[FR Doc. 93-209 Filed 1-5-93; 8:45 am]
BILLING CODE 3510-22-M

50 CFR Parts 672 and 675

[Docket No. 920531-2221]

Groundfish of the Gulf of Alaska; Groundfish Fishery of the Bering Sea and Aleutian Islands Area

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Pacific halibut and red king crab bycatch rate standards; request for comments.

SUMMARY: NMFS announces Pacific halibut and red king crab bycatch rate standards for the first half of 1993. Publication of these bycatch rate standards and the schedule for the 1993 fishing months is necessary for purposes of the vessel incentive program. This action is necessary to implement the bycatch rate standards under this program that must be met by individual trawl vessel operators who participate in the groundfish fisheries. The intent of this action is to reduce prohibited species bycatch rates and promote conservation of groundfish and other fishery resources.

DATES: Effective 12:01 a.m., Alaska local time (A.l.t.), January 20, 1993, through 12 midnight, A.l.t., June 30, 1993. Comments on this action must be received at the following address no later than 4:30 p.m., A.l.t., January 19, 1993.

ADDRESSES: Comments should be mailed to Ronald J. Berg, Chief, Fisheries Management Division, NMFS, P.O. Box 21668, Juneau, Alaska 99802-1668, Attn: Lori Gravel, or be delivered to 9109 Mendenhall Mall Road, Federal Building Annex, Suite 6, Juneau, Alaska.

FOR FURTHER INFORMATION CONTACT: Susan J. Salveson, Fisheries Management Division, Alaska Region, NMFS, 907-586-7228.

SUPPLEMENTARY INFORMATION: The domestic and foreign groundfish fisheries in the exclusive economic zone of the Bering Sea and Aleutian Islands Area (BSAI) and Gulf of Alaska (GOA) are managed by the Secretary of Commerce (Secretary) according to the Fishery Management Plan (FMP) for the Groundfish Fishery of the BSAI and the FMP for Groundfish of the GOA. The FMPs were prepared by the North Pacific Fishery Management Council (Council) under the authority of the Magnuson Fishery Conservation and Management Act (Magnuson Act). The FMPs are implemented by regulations for the foreign fishery at 50 CFR part 611 and for the U.S. fishery at 50 CFR parts 672 and 675. General regulations

that also pertain to the U.S. fishery appear at 50 CFR part 620.

Regulations at §§ 672.26 and 675.26 implement a vessel incentive program to reduce halibut and red king crab bycatch rates in the groundfish trawl fisheries. The vessel incentive program was expanded to include all GOA and BSAI groundfish trawl fisheries under a final rule effective January 20, 1993 (57 FR 43926, September 23, 1992). Under the expanded incentive program, operators of trawl vessels must comply with Pacific halibut bycatch rate standards specified for the BSAI and GOA midwater pollock and "other trawl" fisheries, and the BSAI yellowfin sole and "bottom pollock" fisheries. Vessel operators must also comply with red king crab bycatch standards specified for the BSAI yellowfin sole and "other trawl" fisheries in Bycatch Limitation Zone 1 (defined at § 675.2). The fisheries included under the incentive program are defined in regulations at §§ 672.26(b) and 675.26(b).

Regulations at §§ 672.26(c) and 675.26(c) require that halibut and red king crab bycatch rate standards for each fishery monitored under the incentive program be published in the **Federal Register.** Any vessel operator whose monthly bycatch rate exceeds the bycatch rate standard is in violation of the regulations implementing the incentive program. The standards are in effect for specified seasons within the 6-month periods of January 1 through June 30, and July 1 through December 31. Given that the amended vessel incentive program becomes effective January 20, 1993, and the GOA and BSAI fisheries are closed to trawling until that date (§§ 672.23(e) and 675.23(d), respectively), NMFS is implementing bycatch rate standards for the first half of 1993 effective from January 20, 1993, through June 30, 1993.

At its December 8–13, 1992 meeting, the Council reviewed updated analyses comparing 1991 and 1992 bycatch rates experienced by vessels participating in the fisheries under the incentive program. Based on this and other information presented below, the Council recommended halibut and red king crab bycatch rate standards for the first half of 1993. These standards are set forth in Table 1. As required by §§ 672.26(c) and 675.26(c), the Council's recommended bycatch rate standards for January through June are based on the following information:

(A) Previous years' average observed bycatch rates;

(B) Immediately preceding season's average observed bycatch rates;

(C) The bycatch allowances and associated fishery closures specified under §§ 672.20(f) and 675.21;

(D) Anticipated groundfish harvests;

(E) Anticipated seasonal distribution of fishing effort for groundfish; and

(F) Other information and criteria deemed relevant by the Regional Director.

Bycatch Rate Standards for Pacific Halibut

The Council's Pacific halibut bycatch rate standards for the BSAI and GOA trawl fisheries are based largely on anticipated seasonal fishing effort for groundfish species and historic halibut bycatch rates observed in specified trawl fisheries. Council deliberations on seasonal bycatch rate standards recognized that the 1993 trawl fisheries do not start until January 20 and that the BSAI yellowfin sole fishery is further delayed until May 1 under regulations at § 675.23(c).

The recommended halibut bycatch rate standards for the BSAI yellowfin sole, "bottom pollock," and "other trawl" fisheries approximate the average rates observed on trawl vessels participating in these fisheries during the past 2 years.

The halibut bycatch rate standard recommended for the BSAI and GOA midwater pollock fisheries (1 kilogram (kg) halibut/metric ton (mt) of groundfish) is higher than the bycatch rates normally experienced by vessels participating in these fisheries. The recommended standard is intended to encourage vessel operators to maintain off-bottom trawl operations during their participation in the midwater pollock fisheries. Vessel operators/owners who exceed the halibut bycatch rate standard are subject to prosecution under the incentive program.

The recommended standard for the BSAI "bottom pollock" fishery during the first quarter of 1993 (7.5 kg halibut/mt of groundfish) is set at a level that approximates the average halibut bycatch rate experienced by vessels participating in the "bottom pollock" fishery during the first quarter of 1992 (7.58 kg halibut/mt of groundfish. The recommended bycatch rate standard for the first quarter of 1993 is higher than the standard recommended for the second quarter (5.0 kg halibut/mt of groundfish). The Council anticipates that fishing effort for pollock by the inshore and offshore components will occur during the first quarter of 1993 and that directed fishing allowances specified for the pollock "A" season will be reached before the end of the "A" season (April 15). Directed fishing for pollock by vessels participating in the inshore and offshore component fisheries is prohibited from the end of the pollock "A" season until the beginning of the pollock "B" season (June 1). During its December meeting, the Council took action to delay the opening of the pollock "B" season until August 15. If the Secretary approves the "B" season delay, it could be implemented in 1993. Vessels fishing under the Community Development Quota (CDQ) program (50 CFR § 675.27) could participate in a directed fishery for pollock between the "A" and "B" seasons, subject to other provisions governing the groundfish fisheries.

The 5.0 kg halibut/mt of groundfish bycatch rate standard recommended by the Council for the second quarter of 1993 approximates the average halibut bycatch rate experienced by vessels participating in the "bottom pollock" fishery during the second quarter of 1992 (4.3 kg halibut/mt of groundfish). This bycatch rate standard is intended to accommodate any CDQ fishery that may occur after the first quarter of 1993. This standard also would apply to the inshore and offshore pollock fisheries during the month of June should the Secretary not approve the Council's proposed delay of the pollock "B" season.

The Council recommended a 50 Kg halibut/mt of groundfish bycatch rate standard for the GOA "other trawl" fishery. This standard is unchanged from 1992 and is based on Council intent to simplify the GOA incentive program by specifying a single bycatch rate standard for the fisheries under the incentive program, yet maintain the Council's objective of reducing halibut bycatch rates in the GOA trawl fisheries. Observer data collected from the 1991 GOA trawl fisheries (excluding the midwater pollock fishery) show first and second quarter halibut bycatch rates of 24 and 66 kg halibut/mt of groundfish, respectively. First and second quarter rates from 1992 were lower at 20 and 22 kg/mt of groundfish, respectively. In spite of the apparent reduction in average bycatch rates from 1991 to 1992, the Council determined that a halibut bycatch rate standard of 50 kg halibut/mt of groundfish would continue to provide an incentive to vessel operators to reduce halibut bycatch rates while participating in the GOA trawl fisheries.

Bycatch Rate Standard for Red King Crab

The Council's recommended red king crab bycatch rate standard for the yellowfin sole and "other trawl" fisheries in Zone 1 of the Bering Sea subarea is 2.5 crab/mt of groundfish

during the first half of 1993. This standard is the same as that recommended for 1992.

Little fishing effort for flatfish occurred in Zone 1 during 1991 because commercial concentrations of yellowfin sole normally occur north of this area by the time the fishery opens May 1. As such, limited observer data exist for the 1991 and 1992 yellowfin sole fishery in Zone 1. These data indicate average quarterly red king crab bycatch rates between 1.3 and 1.4 crab/mt of groundfish. During this same period, vessels participating in the "other trawl" fishery experienced average red king crab bycatch rates ranging between 0.8 and 1.7 crab/mt of groundfish. During 1991 and 1992, some fishermen experienced relatively high bycatch rates of halibut north of Zone 1 and expressed a desire to explore fishing grounds in Zone 1 that may have lower halibut bycatch rates. Fishermen were reluctant to fish in Zone 1, however, because of possibly exceeding the red king crab bycatch rate standard. The total bycatch of red king crab by vessels participating in the 1992 trawl fisheries is estimated at 111,325 crab, or about 56 percent of the 200,000 crab bycatch limit established for the trawl fisheries in Zone 1. Recognizing that the red king crab bycatch limit will restrict bycatch amounts to specified levels, the Council maintained the 2.5 red king crab/mt of groundfish bycatch rate standard to support those fishermen who actively pursue alternative fishing grounds in an attempt to reduce halibut bycatch rates.

The Regional Director has determined that Council recommendations for bycatch rate standards are appropriately based on the information and considerations necessary for such determinations under §§ 672.26(c) and 675.26(c). Therefore, the Regional Director concurs in the Council's determinations and recommendations for halibut and red king crab bycatch rate standards for the first half of 1993 as set forth in Table 1. These bycatch rate standards may be revised and published in the **Federal Register** when deemed appropriate by the Regional Director pending his consideration of the information set forth at §§ 672.26(c) and 675.26(c).

Fishing Months

As required in regulations at §§ 672.26(a)(2)(iii) and 675.26(a)(2)(iii), the 1993 fishing months are specified as the following periods for purposes of calculating vessel bycatch rates under the incentive program:

Month 1: January 1 through January 30;
Month 2: January 31 through February 27;
Month 3: February 28 through April 3;
Month 4: April 4 through May 1;
Month 5: May 2 through May 29;
Month 6: May 30 through July 3;
Month 7: July 4 through July 31;
Month 8: August 1 through August 28;
Month 9: August 29 through October 2;
Month 10: October 3 through October 30;
Month 11: October 31 through November 27; and
Month 12: November 28 through December 31.

Classification

This action is taken under 50 CFR 672.26 and 675.26 and complies with E.O. 12291.

Information upon which the recommended bycatch rate standards are based was not available prior to the Council's December 1992 meeting. These standards must be effective by the start of the 1993 trawl season on January 20, to avoid a lapse in vessel accountability under the vessel incentive program. Without this accountability, prohibited species bycatch rates could increase in the groundfish trawl fisheries, prohibited species bycatch allowances could be reached sooner, specified groundfish trawl fisheries could be closed prematurely, and owners and operators of groundfish trawl vessels could incur additional foregone revenues. Therefore, the Assistant Administrator for Fisheries, NOAA, finds for good cause that it is impractical and contrary to the public interest to extend prior notice and comment on this notice beyond the start of the 1993 trawl season, or to delay its effective date.

List of Subjects in 50 CFR Parts 672 and 675

Fisheries, Reporting and recordkeeping requirements.

Authority: 16 U.S.C. 1801 *et seq.*

Dated December 31, 1992.

Richard H. Schaefer,

Director of Office of Fisheries Conservation and Management, National Marine Fisheries Service.

TABLE 1.—BYCATCH RATE STANDARDS, BY FISHERY AND QUARTER, FOR THE FIRST HALF OF 1993 FOR PURPOSES OF THE VESSEL INCENTIVE PROGRAM IN THE BSAI AND GOA.

Fishery and quarter	1993 bycatch standard
Halibut bycatch as kg of halibut/mt of allocated groundfish catch	
BSAI Midwater pollock:	
Qt 1	1.0
Qt 2	1.0
BSAI Bottom pollock:	
Qt 1	7.5
Qt 2	5.0
BSAI Yellowfin sole:	
Qt 1	5.0
Qt 2	5.0
BSAI Other trawl:	
Qt 1	30.0
Qt 2	30.0
GOA Midwater pollock:	
Qt 1	1.0
Qt 2	1.0
GOA Other trawl:	
Qt 1	50.0
Qt 2	50.0
Zone 1 red king crab bycatch rates (number of crab/mt of allocated groundfish)	
BSAI Yellowfin sole:	
Qt 1	2.5
Qt 2	2.5
BSAI Other trawl:	
Qt 1	2.5
Qt 2	2.5

[FR Doc. 92-31956 Filed 12-31-92; 2:59 pm]

BILLING CODE 3510-22-M

Proposed Rules

Federal Register
Vol. 58, No. 3
Wednesday, January 6, 1993

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Farmers Home Administration

7 CFR Part 1944

RIN 0575-AB16

Section 502 Rural Housing Loan Policies, Procedures, and Authorizations

AGENCY: Farmers Home Administration, USDA.

ACTION: Proposed rule.

SUMMARY: The Farmers Home Administration (FmHA) proposes to amend its Single Family Rural Housing loan making regulation. The following actions are taken: The definition of income is being revised pursuant to the Omnibus Budget Reconciliation Act of 1990, Public Law 101-508, which excludes "any earned income tax credit to the extent it exceeds tax liability" from being counted in the annual income; The interests of individual Indians in trust or restricted lands and payments made from the Agent Orange Settlement Fund or any other exempted Federal statutes cannot be used for the purposes of determining eligibility for an FmHA loan, nor can they be considered in determining the amount of interest credit assistance for which a borrower is eligible; Exclusion from the definition of annual income of pay of a member of the Armed Forces stationed in the Operation Desert Storm Combat Zone; FmHA will no longer post the selected Rural Housing applicants' names on the FmHA County Office's bulletin boards; FmHA will require applicants/borrowers to submit Federal income tax returns as part of a completed loan application; and the interest credit regulation is updated and discrepancies with previously published regulations are removed.

DATES: Comments must be received on or before March 5, 1993.

ADDRESSES: Submit written comments, in duplicate, to the Office of the Chief, Regulations Analysis and Control Branch, Farmers Home Administration, U.S. Department of Agriculture, room 6348, South Agriculture Building, 14th and Independence SW., Washington, DC 20250. All written comments will be available for public inspection during regular working hours at the above address.

FOR FURTHER INFORMATION CONTACT: Gloria L. Denson, Loan Specialist, Farmers Home Administration, USDA, room 5334-S, South Agriculture Building, 14th and Independence SW., Washington, DC 20250, Telephone (202) 720-1487.

SUPPLEMENTARY INFORMATION:

Classification

These actions have been reviewed under USDA procedures established in Departmental Regulation 1512-1 which implements Executive Order 12291, and has been determined to be a nonmajor because there is no substantial change from practices under existing rules that would have an annual effect on the economy of $100 million or more. There is no major increase in cost or prices for consumers, individual industries, Federal, State, or local Government agencies, or geographic regions, or significant adverse effects on competition, employment, productivity, innovation, or in the ability of United States based enterprises to compete with foreign-based enterprises in domestic or export markets. These actions are not expected to substantially affect budget outlay or affect more than one Agency or to be controversial. The net result is expected to provide better service to rural residents.

Environmental Impact Statement

This document has been reviewed in accordance with 7 CFR part 1940, subpart G, Environmental Program. It is the determination of FmHA that the proposed action does not constitute a major Federal action significantly affecting the quality of the human environment and in accordance with the National Policy Act of 1949, Public Law 91-90, an Environmental Impact Statement is not required.

Intergovernmental Consultation

For the reason set forth in the final rule related notice to 7 CFR part 3015, subpart V, 48 FR 29115, June 24, 1983, this program/activity is excluded from the scope of Executive Order 12372 which requires intergovernmental consultation with State and local officials.

Program Affected

This program is listed in the catalog of Federal Assistance under 10.410, Low-Income Housing Loans.

Regulatory Flexibility Act

This final rule has been reviewed with respect to the Regulatory Flexibility Act (5 U.S.C. 601-612). The undersigned has determined that this action will not have a significant economic impact on a substantial number of small entities since this rulemaking action does not involve a new or expanded program.

Background/Discussion

FmHA's existing regulations require any earned income tax credit to the extent it exceeds income tax liability to be included in the applicant/borrower's annual income. The Omnibus Budget Reconciliation Act of 1990, Public Law 101-508, excluded the earned income tax credit refund from being considered as income for purposes of FmHA housing programs. This exclusion was effective January 1, 1991. Therefore, the current regulations are being amended to exclude this requirement from the annual income definition.

FmHA is revising its regulations defining income for housing programs to clarify that the interests of individual Indians in trust or restricted lands shall not be considered a resource in determining eligibility for assistance. This change is consistent with 25 U.S.C. 1408.

Revisions are being made to FmHA regulations to exclude payments from the Agent Orange Settlement Fund or any other fund established pursuant to the settlement in the In re Agent Orange product liability litigation as means or resources for purposes of determining eligibility for an FmHA housing loan or interest credit. These changes are required by Public Law 101-201.

Section 501(b)(5) of the Housing Act of 1949 provides that for the purposes of the Housing Act of 1949 the "terms 'income' and 'adjusted income' have the meanings given by sections 3(b)(4) and 3(b)(5), respectively, of the United States Housing Act of 1937." Section 3(b)(4) of the United States Housing Act of 1937, 42 U.S.C. 1437a(b)(4), provides that the "term 'income' means income

from all sources of each member of the household, as determined in accordance with criteria prescribed by the Secretary of [of HUD], in consultation with the Secretary of Agriculture, except that any amounts not actually received by the family may not be considered as income under this paragraph." On January 29, 1991, the HUD Assistant Secretary for Public and Assisted Housing issued Notice H 91–11 which, among other things, waives HUD regulations which required annual income to include "all regular pay, special pay and allowances of a member of the Armed Forces." Thus, for the duration of Operation Desert Storm HUD's definition of annual income does not include military pay of military personnel stationed in the combat zone as defined in Presidential Executive Order 12744 (January 21, 1991). This revision in the definition of annual income is added to the FmHA definition of income for housing programs.

Current regulations require the County Supervisor to post on the County Office bulletin board after each selection period a list of the names of those applicants who have been selected and notified of the processing of their application. Based on recent Supreme Court decisions under the Freedom of Information Act (FOIA), FmHA is deleting this public posting requirement.

Current FmHA regulations do not require the County Supervisor to have the applicants submit, during the application process, audited and/or certified financial statements and income tax returns. The regulations are being revised to require the FmHA County Supervisor to review the Single Family Housing applicants' audited and/or certified financial statements and/or most recent Federal income tax returns as a part of the application process.

In an earlier rule change, FmHA implemented a provision of the Housing and Community Development Act of 1987 that provided for borrowers receiving interest credit assistance to continue their interest credit subsidies even though their incomes exceeded the moderate income level. To eliminate inconsistencies, the Agency proposes to revise the limitation on new interest credits for existing loans to allow borrowers with income not exceeding moderate to receive interest credit. In the past, a borrower had to have a low income to initially receive interest credit, although interest credit could continue to the borrower when the adjusted family income exceeded the moderate income limit. The change will allow existing borrowers who have moderate incomes to qualify to receive interest credit.

A change in the effective period of the Interest Credit Agreement is proposed in situations where the borrower is unemployed. Currently, the Interest Credit Agreement is processed for 12 months based on the borrower's present verified income. When a borrower receives unemployment income, there is potential for confusion about how to estimate the borrower's income for the next 12 months. The Agency proposes to extend the Interest Credit Agreement only for the known period of unemployment benefits or six months. The borrower's income will be reviewed prior to the end of this period and the interest credit agreement revised accordingly.

A change is being made to ensure that the Agency handles a reduction in income consistently between the servicing regulations (7 CFR part 1951 subpart G) and the credit regulations. Currently, married borrowers must be separated for a period of at least six months before additional interest credit assistance can be considered. An income reduction of at least 30 percent within three months of the anniversary date was not considered for additional interest credit assistance until the anniversary date. FmHA servicing regulations permit an account to be accelerated when it is three monthly payments delinquent provided the account has been serviced. Thus it was possible to accelerate a borrower's account before reaching the prescribed eligibility for additional interest credit assistance. Revisions have been made to correct this problem and to allow consideration of interest credit benefits at the end of three months instead of six months. In addition, borrowers may qualify for a reduction in payments at any time, provided the verified change in income results in a payment reduction of at least 15 percent.

The Agency proposes to remove the provision for cancelling interest credit benefits to a family who has improved its property beyond what is considered to be modest for the area. This provision was untenable because the lack of interest credit would make many of these families unable to afford the costs of home ownership.

The Agency proposes to add a District Director review of a representative sample of interest credit agreements in each County Office. The incomes reported on these agreements will be verified with the State Employment Agency, or similar agency, to ensure that all family income has been counted.

Paperwork Reduction Act

The collection of information requirements contained in this regulation have been submitted to the Office of Management and Budget for review under section 3504(h) of the Paperwork Reduction Act of 1980. Public reporting burden for this collection of information is estimated to vary from 15 minutes to 1.5 hours per response, with an average of 30 minutes per response including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, 404–W, Washington, DC 20250; and to the Office of Management and Budget, Attention: Desk Officer for the Farmers Home Administration, Washington, DC 20503.

Civil Justice Reform

The proposed regulation has been reviewed in light of Executive Order (EO) 12778 and meets the applicable standards provided in section 2(a) and (2)(b)(2) of that Order. Provisions within this part which are inconsistent with state law are controlling. All administrative remedies pursuant to 7 CFR part 1900 subpart B must be exhausted prior to filing suit.

Regulatory Reform: Less Burdensome or More Efficient Alternatives

The Department of Agriculture is committed to carrying out its statutory and regulatory mandates in a manner that best serves the public interest. Therefore, where legal discretion permits, the Department actively seeks to promulgate regulations that promote economic growth, create jobs, are minimally burdensome and are easy for the public to understand, use or comply with. In short, the Department is committed to issuing regulations that maximize net benefits to society and minimize costs imposed by those regulations. This principle is articulated in President Bush's January 28, 1992 memorandum to agency heads, and in Executive Orders 12291 and 12498. The Department applies this principle to the full extent possible, consistent with law.

The Department has developed and reviewed this regulatory proposal in accordance with these principles. Nonetheless, the Department believes that public input from all interested persons can be invaluable to ensuring that the final regulatory product is

minimally burdensome and maximally efficient. Therefore, the Department specifically seeks comments and suggestions from the public regarding any less burdensome or more efficient alternative that would accomplish the purposes described in the proposal. Comments suggesting less burdensome or more efficient alternatives should be addressed to the agency as provided in this Notice.

List of Subjects in 7 CFR Part 1944

Home improvement, Loan programs—Housing and community development, Low and moderate income housing—Rental, Mobile homes, Mortgages, Subsidies.

Therefore, as proposed, part 1944, chapter XVIII, title 7, Code of Federal Regulations, is amended as follows:

PART 1944—HOUSING

1. The authority citation for part 1944 continues to read as follows:

Authority: 42 U.S.C. 1480; 5 U.S.C. 301; 7 CFR 2.23 and 2.70.

Subpart A—Section 502 Rural Housing Loan Policies, Procedures, and Authorizations

2. Section 1944.5 is amended by removing paragraph (d)(8) and redesignating current paragraphs (d)(9), (10), and (11), as paragraphs (d)(8), (9), and (10), respectively; and by revising paragraphs (e)(8), (e)(12), and (e)(17) to read as follows:

§ 1944.5 Annual income.

* * * * *

(e) * * *

(8) The hazard duty pay to a service person applicant/borrower or spouse away from home and exposed to hostile fire. The imminent danger duty pay to a service person applicant/borrower or spouse away from home and exposed to hostile fire. Amounts of imminent danger pay for Military personnel stationed in the Combat Zone are excluded from annual income effective August 2, 1990. Any military pay received by persons serving in the Combat Zone received on or after January 17, 1991 is excluded from annual income. The Combat Zone, as defined by the Presidential Executive Order 12744 dated January 21, 1991, consists of the Persian Gulf, the Red Sea, the Gulf of Oman, that portion of the Arabian Sea that lies north of 10 degrees north latitude and west of 68 degrees east longitude, the Gulf of Aden, the total land areas of Iraq, Kuwait, Saudi Arabia, Oman, Bahrain, Qatar, and the United Arab Emirates. Immediately upon notification by the family or based on information from a knowledgeable source that a member of the household is or was serving in the Combat Zone, the County Supervisor shall redetermine the household income retroactive to January 17, 1991, and adjust the borrower's interest credit accordingly.

* * * * *

(12) Any earned income tax credit to the extent it exceeds income tax liability will not be counted as part of annual income, but will remain part of the applicant's income for purposes of repayment ability.

* * * * *

(17) Payments received from the Agent Orange Settlement Fund, income from interests of individual Indians in trust or restricted land, and any funds which a Federal statute specifies must not be used as the basis for denying or reducing Federal financial assistance or benefits to which the recipient would otherwise be entitled.

3. Section 1944.26 is amended by removing paragraph (c) (2) and redesignating paragraphs (c) (3), (4), and (5) as (c) (2), and (3) and (4), respectively; and by adding a paragraph (a) (7) to read as follows:

§ 1994.26 Application processing.

* * * * *

(a) * * *

(7) The applicant must submit a certified financial statement and/or a copy of the applicant's most recently filed Federal income return as part of the completed loan application. The applicant will be advised of this requirement during the application interview.

* * * * *

4. Section 1944.34 is revised to read as follows:

§ 1944.34 Interest credit.

(a) *General.* It is the policy of FmHA to grant interest credit on loans to qualified borrowers to assist them in obtaining and retaining decent, safe, and sanitary dwellings and related facilities. When FmHA contracts out servicing, all actions assigned to the County Supervisor may be performed by the contractor, except approval or cancellation of interest credit.

(b) *Definition.*—(1) *Annual payment borrowers.* Borrowers who signed promissory notes providing for annual payments, including borrowers converted to monthly payments through the use of Form 1951–34, Direct Plan Change.

(2) *Monthly payment borrowers.* Borrowers who signed promissory notes providing for monthly payments.

(3) *Review period.* The review period for an annual payment borrower will be the months of October and November. The review period for a monthly payment borrower will be the second and third months prior to the scheduled expiration date of the borrower's current Interest Credit Agreement.

(4) *Real estate taxes.* Real estate taxes for interest credit purposes means the amount of real estate taxes and assessments that will actually be due and payable on the dwelling and the dwelling site during the interest credit period, reduced by the amount of any tax exemption available to the borrower, regardless of whether such exemption is actually claimed. Tax exemptions may include such things as homestead exemptions, special exemptions for low-income families, senior citizens, veterans, and others.

(c) *Approval authority.* Those FmHA officials who are authorized to approve Section 502 loans are also authorized to approve the Interest Credit Agreement.

(d) *Amount of interest credit.* (1) Loans other than FmHA loans qualified to be considered in the interest credit calculation include only those loans made for authorized Section 502 RH purposes and which are a lien against the FmHA security by virtue of a prior mortgage. Except as provided in paragraph (d)(2) of this section, the amount of interest credit granted will be the lesser of:

(i) The difference between 20 percent of the borrower's adjusted annual income and the sum of the annual installments due at the note interest rate on qualified loans plus the cost of real estate taxes and insurance, or

(ii) The difference between the annual installment due on the FmHA promissory notes eligible for interest credit and the amount the borrower would pay if the loan(s) was amortized at an interest rate of 1 percent.

(2) For repair and rehabilitation loans which meet the requirements of paragraph (f)(6) of this section, interest credit will be granted in an amount to achieve the following effective interest rates:

(i) For borrowers whose adjusted annual income is not more than $5,000, interest credit will be calculated using the amortization factor for 1 percent.

(ii) For borrowers whose adjusted annual income is more than $5,000 but not more than $7,000, interest credit will be calculated using the amortization factor for 2 percent.

(iii) For borrowers whose adjusted annual income is more than $7,000 but not more than $10,000, interest credit will be calculated using the amortization factor for 3 percent.

(3) Borrowers qualifying for interest credit assistance under both paragraphs (d) (1) and (2) of this section will be granted only the one type of interest credit assistance that is most beneficial to them. Interest credit on initial and subsequent loans will always be the same type. There is no provision for switching from one type of interest credit to the other.

(e) *Recapture.* At the applicant interview, FmHA will advise all Section 502 RH applicants that interest credit is subject to recapture.

(f) *Eligibility.* To be eligible for interest credit, a borrower must qualify for a Section 502 loan, must personally occupy the dwelling, and must meet the following additional requirements:

(1) *Initial loans including credit sales.* Interest credit may be granted at loan closing if:

(i) The borrower's adjusted annual income at time of loan approval did not exceed the applicable low-income limit in Exhibit C of this subpart. (Available in any FmHA office).

(ii) The borrower's net family assets do not exceed $7,500, (maximum as defined in § 1944.2(n) of this subpart) (net family assets of $10,000 will be allowed for an elderly family as defined in § 1944.2(d) of this subpart) unless an exception is authorized. The calculation of net family assets will exclude the value of the dwelling and a minimum adequate dwelling site, cash on hand which will be used to reduce the amount of the loan, and household goods and personal automobile(s) and the debts against them.

(iii) The term of the loan will be determined in accordance with § 1944.25 of this subpart. Interest credit will not be granted on loans with a term of less than 25 years, except as provided in paragraphs (f) (4) and (6) of this section.

(iv) The loan was approved on or after August 1, 1968, and

(v) The amount of interest credit will be $5 or more per month or $60 or more annually.

(2) *Subsequent loans.* Interest credit may be granted on subsequent loans which meet the requirements of paragraph (f)(1) of this section. If interest credit is presently being granted on the initial loan and the borrower's adjusted income does not exceed the moderate-income limit, it may also be granted on the subsequent loan if the term of the subsequent loan is 25 years or more.

(3) *Assumptions.* Interest credit may be granted to a borrower assuming a RH loan provided the assuming party(ies) qualifies according to paragraph (f)(1) of this section.

(4) *Reamortization.* Interest credit may be granted on loans made as low- and moderate-income loans after reamortization:

(i) If the loan was eligible for interest credit prior to reamortization, interest credit may continue to be granted regardless of the remaining reamortization period.

(ii) If the loan was not eligible for interest credit prior to reamortization, the reamortized term of the loan must be 25 or more years and all other conditions of paragraph (f)(1) of this section must be met.

(5) *Existing loans.* Interest credit may be granted at any time after loan closing if:

(i) the requirements of paragraphs (f)(1) (ii), (iii), and (v) of this section are met;

(ii) the loan was approved as a "low or moderate" Section 502 loan on or after August 1, 1968;

(iii) the borrower's adjusted annual income does not exceed the moderate income limit in Exhibit C of this subpart (available in any FmHA Office).

(iv) Due to a change in circumstances, the borrower requests interest credit, or FmHA determines that interest credit is needed to enable the borrower to repay the loan. In the case of co-borrowers, when one co-borrower has left the dwelling due to domestic discord, interest credit based on the remaining co-borrower's income may be extended to the remaining co-borrower if:

(A) the remaining co-borrower is occupying the dwelling, owns a legal interest in the property, and is liable for the debt;

(B) legal papers have been filed with the appropriate court to commence divorce or legal separation proceedings, or one co-borrower has not been living in the dwelling for at least three months. Interest credit will not be granted if separation is due only to work assignment or military order; and

(C) The remaining co-borrower is informed and agrees that should the co-borrower return to live in the dwelling, that co-borrower's income will then be counted toward annual income and interest credit may be reduced or cancelled.

(6) *Repair and rehabilitation loans.* Interest credit may be granted on Section 502 RH loans made to repair or rehabilitate a dwelling already owned by the applicant provided the following conditions are met:

(i) The initial interest will be granted at the time of loan closing and the loan will be secured by a real estate mortgage;

(ii) The dwelling is, or will be, occupied by an eligible borrower after the loan is made;

(iii) The amount of the loan will not exceed $10,000, or be amortized for not more than 25 years;

(iv) The applicant's adjusted annual income does not exceed $10,000;

(v) The repairs will be made to bring a substandard dwelling up to the standards outlined in Section 1944.16(j); and

(vi) The net family asset requirements in paragraph (f)(1)(ii) of this section are met.

(g) *Processing interest credit*—(1) *General.* The amount of interest credit for which a borrower may be eligible will be determined by use of Form FmHA 1944–6 or Form 1944–A6, "Interest Credit Agreement," as outlined in paragraph (d) of this section.

(i) *Determination of Income.* The County Supervisor is responsible for determining the borrower's annual and adjusted annual income as defined in § 1944.2, paragraphs (b) and (c) respectively, of this subpart. A borrower interview will be conducted in all cases for granting initial interest credit. Form FmHA 1910–5 will be used to verify the earning from employment of all persons whose income is included in "Annual Income."

(ii) *Effective period.* Interest Credit Agreements on loans made to monthly payment borrowers will be for a 12-month period. For annual payment borrowers and annual converted to monthly borrowers, the agreements will be in effect until January 1 after the effective date. For an unemployed borrower receiving unemployment benefits, the agreement will be effective for the period during which the borrower will receive unemployment benefits, or if the period if unknown, no longer than 6 months. The expiration date will be established by FmHA.

(iii) *Partial year interest credit.* For an annual payment borrower with an initial installment less than a regular installment, and who will receive less than a full year of interest credit assistance, the interest credit granted will be pro rata portion calculated on the number of months left in the current calendar year, including the month in which the loan is closed.

(iv) *Advance from the RHIF.* The repayment schedule for advances made from the Rural Housing Insurance Fund will be computed at the interest rate shown on the promissory note.

(v) *Preparation of the transaction record.* For borrowers receiving interest credit in Western Pacific Territory field offices, the following changes will be shown on Form 451–26, Transaction

Record, when prepared by the Finance Office:

(A) *Interest rate field.* The interest rate field of the form will continue to show the interest rate on the note. The Finance Office will compute the effective interest rate charged the borrower based on the amount of interest credit granted. The computed rate, rounded to the nearest ⅛ of a percent, will be shown as a footnote on the form as "Interest Rate reduced to ____%." Subsequent transactions will be applied to the loan by the Finance Office at the reduced interest rate until such time as renewal, change, or cancellation occurs.

(B) *Daily interest accrual field.* The daily interest accrual will be shown at the reduced interest rate and the interest will accrue at the same interest rate until such time as the interest credit is renewed, changed, or cancelled.

(C) *Application of credit field.* The initial transaction record form will not have an entry in the "Application of Credit" field. The Interest Credit Transaction Code for this method of processing interest credit will be 4 Z.

(D) Payment status field. The payment status field will not reflect the dollar amount of the interest credit granted. No entry will be made for monthly payment borrowers.

(E) Minimum amount due by date show field. For annual payment borrowers, the amount of the installment, reduced by the amount of interest credit granted, will be shown. For monthly payment borrowers the word "monthly" will be entered in the space provided.

(2) *Initial and subsequent loans*—(i) *County Office action.* The County Supervisor will:

(A) Determine the borrower's adjusted annual income and document the calculations in the case file running record.

(B) Enter on Form FmHA 1940–1 the adjusted annual income, the estimated real estate taxes that will become due and payable during the first and second years of the agreement, and the amount of the annual property insurance premium for the dwelling.

(C) For initial loans approved with interest credit and closed under the multiple advance feature of the loan disbursement system outlined in Subpart A of Part 1902 of this Chapter, further review of the borrower's financial status is not required unless the Interest Credit Agreement will be approved more than 90 days after the last "Verification of Employment" or there is evidence which indicates the borrower's financial status has changed significantly. If prior to the approval of the Interest Credit Agreement, the County Supervisor finds that the adjusted income has increased, interest credit will be granted on the basis of the borrower's new circumstances.

(D) Complete a corrected Interest Credit Agreement when the loan is closed or at the amortization effective date if the borrower's circumstances have changed do that the amount of interest credit would be increased or decreased by at least $5 monthly or $60 annually.

(3) *Reamortization, credit sales and transfers.* Interest credit to a borrower whose loan(s) is being reamortized, or a borrower who assumes an RH loan or purchases property from inventory will be calculated by the County Office on Form FmHA 1944–6.

(4) *Existing loans.* Interest credit granted in accordance with paragraph (f)(5) of this section can be processed at any time in the same manner as interest credit on initial loans, except that the County Office will complete Form FmHA 1944–6 and calculate the amount of interest credit assistance the borrower will receive.

(h) *Interest credit modification*—(1) *Before expiration.* When approving a change in interest credit assistance before the expiration of a current Interest Credit Agreement in accordance with paragraph (i)(3) of this section, FmHA will interview the borrower and determine the borrower's adjusted annual income.

(2) *Correction of Interest Credit Agreement.* When an error by a FmHA employee results in granting at least $5 per month ($60 per year) less interest credit than the borrower was eligible to receive, a corrected agreement will be prepared. The effective date of the corrected agreement will be the same as the agreement in error. Payments made under the previous agreement will be reapplied according to the terms of the new Interest Credit Agreement.

(3) *Interest credit renewal.* Pursuant to delegations of procurement authority included in FmHA Instruction 2024–A (available in any FmHA Office), FmHA is authorized to enter into contracts for the processing of interest credit renewals. Contractors will not be given the authority to approve or disapprove Interest Credit Agreements.

(i) *Borrower responsibility.* The interest credit renewal packages are issued annually to determine the borrower's eligibility for interest credit assistance and to verify the earnings or incomes of all persons whose incomes are included in the annual income. Upon receipt of the package, the borrower's responsibility will to give one copy of the Verification of Employment (Form FmHA 1910–5) to the employer or employers of each member of the household who has income to be considered. An envelope will be provided each employer to facilitate the mailing of the form directly to the County Office or to the contractor, if applicable. The borrower will also complete Part II of the interest form, sign the original form and bring the original and all copies to the FmHA or the interest credit contractor. Postage for these envelopes will be provided as set forth in § 1944.26(a)(5) of this subpart.

(ii) *County Office actions.* The County Supervisor, or designee will:

(A) One month prior to the interest credit agreement expiration date, Transaction Code (T/C) IC will become available for a borrower and the county office will access the workfile to enter the required renewal information using Transaction Code T/C IC, Interest Credit Workfile, via the Automated Discrepancy Processing System (ADPS). At this time, the County Office may input the necessary data which will be updated to the borrower's account on the expiration date. The county office should not attempt to change the process code, this will be taken care of systemically.

(B) Conduct an interview with the borrower to review the information on Forms FmHA 1944–A6 and FmHA 1910–5 for completeness and accuracy. The interview should, when possible, be face to face contact. After discussing the interest credit renewal with the borrower, a typewriter should be used to complete actions III and V on the Form FmHA 1944–A6. All amounts should be rounded in accordance with the Forms Manual Insert and shown in dollars only.

(C) Determine the adjusted annual income and document the calculations in the case file running record. After completion and verification of the information on Form FmHA 1944–A6, retain the original in the County Office for use in processing the renewal to the IC workfile and as part of the borrower's official record. Return the last copy to the borrower. Do not return Form 1944–A6, Interest Credit Agreement, for monthly borrowers to the Finance Office.

(D) If the borrower is no longer eligible for interest credit, notify the borrower by using Exhibit B 1 to 7 CFR part 1900, subpart B. The letter must notify the borrower of the right to appeal as outlined in 7 CFR part 1900, subpart B. A new Form FmHA 440–9 will be obtained when needed.

(E) Effective with the processing of interest renewal information to the workfile, annotate on the Form 1944–A6

and the list the name of the employee entering the data, date information entered, and related ADPS block number of T/C IC. FmHA Instruction 2033–A, Exhibit C, provides the program records retention requirements for source/input documents processed to ADPS via the Field office terminal system.

(iii) *Finance Office actions.* The Finance Office will update automated monthly interest credit renewals daily, based upon the effective date. Direct payment coupons will be mailed in time to ensure that borrowers are provided their new payment packet in sufficient time to make their next payment as scheduled.

(iv) *Processing interest credit renewals not received during the interview period.* Interest credit agreements not updated via the Interest Credit Workfile will automatically be canceled as of the expiration date. To ensure continued interest credit, it is imperative that renewals are processed to the workfile before the agreement effective date.

(v) *Renewals not updated before the expiration date.* If a renewal was not updated before the expiration date, perform the following:

(A) Access and verify that the renewal record for the applicable borrower's case number is not on the Automated Discrepancy Processing System (ADPS) recap and resequence screen.

(B) If the renewal is on the ADPS, enter the renewal information.

(C) If the renewal is not on the ADPS, verify that the borrower's interest credit has been canceled by viewing the related on-line history information.

(D) If interest credit was canceled, verify that there is no later activity (transactions) that has processed and process the renewal through the field office terminal system.

(E) If later activity has processed, manuscript and route the renewal transaction to the Finance Office servicing team.

(i) *Eligibility review.* The eligibility reviews of borrowers currently receiving interest credits are based on verified earnings or incomes of all persons whose incomes are included in the annual income. The eligibility of those borrowers will be reviewed as follows:

(1) *Annual review.* The eligibility of borrowers will be reviewed annually during the review period.

(i) If the value of the borrower's net family assets increases above the applicable eligibility limit, interest credit will be renewed unless the increase is sufficient to enable the borrower to graduate to another source of credit.

(ii) Interest credit will not be renewed if the amount of interest credit for which the borrower qualifies is less than $5 monthly or $60 annually.

(2) *Renewal not completed during the review period.* When the borrower's renewal Interest Credit Agreement is not completed during the review period, it will be processed in accordance with § 1944.34(h)(3)(v).

(3) *Change in borrower's circumstances.* FmHA is not responsible for monitoring whether a borrower's income, family size, real estate taxes, or insurance costs have changed after an Interest Credit Agreement is approved. If, however, it becomes known that the borrower's circumstances have changed significantly, FmHA will take action in accordance with the following:

(i) Increased adjusted income outside the regular review period. If FmHA determines that the borrower's adjusted income has increased to the level where the interest credit is less than $5 monthly or $60 annually, the interest credit will be cancelled effective the date FmHA becomes aware of the situation. The borrower will be notified in accordance with paragraph (l) of this section.

(ii) Decreased adjusted income. Changes in interest credit will not be made unless the borrower's payment would be reduced by at least 15 percent.

(iii) FmHA will not count any military pay received by persons serving in the Combat Zone. If such income was counted, the FmHA County Supervisors should process a revised interest credit agreement, if not counting such pay would result in a change in the amount of interest credit. After the County Supervisor becomes aware that a borrower has entered active military duty after the loan is closed, the servicing of the account should be handled under § 1951.317 of Subpart G of Part 1951 of this chapter.

(j) *Unauthorized interest credit.* When it is determined that a borrower has received interest credit to which he/she was not entitled (unauthorized interest credit), the case will be serviced according to Subpart M of Part 1951 of this chapter.

(k) *Cancellation of interest credit agreements*—(1) *Reasons for cancellation.* An existing Interest Credit Agreement will be cancelled whenever:

(i) The borrower does not physically occupy the dwelling as his/her primary residence. Nursing homes and specialized care facilities are considered full time residences. The following may be indicators of non-occupancy:

(A) The borrower does not physically occupy the property more than half of the year

(B) The borrower's children are enrolled in a day school that is not considered within commuting distance of the dwelling

(C) The borrower's primary source of year round employment is not within commuting distance of the dwelling and/or

(D) The borrower routinely stays at another residence.

(ii) The borrower rents, leases, sells or conveys the title to the property.

(iii) The borrower has received improper interest credit as outlined in subpart M of part 1951 of this chapter and a corrected Interest Credit Agreement will not be submitted.

(iv) The borrower has an increase in income as outlined in § 1994.34(i)(3)(i) and is no longer eligible for interest credit.

(v) The security property is acquired by FmHA.

(vi) The borrower provides fraudulent or materially inaccurate financial information in connection with an interest credit application/renewal.

(2) *Effective date of cancellation.* The effective date of cancellation if the borrower has never occupied the property will be the date of loan closing. The effective date of cancellation for paragraphs (k)(1) (i), (ii), (iii), (iv) and (vi) of this section will be the date on which the earliest action occurs which causes the cancellation. If the date cannot be determined, the date on which FmHA became aware of the situation will be used. The effective date of cancellation for paragraph (k)(1)(v) of this section will be the date the property is acquired by FmHA. When an account has been accelerated and one of the conditions outlined in paragraph (k)(1) of this section exists, the Interest Credit Agreement will remain in effect until it expires. No interest credit renewals will be processed on accounts that are under acceleration. If foreclosure action is dismissed, withdrawn or terminates without sale of the property or payment of the loan in full, a renewal agreement will be prepared with an effective date as of the expiration of the previous agreement.

(l) *Applicant or borrower notice of right to appeal.* All applicants or borrowers who request and are denied interest credit or whose interest credits are reduced, cancelled, or not renewed, will be notified of their appeal rights. If a decision is not appealable, such as decisions based on verified income, or clear and objective statutory or regulatory requirements, the applicant or borrower will receive review rights.

5. Exhibit D of Subpart A is amended by redesignating paragraphs 5 through

21 as 6 through 22 and adding a new paragraph 5 to read as follows:

Exhibit D—Rural Housing Applicant Interview

5. *Review of Federal Tax Returns and/or Audited or Certified Financial Statements:* The County Supervisor will review the applicant/borrower's most recently filed Federal income tax return and/or certified financial statement as part of the completed loan application during the application processing/interview.

* * * * *

Dated: November 24, 1992.

La Verne Ausman,

Administrator, Farmers Home Administration.

[FR Doc. 93-20 Filed 1-5-93; 8:45 am]

BILLING CODE 3410-07-M

FEDERAL RESERVE SYSTEM

12 CFR Part 211

[Regulation K; Docket No. R-0793]

International Banking Operations

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Proposed rule.

SUMMARY: The Board is proposing an amendment to part 211 of its regulations concerning the permissible activities of state-licensed branches and agencies of foreign banks. Section 202(a) of the Federal Deposit Insurance Corporation Improvement Act of 1991 provides that after December 19, 1992, a state-licensed branch or agency of a foreign bank may not engage in any activity that is not permissible for a federal branch of a foreign bank unless the Board has determined that the activity is consistent with sound banking practice, and in the case of an insured branch, the Federal Deposit Insurance Corporation (FDIC) has determined that the activity would pose no significant risk to the deposit insurance fund. This proposed amendment to Regulation K sets forth the application procedures that state-licensed branches and agencies of foreign banks will be required to follow in order to request the Board's permission to engage in or continue to engage in an activity that is not permissible for a federal branch of a foreign bank and the requirements of divestiture and cessation plans. Insured branches are also required to seek the approval of the FDIC to engage in or to continue to engage in such an activity.

DATES: Comments must be received by March 5, 1993.

ADDRESSES: Comments, which should refer to Docket No. R-0793, may be mailed to the Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, NW., Washington, DC 20551, to the attention of Mr. William W. Wiles, Secretary. Comments addressed to the attention to Mr. Wiles may be delivered to the Board's mailroom between the 8:45 am and 5:15 pm, and to the security control room outside of those hours. Both the mailroom and the security control room are accessible from the courtyard entrance on 20th Street between Constitution Avenue and C Street, NW. Comments may be inspected in room B-1122 between 9 am and 5 pm, except as provided in § 261.8 of the Board's Rules Regarding the Availability of Information, 12 CFR 261.8.

FOR FURTHER INFORMATION CONTACT: Kathleen M. O'Day, Associate General Counsel (202/452-3786), Ann E. Misback, Senior Attorney (202/452-3788), Margaret E. Miniter, Attorney (202/452-3900), John W. Rogers, Attorney (202/452-2798), Legal Division; Michael G. Martinson, Assistant Director (202/452-3640), Division of Banking Supervision and Regulation, Board of Governors of the Federal Reserve System. For the hearing impaired *only*, Telecommunication Device for the Deaf (TDD), Dorothea Thompson (202/452-3544), Board of Governors of the Federal Reserve System, 20th and C Street, NW., Washington, DC 20551.

SUPPLEMENTARY INFORMATION: Section 202 of the Act amended section 7 of the IBA by adding several new subsections concerning the establishment and termination of foreign bank branches in the United States. New subsection 7(h) of the IBA provides that after December 19, 1992, a state branch or state agency may not engage in any type of activity that is not permissible for a federal branch unless the Federal Reserve Board has determined that such activity is consistent with sound banking practice; and, in the case of an insured branch, the FDIC has determined that the activity would pose no significant risk to the deposit insurance fund. 12 U.S.C. 3105(h)(1).

In order to implement this provision, the Board is proposing to amend Regulation K (12 CFR part 211) concerning international banking operations by adding a new section to Subpart B entitled "Applications by State-Licensed Branches and Agencies to Conduct Activities Not Permissible for Federal Branches." This proposed new section provides that a foreign bank operating a state-licensed branch or agency in the United States, which desires to engage in or continue to engage in an activity that is not permissible for a federal branch, pursuant to statute, regulation or order or interpretation issued by the Comptroller of the Currency (OCC), shall file an application for permission to conduct or to continue conducting such activity with the Board.

Contents of Application

Section 211.29(b) of the proposed regulation provides that the application shall be in letter form and shall contain certain information, including among other things, a description of the activity in which the branch or agency desires to engage or in which it is already engaged, the foreign bank's financial condition, the assets and liabilities of the branch or agency, the projected effect of the proposed activity on the financial condition of the foreign bank and the branch or agency, and in the case of an application by a state-licensed insured branch, a statement of why the proposed activity will pose no significant risk to the deposit insurance fund.

In view of the fact that section 202(h) of the Act became effective on December 19, 1992, a foreign bank with a state branch or agency that currently is conducting an activity that is determined to be impermissible for a federal branch will not be able to obtain the Board's permission to continue the activity prior to that effective date. In such cases, the Board may permit any such branch or agency to continue to conduct the activity in question (at existing levels) until such time as the Board acts on its application. The Board expects any foreign bank engaged in an impermissible activity in a state-licensed branch or agency to file the required application promptly.

The Board and the FDIC have consulted concerning the type of information that each agency will need in order to make an informed judgment, and have agreed on a common list of information in order that applicants will need to prepare only one application which, in the case of insured branches, may be submitted to both agencies. It is contemplated that the Board and the FDIC will review such applications simultaneously. Moreover, the Board and the FDIC have attempted to balance their need for information on which to base their decisions with the cost to the applicant of gathering, organizing and submitting an application.

The Board is particularly interested in receiving comments concerning the amount and type of information requested pursuant to § 211.29(b) of the proposed regulation. Comment is also requested on whether there are certain

classes of activities that, even though not permitted for federal branches, nonetheless are consistent with sound banking practices, and whether a more limited prior written notice rather than a letter application could be utilized in connection with these types of activities. With respect to the activities described in the preceding sentence, commenters are requested to describe the activity in detail and to explain why its conduct by a state-licensed branch or agency would be consistent with sound banking practice.

In addition, the Board requests comment concerning whether the conduct by a state-licensed branch or agency of activities permitted by the OCC pursuant to informal interpretation, opinion or advice rather than by formal interpretation or opinion should require the filing of an application. In this regard, the Board will initiate consultations with the OCC on any questions of whether a particular activity is or is not permissible for a federal branch. The Board also seeks comment on potential coordination between applications to the Board and the FDIC as a way to make this process as efficient as possible.

Finally, the Board requests comment on whether an application should be required when a foreign bank wishes to convert a federally-licensed branch or agency to a state-licensed branch or agency. When the Board approved the final amendments to Regulation K concerning establishment of branches and agencies, the Board decided that an application would *not* be required when a foreign bank wished to convert from a state license to a federal license, because it would be converting from a less restrictive to a more restrictive regime. In light of the statutory provision limiting state office powers to those of a federal branch unless the Board and, in the case of an insured branch, the FDIC approve the activities; the Board is requesting comment on whether it is necessary to require an application when a foreign bank seeks to convert from a federal to a state license.

Standards to be Examined

Section 211.29(c) sets forth the standards that the Board will examine in order to determine whether a particular practice in consistent with sound banking practice. These factors are:

(1) What types of risks, if any, the activity poses to the foreign banking organization;

(2) If the activity poses any such risks, the magnitude of each risk; and

(3) If a risk is not *de minimis*, the actual or proposed procedures to control and minimize such risk.

Each of these factors shall be evaluated in light of the financial condition of the foreign bank in general and the branch or agency in particular and the volume of the proposed activity. The Board may also determine that a particular activity, after consideration of the above factors and subject to any conditions or limits imposed by the Board, may be conducted by any state-licensed branch or agency without further application to the Board.

Divestiture or Cessation

In the event that a state branch or agency is required to cease conducting an activity pursuant to the proposed regulation, § 211.29(e) of the proposed regulation sets forth the guidelines that must be followed to divest or cease the impermissible activity. Generally, this section provides that the state branch or agency shall submit a written plan of divestiture or cessation within 60 days of

(1) Being notified by the Board or the FDIC that an application to continue to conduct the activity has been denied;

(2) The effective date of the regulation in the event that the foreign bank elects not to apply for permission to continue to conduct the activity; and

(3) Any change in statute, regulation, order or OCC interpretation that renders the activity impermissible.

Divestiture or cessation shall be completed within one year, or sooner if the Board so directs. The Board requests comment on whether this period of time should be longer or shorter.

Application Not Required in Certain Instances.

The Board has determined that an application under this section normally shall not be required where an activity is permissible to a federal branch, but the OCC imposes a quantitative restriction on the conduct of such activity by the federal branch. As described in further detail above, the Board is requesting comment on whether there are any other classes of activities for which more limited prior notice would suffice.

Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (Pub. L. 96-354, 5 U.S.C. 601 *et seq.*), it is certified that the proposed rule would not have a significant impact on a substantial number of small entities.

List of Subjects in 12 CFR Part 211

Exports, Federal Reserve System, Foreign banking, Holding companies, Investments, Reporting and recordkeeping requirements.

For the reasons outlined above, the Board is proposing to amend 12 CFR part 211 as set forth below:

PART 211—INTERNATIONAL BANKING OPERATIONS

1. The authority citation for part 211 continues to read as follows:

Authority: Federal Reserve Act (12 U.S.C. 221 *et seq.*); Bank Holding Company Act of 1956, as amended (12 U.S.C. 1841 *et seq.*); the International Banking Act of 1978, (Pub. L. 95-369; 92 Stat. 607; 12 U.S.C. 3101 *et seq.*); the Bank Export Services Act (Title II, Pub. L. 97-290, 96 Stat. 1235); the International Lending Supervision Act (Title IX, Pub. L. 96181, 97 Stat. 1153, 12 U.S.C. 3901 *et seq.*); and the Export Trading Company Act Amendments of 1988 (Title III, Pub. L. 100-418, 102 Stat 1384 (1988)).

2. Part 211 is amended by revising § 211.29 to subpart B to read as follows:

§ 211.29 Applications by state-licensed branches and agencies to conduct activities not permissible for federal branches.

(a) *Scope.* Any state-licensed branch or agency that desires to engage in or continue to engage, after December 19, 1992, in any type of activity that is not permissible for a federal branch, pursuant to statute, regulation or order or interpretation issued by the Comptroller, shall file a prior written application for permission to conduct such activity with the Board pursuant to this section.

(b) *Content of application.* An application submitted pursuant to paragraph (a) of this section shall be in letter form and shall contain the following information:

(1) A brief description of the activity, including the manner in which it will be conducted and an estimate of the expected dollar value;

(2) A discussion by management of its analysis regarding the impact of the proposed activity on the applicant's earnings, capital adequacy, and general condition, and on the balance sheet, earnings and condition of the branch or agency, including a copy, if available, of any feasibility study, management plan, financial projections, business plan, or similar document concerning the conduct of the activity;

(3) A current statement of the applicant's assets, liabilities, and capital;

(4) A current statement of the assets and liabilities of the branch or agency;

(5) A copy of applicant's most recent audited financial statements;

(6) A resolution by the applicant's board of directors or, if a resolution is not required pursuant to the applicant's organizational documents, evidence of approval by senior management, authorizing the conduct of such activity and the filing of this application;

(7) In the case of an insured branch, a statement by the applicant of whether or not it is in compliance with §§ 346.19 and 346.20, Pledge of Assets and Asset Maintenance, respectively, of 12 CFR part 346;

(8) In the case of an insured branch, a statement by the applicant that it has complied with all requirements of the Federal Deposit Insurance Corporation concerning applications to conduct the activity in question and the status of such application, including a copy of the FDIC's disposition of such application, if applicable;

(9) In the case of an insured branch, a statement of why the activity will pose no significant risk to the deposit insurance fund; and

(10) Any other information that the Reserve Bank deems appropriate.

(c) *Factors to be considered in determination.*

(1) The Board may consider the following factors in order to determine whether a proposed activity is consistent with sound banking practice:

(i) The types of risks, if any, the activity poses to the foreign banking organization;

(ii) If the activity poses any such risks, the magnitude of each risk; and

(iii) If a risk is not de minimis, the actual or proposed procedures to control and minimize such risk.

(2) Each of the factors set forth in paragraph (c)(1) of this section, shall be evaluated in light of the financial condition of the foreign bank in general and the branch or agency in particular and the volume of the activity.

(d) *Application procedures.* Applications pursuant to this section shall be filed with the responsible Reserve Bank for the foreign bank. An application shall not be deemed complete until it contains all the information requested by the Reserve Bank and has been accepted. Approval of such an application may be conditioned on the applicant's agreement to conduct the activity subject to specific conditions or limitations.

(e) *Divestiture or Cessation.*

(1) In the event that an applicant's application for permission to continue to conduct an activity is not approved by the Board or the FDIC, the applicant shall submit a detailed written plan of divestiture or cessation of the activity to the responsible Reserve Bank within 60 days of the disapproval. The divestiture or cessation plan shall describe in detail the manner in which the applicant will divest itself of or cease the activity in question and shall include a projected timetable describing how long the divestiture or cessation is expected to take. Divestitures or cessation shall be complete within one year from the date of the disapproval, or within such shorter period of time as the Board shall direct.

(2) In the event that a foreign bank operating a state branch or agency chooses not to apply to the Board for permission to continue to conduct an activity that is not permissible for a federal branch or which is rendered impermissible due to a subsequent change in statute, regulation, order or interpretation, the foreign bank shall submit a written plan of divestiture or cessation, in conformance with § 211.29(d)(1) of this part, within 60 days of the effective date of this rule or of such change in statute, regulation, order or interpretation, respectively.

By order of the Board of Governors of the Federal Reserve System, December 30, 1992.

William W. Wiles,

Secretary of the Board.

[FR Doc. 93-163 Filed 1-5-93; 8:45 am]

BILLING CODE 6210-01-F

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 92-NM-215-AD]

Airworthiness Directives; Airbus Industrie Model A320 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Airbus Model A320 series airplanes. This proposal would require modification of the inner rear spar web. This proposal is prompted by reports that cracking was found in the inner rear spar web during fatigue testing. The actions specified by the proposed AD are intended to prevent fatigue cracking, which may lead to reduced structural integrity of the main landing gear.

DATES: Comments must be received by March 2, 1993.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 92-NM-215-Ad, 1601 Lind Avenue, SW., Renton, Washington 98055-4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Airbus Industrie, Airbus Support Division, Avenue Didier Daurat, 31700 Blagnac, France. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Greg Holt, Aerospace Engineer, Standardization Branch, ANM-113, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (206) 227-2140; fax (206) 227-1320.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 92-NM-215-AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the

FAA, Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 92-NM-215-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

Discussion

The Direction Générale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, recently notified the FAA that an unsafe condition may exist on Airbus Model A320 series airplanes. The DGAC advises that during fatigue testing, cracking was found in the inner rear spar adjacent to 10 bolt holes. Cracking adjacent to two of the holes was located at rib 5 of the main landing gear (MLG) support. Cracking adjacent to the other eight holes was located at the anchorage of the MLG actuating cylinder. This cracking occurred at 64,120 simulated flights. Fatigue cracking, if not detected and corrected, could result in reduced structural integrity of the main landing gear.

Airbus Industrie has issued Service Bulletin A320-57-1004, Revision 1, dated September 24, 1992, which describes procedures for modification of the inner rear spar web. This modification consists of cold working the 10 bolt holes in which cracking was found during fatigue testing of an Airbus Model A320 series airplane. The French DGAC classified this service bulletin as mandatory and issued Airworthiness Directive 92-202-031(B), dated September 30, 1992, in order to assure the continued airworthiness of these airplanes in France.

This airplane model is manufactured in France and is type certificated for operation in the United States under the provisions of § 21.29 of the Federal Aviation Regulations and the applicable bilateral airworthiness agreement. pursuant to this bilateral airworthiness agreement, the French DGAC has kept the FAA informed of the situation described above. The FAA has examined the findings of the French DGAC, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would require modification of the inner rear spar web. The actions would be required to be accomplished in accordance with the service bulletin described previously.

Currently, no airplanes of U.S. registry would be affected by this AD. However, should one of the affected airplanes be imported and placed on the U.S. register, it would take approximately 60 work hours per airplane to accomplish the required actions, and the average labor cost would be $55 per work hour. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $3,300 per airplane.

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption "**ADDRESSES.**"

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 14 CFR Part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Airbus Industrie: Docket 92-NM-215-AD.

Applicability: Model A320 series airplanes, manufacturer's serial numbers (MSN) 003 through 008, inclusive; MSN's 018 through 021, inclusive; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent fatigue cracking, which may lead to reduced structural integrity of the main landing gear, accomplish the following:

(a) Prior to the accumulation of 12,000 landings, or within 500 landings after the effective date of this AD, whichever occurs later, modify the inner rear spar web in accordance with Airbus Industrie Service Bulletin A320-57-1004, Revision 1, dated September 24, 1992.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, ANM-113. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and the sent it to the Manager, Standardization Branch.

Note: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch.

(c) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on December 29, 1992.

David Hmiel,

Acting Manager.

[FR Doc. 93-92 Filed 1-5-93; 8:45 am]

BILLING CODE 4910-13-M

Office of the Secretary

14 CFR Part 300

[Docket 4852, Notice No. 92-36]

RIN 2105-AB89

Rules of Conduct in DOT Proceedings

AGENCY: Department of Transportation, Office of the Secretary.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Transportation is proposing amendments to its procedural regulations to permit Department staff to communicate informally with applicants and any objectors or other commenters in the initial investigation stage of air carrier initial certificate application and continuing fitness cases (collectively referred to as "fitness cases") where the issues are limited solely to fitness and/or U.S. citizenship. Under this proposal, once either a show cause order or an order instituting a formal proceeding is issued, the Department's current *ex parte* restrictions would apply. In several fitness proceedings, processing of those cases has been delayed unnecessarily or made more difficult because of the Department's inability under the current procedural regulations to discuss

informally aspects of the cases, in oral or written communications, with either the applicant carrier or objecting parties or other commenters. The proposed amendment would give the Department an added degree of flexibility in seeking information from all interested parties and would decrease the burden on applicants as well as objectors and other comments. However, it would still provide those parties a fair and complete opportunity to be heard and ensure an adequate record for the proceeding.

DATES: Comments must be submitted on or before February 22, 1993. Comments received after this date will be considered to the extent practicable. If adopted as a final rule, these amendments would take effect 30 days after publication of the final rule in the **Federal Register**.

ADDRESSES: Comments should refer to Docket 48582, and be submitted to: Docket Section (C–55), room 4107, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590. The Docket Section is open from 9 a.m. to 5 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Patricia T. Szrom, Chief, Air Carrier Fitness Division (P–56), Office of the Secretary, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590, (202) 366–9721.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in this rulemaking proceeding by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions. Communications should identify the regulatory docket number and be submitted in duplicate to the address listed above. Commenters wishing the Department to acknowledge receipt of their comments must submit with those comments a self-addressed stamped postcard on which the following statement is made: "Comments on Docket 48582." The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date will be considered by the Assistant Secretary for Policy and International Affairs before taking action on any further rulemaking. Also, this proposal may be changed in light of comments received. All comments submitted will be available for examination in Docket 48528. A report summarizing each substantive public contact with DOT personnel concerned with this rulemaking will be filed in the docket.

Background

Under section 401(a) of the Federal Aviation Act (the Act), a Certificate of Public Convenience and Necessity (certificate) must be obtained from the Department of Transportation (the Department) before an air carrier may engage in any air transportation operations (49 U.S.C. app. 1371(a)).[1] Section 418 of the Act contains a similar certification requirement for air carriers proposing to engage in domestic all-cargo air service (49 U.S.C. app. 1388). Following an investigation, if the Department finds that an applicant for authority under section 401 or 418 is a U.S. citizen that is "fit, willing, and able" to engage in air transportation operations and comply with the Act and the Department's regulations, a certificate is issued. The Department's "fitness" requirement is a continuing one for carriers; that is, once a carrier is found fit initially, it must remain fit in order to continue to hold its authority section 401(r) of the Act, 49 U.S.C. app. 1371(r)).

Carriers that apply for fitness determinations must comply with the Department's regulations concerning specific and general requirements for certificate applications (14 CFR part 201), including providing supporting data (14 CFR part 204). The Department's regulations allow any person to file an answer in support of or in opposition to the application within 28 days of the filing date of the application (14 CFR 302.1720(d)). If the application is opposed, the Department's regulations concerning prohibited communications come into play.

Part 300 of the Department's aviation economic regulations establishes the terms and conditions governing the rules of conduct for Department proceedings under Chapter II of Title 14 of the Code of Federal Regulations (14 CFR part 300). Among other provisions, part 300 generally prohibits oral or written communications relevant to the merits of a public proceeding between any concerned Department employee and any interested person outside the Department until after the Department's final disposition of the proceeding (the *ex parte* rule) (14 CFR 300.2). For purposes of the Department's review of the fitness of applicants for certificate authority or its consideration of docketed petitions for review of an air carrier's continuing fitness, the *ex parte* rules are triggered by the filing in the docket of an identifiable written opposition to the initiating document (14 CFR 300.2(b)(4)).

The Department's *ex parte* rules in fitness cases are more restrictive than the *ex parte* requirements established by the Administrative Procedure Act, 5 U.S.C. 557(d). Those requirements cover only proceedings for which a formal hearing is required by statute. Since section 401 of the Act gives us the discretion to determine whether an oral evidentiary hearing should be held in fitness cases, the Administrative Procedure Act's *ex parte* requirements do not apply to applications for certificate authority.

Proposed Rules

As described above, the *ex parte* rules, with a limited exception,[2] require that once a written opposition to an application for certificate authority is filed all substantive communications between the Department and either the applicant or the opposing party or other commenters be made through documents that are filed in the docket and distributed to all the parties. In practice, the Department has found that the *ex parte* provisions of part 300 often unnecessarily delay the processing of fitness cases or make the processing unduly difficult.

The Department believes that application of the *ex parte* rules to all stages of fitness cases is often counter-productive. Many complex issues relating to the application and the objections to the application could more readily be resolved through informal investigative-type discussions with the applicant, the objectors, or any other interested parties. However, that informal type of inquiry is prohibited by the current rules.

Instead, the Department's staff must go through the burdensome task of putting all of its questions in writing, filing them in the docket, and serving them on all parties. The applicant must likewise respond in writing through the docket, with copies to all parties. Often responses to staff questions need clarification or spawn further inquiries. Moreover, questions asked by the Department's staff of the applicant may

[1] The Department has the authority under section 416(b) of the Act (49 U.S.C. 1386(b)) to exempt carriers from the certification requirement when doing so would be consistent with the public interest. For example, under 14 CFR 298.11, air taxi operators are exempt from the certification requirement.

[2] The exception concerns documents placed in the correspondence section of the docket per 14 CFR 300.3.

themselves require clarification before a proper response can be made. As a result, often matters that could be cleared up in minutes by telephone or in a meeting can drag on for days or weeks solely due to the tedious procedures of on-the-record communications required under the current rules. Overall, the process is often cumbersome and time-consuming.

Carrier applicants are not the only persons who suffer as a result. For example, the Department's staff cannot under present *ex parte* rules ask simple questions of an objector in an effort to verify the facts contained in the filing objecting to the application without a similarly unwieldy and protracted written procedure.

The fact-finding nature of the initial phase of fitness cases lends itself to an informal, rather than a formal, on-the-record investigative procedure. The Act requires that the Department find an applicant "fit, willing, and able." In fitness cases where the issues are limited to determinations of fitness and/or U.S. citizenship, the Act does not require that the Department choose the best applicant; there are no comparative rights at issue.[3] The Department believes that for fitness cases where the issues are thus limited, the intensive fact-finding required in the initial phase of those cases is best achieved by unobstructed lines of communication between the Department, the applicant, and other interested persons.

The Department continues to believe that the *ex parte* restrictions are appropriate once a show cause order or an order instituting a formal proceeding is issued to ensure due process for all applicants and informed, on-the-record decisionmaking. Therefore, the Department would retain the benefits offered by the *ex parte* restrictions where they are most appropriate to on-the-record decisionmaking: after issuance of a show cause order or other order instituting a formal proceeding. Moreover, the Department's orders ruling on the merits of a certificate application will set forth the factual basis for the Department's tentative and final conclusions on the applicant's fitness and citizenship, if the Department uses show-cause procedures for considering the application. Parties will therefore know what information is being relied upon by the Department in its analysis and will have an opportunity to comment on the findings of fact. If the Department determines to hold an oral evidentiary hearing on an application, the Department's ultimate decision will be based on the record developed in the formal hearing proceeding. As a result, the proposed rule will not deny any party ability to participate fully and fairly in a fitness proceeding.

In line with the action proposed here, where expedition and an unfettered ability to gather information is in the public interest, part 300 already provides for several exceptions to the prohibition against substantive *ex parte* communications (14 CFR 300.2(c)). For example, part 300 permits communications made in the course of an investigation to determine whether formal enforcement action should be taken (14 CFR 300.2(c)(3)). The initial review phase of a fitness case is very similar to an investigation conducted to determine whether reasonable cause exists to institute a formal enforcement proceeding, with the issuance of a show cause order in a fitness proceeding the equivalent of the issuance of a Notice of Enforcement Proceeding and filing of an accompanying formal complaint in the enforcement context.[4]

Accordingly, the Department proposes to amend section 300.2, *Prohibited communications*, by adding paragraph (c)(10) that would create an exception to the prohibition of *ex parte* communications made in the course of docketed cases where the issues are limited to determinations of fitness and/or U.S. citizenship, prior to the issuance of a show cause order or an order instituting a formal proceeding. Once either type of order is issued, the *ex parte* communications prohibitions would apply. This proposal would facilitate the collection of information needed for consideration of cases, minimize the time and resources necessary for parties to process cases, yet continue to ensure procedural fairness for all parties.

Executive Order 12291 (Federal Regulation) and DOT Regulatory Policies and Procedures

The Department has analyzed the economic and other effects of this proposal and has determined that they are neither "major" within the meaning of Executive Order 12291 nor "significant" within the meaning of the Department's regulatory policies and procedures. The Department has also determined that the economic effects of the proposed amendments are so minimal that a full regulatory evaluation is not required. If these amendments are adopted, fitness application costs to carriers and costs to opposing parties should be slightly lower due to the less formal procedures that would replace the current procedures.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act, the Department has evaluated the effects of this proposed action on small entities. Based upon this evaluation, the Department certifies that the proposed amendments would not have a significant economic impact on a substantial number of small entities. As stated above, the Department believes that the proposed amendments would create a slight economic benefit for parties in fitness cases.

Executive Order 12612 (Federalism)

This proposed rule has been analyzed in accordance with the principles and criteria contained in Executive Order 12612. The Department has determined that the proposed rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. This proposed rule would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Naitonal Environmental Policy Act

The Department has also analyzed this proposed rule for the purpose of the National Environmental Policy Act. The Department has determined that the proposed rule would not have any significant impact on the quality of the human environment.

List of Subjects in 14 CFR Part 300

Administration practice and procedure, Conflict of interests, Rules of conduct, Prohibited communications.

For the reasons set out in the Supplementary Information, title 14, chapter II of the Code of Federal Regulations is proposed to be amended as follows:

PART 300—[AMENDED]

1. The authority citation for part 300 would continue to read as follows:

Authority: 49 U.S.C. 1324, 1371–1389, 1471, 1473, 1481, 1482, and 1487, 18 U.S.C. 20(b)(c); 49 U.S.C. Subtitle I.

2. Section 300.2 would be amended by adding new paragraph (c)(10) to read as follows:

[3] In cases where comparative rights are at issue, such as where the authority sought includes a market or markets where entry is limited by a bilateral agreement and there are competing proposals, the current *ex parte* rules would continue to apply.

[4] Indeed, certain continuing fitness proceedings may be more akin to enforcement investigations than to initial fitness proceedings.

§ 300.2 Prohibited communications.

* * * * *

(c) * * *

(10) Docketed proceedings involving determinations of fitness and/or U.S. citizenship only, for that portion of the proceeding that precedes the issuance of a show cause order or an order instituting a formal proceeding.

* * * * *

Issued in Washington, DC, on December 30, 1992.

Jeffrey N. Shane,

Assistant Secretary for Policy and International Affairs.

[FR Doc. 93-225 Filed 1-5-93; 8:45 am]

BILLING CODE 4910-62-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 35 and 290

[Docket No. RM85-17-000]

Regulation of Electricity Sales-for-Resale and Transmission Service

Issued December 28, 1992

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Order Terminating Docket.

SUMMARY: The Federal Energy Regulatory Commission (Commission) is terminating this proceeding because the Notices of Inquiry accomplished their purpose by generating public comments on the Commission's pricing and other regulatory policies, and because the information collected has since been overtaken by events.

FOR FURTHER INFORMATION CONTACT: Lawrence R. Greenfield, Deputy Assistant General Counsel, Office of the General Counsel, Federal Energy Regulatory Commission, 825 N. Capitol St., NE., Washington, DC 20426, Telephone: (202) 208-0415.

SUPPLEMENTARY INFORMATION: In addition to publishing the full text of this document in the **Federal Register**, the Commission also provides all interested persons an opportunity to inspect or copy the contents of this document during normal business hours in room 3308, 941 North Capitol Street, NE., Washington, DC 20426.

The Commission Issuance Posting System (CIPS), an electronic bulletin board service, provides access to the texts of formal documents issued by the Commission. CIPS is available at no charge to the user and may be accessed using a personal computer with a modem by dialing (202) 208-1397. To access CIPS, set your communications software to use 300, 1200 or 2400 baud, full duplex, no parity, 8 data bits, and 1 stop bit. The full text of this document will be available on CIPS for 10 days from the date of issuance. The complete text on diskette in WordPerfect format may also be purchased from the Commission's copy contractor, La Dorn Systems Corporation, also located in room 3308, 941 North Capitol Street, NE., Washington, DC 20426.

Order Terminating Docket

On May 30, 1985 and June 28, 1985, the Commission issued two Notices of Inquiry in this proceeding to evaluate its then-present policies toward wholesale electricity transactions and transmission service, and to evaluate whether those policies promoted or impeded efficiency in electricity markets and whether there were alternatives or possible revisions that would further promote efficiency in the electric utility industry.[1] For the reasons given below, we are terminating this docket.

Background

As noted, in mid-1985, the Commission issued two Notices of Inquiry in a "broad inquiry into the regulation of electric utilities selling in wholesale markets."[2]

In the first Notice of Inquiry, the Commission addressed its regulation of coordination transactions and transmission service. With respect to such coordination transactions, the Commission reviewed its pricing policies, summarizing its then-current policies and asking commenters to address both those policies as well as possible alternatives.[3] With respect to transmission service, the Commission reviewed both pricing and availability, again summarizing its then-current policies and asking commenters to address those policies and possible alternatives.[4]

In the second Notice of Inquiry, the Commission addressed its regulation of requirements service. The Commission reviewed its then-current pricing practices and possible alternatives, as well as questions concerning the allocation of risk, and asked commenters to address these matters.[5]

Comments were filed as to both Notices of Inquiry by a broad cross-section of those involved in the electric utility industry—Federal and state governmental bodies (including the United States Department of Energy and various state commissions), electric utilities, customers and customer groups, and consultants and other persons active in the industry. In addition, the Commission held public conferences at which the matters raised by the Commission and commented upon by the various commenters were discussed.

Discussion

The Commission issued the two Notices of Inquiry, solicited comments, and held public conferences to learn whether the various segments of the electric utility industry—including utilities, customers, and regulations—believed the Commission's pricing and other regulatory policies were promoting or impeding efficiency, and what alternatives or changes might better promote efficiency.[6] Having received comments and having held the public conferences, that purpose was accomplished.

Moreover, much has changed since 1985. The Energy Policy Act of 1992, Public Law No. 102-486, 106 Stat. 2776 (1992), has been enacted. That Act, *inter alia*, provides for a new category of power producers, exempt wholesale generators or EWGs, which are exempt from regulation by the Securities and Exchange Commission under the Public Utility Holding Company Act of 1935, 15 U.S.C. 79a *et seq.* (1988). That Act also expands the Commission's ability to order transmission. Additionally, the Commission itself has, for example, accepted non-cost-based, market-based rates for service,[7] and has permitted public utilities to price their power and energy to respond to competitive pressures.[8]

In sum, the information sought by the Commission in its NOI's, and provided

[1] Regulation of Electricity Sales-for-Resale and Transmission Service, Notice of Inquiry, 50 FR 23445 (June 4, 1985), IV FERC Stats. & Regs. ¶35,518 (1985) (*NOI I*); Regulation of Electricity Sales-for-Resale and Transmission Service, Notice of Inquiry, 50 FR 27604 (July 5, 1985), IV FERC Stats. & Regs. ¶35,519 (1985) (*NOI II*).

[2] *NOI II*, IV FERC Stats. & Regs. at 35,637.

[3] *NOI I*, IV FERC Stats. & Regs. at 35,628-33.

[4] *Id.* at 35,633-35.

[5] *NOI II*, IV FERC Stats. & Regs. at 35,637-53.

[6] See Pacific Gas & Electric Company, 38 FERC ¶61,242 at 61,781 (1987) (NOI's were issued "to gather information to be used to evaluate [Commission's] policies toward wholesale electricity transactions and transmission service").

[7] *E.g.*, Commonwealth Atlantic Limited Partnership, 54 FERC § 61,288 (1991); Commonwealth Atlantic Limited Partnership, 51 FERC ¶61,368 (1990); Public Service Company of Indiana, Inc., Opinion No. 349, 51 FERC ¶61,367, *order on reh'g sub nom.* PSI Energy, Inc., Opinion No. 349-A, 52 FERC ¶61,260, *clarified*, 53 FERC ¶61,131 (1990), *appeal dismissed sub nom. Northern Indiana Public Service Company* v. *FERC, 954 F.2d 736 (D.C. Cir. 1992).*

[8] *E.g.*, Public Service Company of Oklahoma, 54 FERC ¶61,021 (1991); Oklahoma Gas & Electric Company, 54 FERC ¶61,212, *reh'g denied*, 55 FERC ¶61,142 (1992).

in the comments and public conferences, served to educate the Commission. In many respects, however, that information has been overtaken by events and is now, quite simply, stale. Accordingly, as a matter of "administrative housekeeping", the Commission will terminate the docket.[9]

The Commission Orders:

Docket No. RM85-17-000 is hereby terminated.

By the Commission.

Lois D. Cashell,

Secretary.

[FR Doc. 92-110 Filed 1-5-92; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 135

[Docket No. 88P-0251]

Frozen Desserts: Removal of Standards of Identity for Ice Milk and Goat's Milk Ice Milk; Amendment of Standards of Identity for Ice Cream and Frozen Custard and Goat's Milk Ice Cream

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing: (1) To remove the standard of identity for ice milk, and (2) to amend the standard of identity for ice cream and frozen custard to provide for the use of safe and suitable sweeteners and to allow for the use of skim milk that may be concentrated, and from which part or all of the lactose has been removed by a safe and suitable procedure, in the food. To ensure consistency with the removal of the standard of identity for ice milk and the proposed changes in the standard of identity for ice cream and frozen custard, FDA is also proposing to remove the standard of identity for goat's milk ice milk and to make comparable changes in the standard of identity for goat's milk ice cream which cross-references the standard of identity for ice cream and frozen custard. FDA tentatively finds that these actions will promote honesty and fair dealing in the interest of consumers.

DATES: Comments by March 8, 1993. FDA proposes that any final rule that may issue based on this proposal, unless stayed by the filing of proper objections, become effective 1 year following the date of publication of the final rule in the **Federal Register.**

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Margaret E. Cole, Center for Food Safety and Applied Nutrition (HFF-414), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4745.

SUPPLEMENTARY INFORMATION:

I. Background

A. The 1991 Advance Notice of Proposed Rulemaking

In the **Federal Register** of January 22, 1991 (56 FR 2149), FDA announced, in an advance notice of proposed rulemaking (ANPRM), that petitions had been filed in Docket No. 88P-0251 by the International Ice Cream Association (IICA), 888 16th St. NW., Washington, DC 20006, a trade association representing manufacturers and distributors of ice cream and other frozen desserts (petition dated February 23, 1990, and amended March 29, 1990); Public Voice for Food and Health Policy (Public Voice), 1001 Connecticut Ave. NW., Suite 522, Washington, DC 20036, a national nonprofit consumer research, education, and advocacy organization (petition dated March 30, 1990); The Calorie Control Council (the Council), 5775 Peachtree-Dunwoody Rd., Atlanta, GA 30342, an international association of manufacturers of low calorie and diet foods and beverages, including manufacturers of a variety of sweeteners and other low calorie ingredients (petition dated March 5, 1990); and Kraft General Foods (KGF), 1880 JFK Blvd., Philadelphia, PA 19103, a manufacturer and distributor of a broad range of food products within the United States (petition dated October 16, 1989, and submitted on March 14, 1990). The petitioners requested that the agency: (1) Amend the standard of identity for ice milk (§ 135.120 (21 CFR 135.120)) to change the name of the food from "ice milk" to "reduced fat ice cream;" (2) establish new standards of identity for "lowfat ice cream" and "nonfat ice cream;" (3) provide for the use of any safe and suitable sweeteners in the new or revised standards for "reduced fat," "lowfat," and "nonfat" ice cream products; and (4) amend the standard of identity for ice cream (135.110 (21 CFR 135.110)) to provide for the use of any safe and suitable sweeteners. Interested persons were given until March 25, 1991, to comment.

In the ANPRM, FDA specifically requested comments on whether the suggested names "reduced fat ice cream," "lowfat ice cream," and "nonfat ice cream" would be misleading to consumers. The agency also requested data and information concerning the need for, and appropriateness of, such new or revised standards, as well as on a number of factors including, but not limited to:

(1) The minimum weight per gallon requirement;

(2) The minimum total nonfat milk solids requirement;

(3) The milkfat content requirements;

(4) The use of "nonfat" on a product that may contain up to 0.5 percent milkfat;

(5) The use of "lowfat" on a product that may contain 2 percent milkfat;

(6) Whether the limitations on fat content should apply to the milkfat content of the basic mix or to the total fat content of the product including the fat contributed by characterizing flavoring ingredients (e.g., milk chocolate, butterscotch, and nuts) that may be added to the basic ice cream mix;

(7) Nutritional equivalency, i.e., whether these products should contain added vitamins and minerals;

(8) The suitability of, need for, and conditions of use of any safe and suitable sweeteners, including alternative sweeteners such as saccharin and aspartame;

(9) The need to amend the goat's milk ice cream and goat's milk ice milk standards of identity (§§ 135.115 and 135.125 (21 CFR 135.115 and 135.125)) to be consistent with any changes made in the ice cream and ice milk standards of identity (§§ 135.110 and 135.120);

(10) Alternative ways of addressing the underlying issue raised by the petitions, i.e., providing for lower fat ice cream products under the name "ice cream;"

(11) The alternative language, suggested by FDA, to describe the

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[9] As to an agency's considerable discretion not to initiate a rulemaking and its discretion not to promulgate a final rule after a notice of proposed rulemaking has been issued, *see, e.g.*, Western Fuels-Illinois, Inc. v. ICC, 878 F.2d 1025, 1027, 1031 (7th Cir. 1989); Williams Natural Gas Company v. FERC, 872 F.2d 438, 443-44, 450 (D.C. Cir. 1989); Arkansas Power & Light Company v. ICC, 725 F.2d 716, 723 (D.C. Cir. 1984); Professional Drivers Council v. Bureau of Motor Carrier Safety, 706 F.2d 1216, 1220-21 (D.C. Cir. 1983).

These decisions involve situations different than the facts here—*i.e.*, decisions not to institute rulemaking proceedings at all or not to promulgate final rules after notices of proposed rulemaking, as compared to terminating a proceeding involving a notice of inquiry. However, the deference accorded to administrative agencies in the former circumstances (and especially the considerable deference accorded if the agency's decision is not to institute rulemkaing proceedings) is no less appropriate here.

permitted optional sweeteners as "any sweetener that has been affirmed as generally recognized as safe (GRAS) or approved as a food additive for this use by the FDA" instead of the phrase "any safe and suitable sweeteners," as suggested by the petitioners; and

(12) The impact on small businesses if proposals, as suggested by the petitioners, were adopted.

B. The 1991 Proposals

On November 8, 1990, the President signed into law the Nutrition Labeling and Education Act of 1990 (1990 amendments) (Pub. L. 101–535). Section 3(b)(1)(A) of the 1990 amendments (21 U.S.C. 343) requires FDA to issue regulations that define claims characterizing the level of any nutrient that is of a type required to be declared in nutrition labeling. Specifically, the 1990 amendments direct FDA to promulgate regulations prescribing the use of the terms "free," "low," "light" or "lite," "reduced," "less," and "high" to characterize the level of these nutrients, unless the Secretary of Health and Human Services finds that the use of any such term would be misleading (section 3(b)(1)(A)(iii) of the 1990 amendments).

In its implementation of the 1990 amendments, FDA published a number of food labeling proposals in the November 27, 1991, **Federal Register**. In one document entitled "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms" (56 FR 60421), FDA proposed to establish regulations that define specific nutrient content claims including the terms "low," "free," "reduced," "light" or "lite," "source," and "high." Further, in the November 27, 1991, document the agency proposed to provide for comparative claims that use the terms "less," "fewer,"and "more." In another document entitled "Food Labeling: Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food" (56 FR 60478), FDA proposed to establish definitions for fat, fatty acid, and cholesterol claims as well as requirements for the proper use of such terms as "reduced fat," "lowfat," and "nonfat" on food labels.

In the November 27, 1991, **Federal Register**, FDA also published a proposal entitled "Food Standards: Requirements for Substitute Foods Named by Use of a Nutrient Content Claim and a Standardized Term" (hereinafter referred to as the general standard proposal) (56 FR 60512). In that document, FDA proposed to amend the general provisions for food standards to prescribe a general definition and standard of identity for foods named by use of a nutrient content claim defined in part 101 (21 CFR part 101) (such as "fat free," "low calorie," and "light") in conjunction with a traditional standardized name (e.g., "reduced fat ice cream").

After consulting with Public Voice and KGF about the course of action that should be taken in light of the general standard proposal (56 FR 60512), IICA, in a letter dated January 15, 1992, amended its petitions of February 23, 1990, and March 29, 1990. IICA's amended petition withdrew its February 23, 1990, petition as it related to the establishment of standards of identity for "reduced fat ice cream," "lowfat ice cream," and "nonfat ice cream" and requested that the standard of identity for ice milk be removed. Subsequently, in a letter dated March 12, 1992, KGF withdrew its petition to establish a new standard of identity for nonfat ice cream. Shortly thereafter, on April 10, 1992, Public Voice withdrew its petition. Both KGF and Public Voice supported IICA's request that the standard of identity for ice milk be removed. KGF also supported IICA's petition for the use of safe and suitable sweeteners. Public Voice stated that it neither supported nor opposed IICA's recommendation on this issue.

C. The 1992 Final Rules

Elsewhere in this issue of the **Federal Register**, FDA is publishing two related final rules to implement section 3(b)(1)(A) of the 1990 amendments. They are: (1) "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definitions of Terms" (hereinafter referred to as the nutrient content claims final rule); and (2) "Food Standards: Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term" (hereinafter referred to as the general standard final rule).

In the nutrient content claims final rule, FDA is establishing in part 101 definitions for nutrient content claims together with general principles and procedures governing their use. Nutrient content claims for the fat content of foods are defined in new § 101.62 and include: "nonfat" (new § 101.62(b)(1)), "lowfat" (new § 101.62(b)(2)), and "reduced fat" (new § 101.62(b)(4)). The term "light" (or "lite") is defined in new § 101.56.

In the general standard final rule, FDA is establishing a general definition and standard of identity in new § 130.10 for modified versions of standardized foods. Specifically, the new general standard final rule, in new § 130.10, permits the use of FDA-defined nutrient content claims for fat content, such as "reduced fat," "lowfat," and "nonfat," in conjunction with the names of traditional standardized foods in parts 131 through 169 (21 CFR parts 131 through 169) in naming these new foods that have been specially formulated to reduce the level of fat in the product in new § 130.10(a). For example, the general standard final rule establishes conditions whereby the terms "reduced fat," "lowfat," and "nonfat" can be used with the standardized term "ice cream" for foods that resemble and substitute for ice cream but contain less milkfat than regular ice cream.

Under the general standard final rule, the modified version of the traditional product must not be nutritionally inferior to the traditional food that it resembles and for which it is intended to substitute (new § 130.10(b)). In addition, the food must possess similar performance properties and organoleptic characteristics (new § 130.10(c)), and it must be prepared from the same ingredients as the traditional standardized food, except that safe and suitable ingredients to improve texture, add flavor, add sweetness, prevent syneresis, extend shelf life, or improve appearance are allowed (new § 130.10(d)(1)). Further, to replace fat and calories, appropriate fat analogs and water may be added to modified versions of the traditional standardized foods defined in parts 131 through 169 (new § 130.10(d)(5)). Ingredients not provided for by the standard of identity, and ingredients used in excess of those provided for by the standard e.g., water to replace fat, must be identified as such in the ingredient statement (new § 130.10(f)(2)).

Thus, terms such as "reduced fat," "lowfat," and "nonfat" can be used in conjunction with the name "ice cream" as long as their use complies with new § 130.10 and is not false or misleading to consumers, and as long as the modified version does not purport to be a food to which another standard of identity applies. For example, without the changes proposed below, a reduced fat ice cream product that complies with the existing standard of identity for ice milk must be labeled as "ice milk."

II. Frozen Desserts—Legal Authority

Section 8 of the 1990 amendments removes food standards from the coverage of section 701(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(e)) except for:

* * * any action for the amendment or repeal of any definition and standard of identity under section 401 of the act for any dairy products (including products regulated under parts 131, 133, and 135 of title 21,

ıde of Federal Regulations) or maple sirup ıgulated under § 168.140 of title 21, Code Federal Regulations).

In this document, FDA is proposing to move (i.e., repeal) the standards of entity for ice milk (§ 135.120) and ıat's milk ice milk (§ 135.125) and to nend the standards of identity for ice eam (§ 135.110 (21 CFR 135.110)) and ıat's milk ice cream (§ 135.115 (21 CFR 15.115)). Because these proposed tions are to remove and to amend andards for dairy products, they are ıbject to the formal rulemaking ocedures of section 701(e) of the act. ction 701(e) of the act, unlike the formal rulemaking procedures of ction 701(a) of the act, requires that e agency hold a formal evidentiary aring if objections that raise issues of aterial fact are filed in response to ıal rules to establish, amend, or move a food standard.

I. IICA's and the Council's Statement Grounds and Review of Comments

. IICA's and the Council's Statement of rounds

FDA summarized in the ANPRM the atements of grounds submitted by CA and the Council in support of their ggested changes concerning safe and itable sweeteners. In that ANPRM, DA noted that the petitioners had gued that permitting the use of safe ıd suitable sweeteners in frozen sserts would help consumers to meet ıtional nutritional goals and would timately enhance the public health by creasing the availability in the arketplace of ice cream products low calories and sugars. Further, the gency noted that the petitioners had serted that the provision concerning fe and suitable sweeteners would eate consistency in the naming of new e cream products and would provide bel information about sweeteners to ınsumers.

. Summary of Comments

FDA received and reviewed 65 letters, ıch containing one or more comments, ım consumers, the food industry, ademia, trade associations, and ınsumer organizations in response to e ANPRM on the standards for ice eam and ice milk and the need to tablish standards for reduced fat, wfat, and nonfat ice creams. The ımments generally supported the etitioners' requests as published in the NPRM.

Some comments addressed issues ırelated to the establishment of andards of identity for "reduced fat ice eam," "lowfat ice cream," and "nonfat e cream." However, many comments ıecifically addressed the need to establish such standards. With regard to the need to establish such standards, FDA received one or more comments addressing each of the following issues:

(1) Percentage declaration of milkfat content;

(2) Minimum weight per gallon;

(3) Total solids requirement for lowfat and nonfat ice cream;

(4) Establishment of 5 percent milkfat, as compared to 7 percent milkfat, as the maximum milkfat content of reduced fat ice cream;

(5) Maximum fat level in nonfat ice cream and the contribution of high fat flavoring ingredients;

(6) Nutritional equivalency;

(7) Declaration of the fat content to include flavoring ingredients; and

(8) "Reduced fat" labeling on products with a 50 percent reduction in fat.

The agency believes that the new requirements that it has established in the general standard final rule in new § 130.10 for modified foods named by use of a nutrient content claim and a standardized term (e.g., reduced fat ice cream) eliminate the need for individual standards of identity for these lower fat ice cream products. Moreover, in that document, FDA responds to many of the comments on the need for such standards. For example, among other issues, the preamble to the general standard final rule addresses the issues of minimum weight per gallon, the total solids requirement, the definition of "reduced fat ice cream," the definition of "nonfat ice cream," and nutritional equivalency. Therefore, in light of: (1) New § 130.10 in the general standard final rule; and (2) the petitioners' concurrence that individual standards are no longer necessary, as evidenced by the withdrawal of their petitions for establishing such individual standards, FDA believes that further regulatory action to establish standards for reduced fat, lowfat, and nonfat ice cream products is unnecessary. Therefore, FDA has fully addressed the comments relating to this issue, and there is no need to address them any further.

The agency will describe the relevant comments as they relate to the removal of the ice milk standard and to the amendment of the ice cream standard in the discussion of the proposed regulation that follows.

IV. The Proposal

A. Ice Milk

Comments received by the agency in response to the ANPRM did not specifically address the issue of removing the standard of identity for ice milk. However, the amended petitions from IICA, Public Voice, and KGF supported the removal of the ice milk standard so as to provide for lower fat ice cream products such as "reduced fat ice cream."

If FDA removes the "ice milk" standard, then under the general standard final rule, manufacturers will be free to label as "reduced fat ice cream" those frozen desserts that meet the agency's definition of "reduced fat" in new § 101.62(a)(4) of the nutrient content claim final rule and that comply with the definition and standard of identity for ice cream in § 135.110 except for those deviations from that standard that are provided for in new § 130.10 of the general standard final rule. The agency is defining "reduced fat" to mean a total fat content at least 25 percent less than the total fat content of an appropriate reference food (new § 101.62(b)(4)). Many products that now bear the name "ice milk" on their labels could, without reformulation, be redesignated as "reduced fat ice cream" under the general standard of identity (new § 130.10) if the ice milk standard is removed.

However, reduced fat ice cream must also contain less than the minimum 10 percent milkfat provided for in traditional standardized ice cream in accordance with § 135.110(a)(2). Frozen dessert products that meet the standard for ice cream (i.e., that contain a minimum of 10 percent milkfat or a minimum of 8 percent milkfat in products where bulky flavors are used) must be labeled as ice cream. Thus, a manufacturer that reduces the fat level in the company's "super premium" product (e.g., vanilla ice cream with a milkfat content of 14 percent) by 25 percent would not be able to designate the product as "reduced fat ice cream." In this instance, because the product would contain a level of milkfat that is consistent with the minimum milkfat level for ice cream in § 135.110(a)(2), the product would still be ice cream and would have to be named accordingly. However, the product could bear on its label a truthful statement explaining that the product contains 25 percent less fat than the company's "super premium" product.

Moreover, Public Voice mentioned in its petition that the use of the name "ice milk" reduces the marketability of a food that is similar to ice cream but that contains less fat. Thus, redesignation of the product as "reduced fat ice cream" may improve the marketability of the product and consequently may promote its consumption in place of full fat ice cream. Replacement of regular full fat ice cream in the diet with a lower fat version of ice cream will help

consumers to achieve one of the recommended national nutritional goals (i.e., to reduce dietary fat levels).

Therefore, the agency is proposing to remove the standard of identity for ice milk in § 135.120.

B. Safe and Suitable Sweeteners

In their petitions, IICA and the Council requested that FDA provide for the use of any safe and suitable sweeteners in ice cream products. In the ANPRM, the agency asked whether the language in the current standards that requires that all ingredients used in the food be "safe and suitable" should be expanded to provide for the use of "any safe and suitable sweeteners." FDA notes that the standard of identity in § 135.110 now provides only for the use of safe and suitable nutritive carbohydrate sweeteners in ice cream. Further, to ensure that the use of sweeteners that have not been determined by FDA to be safe is prohibited in these foods, the agency suggested that the permitted optional sweeteners be described in the standards as "any sweetener that has been affirmed as GRAS or approved as a food additive for this use by the FDA."

The majority of the comments addressing this issue supported the use of alternative sweeteners (i.e., sweeteners other than nutritive carbohydrate sweeteners), such as aspartame and saccharin, in new food products because the use of these sweeteners would increase the availability of lower calorie frozen desserts. Many of these comments also approved of the language, suggested by FDA, that the sweeteners used in the ice cream products be either "affirmed as GRAS or approved for this use by FDA" instead of the usual "safe and suitable" language. Several persons maintained that this language would ensure that the sweeteners used would be safe for this use. Other comments believed that either statement is acceptable.

A few comments, however, were concerned that the proposed FDA language would create a mandatory safety evaluation system for all optional sweeteners in ice cream products irrespective of their possible GRAS status. The comments contended that such a requirement would be an inappropriate use of food standards and would use standards as a vehicle for circumventing the safety review procedures established by the act. A trade association was concerned that the FDA suggested language was a return to the pre-1974 practice of defining acceptable ingredients for each food standard.

A comment from the Council stated that FDA's concern about the use of unapproved food additives is fully addressed by the use of the term "safe and suitable," which the agency already has defined in § 130.3(d)(21 CFR 130.3(d). The comment pointed out that the purpose of FDA's codification of the definition of "safe and suitable" was to avoid repeating the same definition in each individual standard. The comment concluded that a change in the "safe and suitable" language of the standards is not necessary.

Although the "safe and suitable" language does not directly cite GRAS substances, the agency acknowledges that this language includes them because safe and suitable ingredients include substances that are not unapproved food additives. The agency acknowledges that the suggested alternative FDA language could be interpreted as eliminating from use in ice cream products certain sweetening ingredients whose use is not specifically provided for in current FDA regulations. The agency also notes that the general provisions for food standards in § 130.3(c) strengthen the safety requirements of § 130.3(d). These general provisions provide that no provisions of food standards may be construed as in any way affecting the concurrent applicability of the general provisions of the act and the regulations thereunder relating to adulteration and misbranding. Thus, § 130.3(c) of the general provisions for food standards reinforces the requirement that sweetening additives must be safe and in compliance with sections 201(s) and 409 of the act (21 U.S.C. 321(s) and 348). Therefore, FDA has decided to use the safe and suitable language in describing the sweetening ingredients permitted in ice cream products in this proposal.

However, this tentative decision should not be construed as agency concurrence with independent GRAS determinations. The agency points out that it cannot agree that a sweetener is GRAS for some intended use in a food until it has reviewed all pertinent data on the ingredient and made a determination that it is safe for such use. FDA cautions that, without appropriate authorization, companies or individuals who make a GRAS determination on an ingredient take the risk that the agency will disagree with them and take regulatory action against the use of the substance.

One comment stated that the agency should reject the petition to add a provision to permit the use of "any safe and suitable sweeteners" in these products. It expressed the opinion that more information is needed on the long-term safety of some alternative sweeteners that may be used in foods.

FDA advises that any safe and suitable sweetener, whether GRAS or an approved food additive, presumably is viewed as safe for its intended use by experts, qualified by scientific training and experience, to evaluate the safety of such substances. In addition, traditional sweeteners, such as honey which has been used for many years for this purpose, were not intended to be excluded from use in ice cream products by the suggested language that referred to the GRAS status of the sweetener (§ 170.30(d) 21 CFR 170.30(d)). Therefore, as discussed above, FDA is proposing to provide in § 135.110(a)(1) for the use of both nutritive and nonnutritive safe and suitable sweeteners in the standards set forth below.

FDA points out that another option is to retain the provision in § 135.110(a)(1) that requires the use of "nutritive carbohydrate sweeteners" as mandatory ingredients in ice cream and to allow ice cream products containing alternative sweeteners to be subject to the general standard of identity in new § 130.10, as has been done with other standardized foods. FDA notes, however, that new § 130.10(d)(4) of the general standard final rule requires that an ingredient that is specifically required by the standard (e.g., nutritive carbohydrate sweetener in ice cream) must be present in the product in a significant amount (i.e., at least that amount that is required to achieve the technical effect of that ingredient in the food). Thus, this option would prevent manufacturers from replacing all of the nutritive carbohydrate sweetener in such a product with one or more alternative sweeteners unless they called the product by a name other than the standardized name of the food.

The agency is requesting comments on the need for, and appropriateness of, the proposed change in § 135.110(a)(1) and proposed § 135.110(e)(7) with respect to the use of "safe and suitable sweeteners" in ice cream products as opposed to the general provision of new § 130.10.

One comment requested that the standards for ice cream products require that the artificial sweeteners used in these foods be declared on the principal display panel.

FDA recognizes that some consumers want to avoid frozen dessert products that contain the alternative sweeteners for which the standard of identity for ice cream does not now provide. In § 102.5 (21 CFR 102.5), FDA has established general principles for establishing common or usual names for

nonstandardized foods when the presence of a characterizing ingredient or component of an ingredient in such foods has a material bearing on consumer acceptance. However, there are no similar requirements for standardized foods unless specifically provided for in the standard of identity for a given food. FDA believes that ice cream made in compliance with § 135.110, but that is sweetened with an alternative sweetener, is a distinctly different product than that sweetened with a nutritive carbohydrate sweetener as the standard for this food now permits and accordingly should be clearly distinguished from the traditional food. Therefore, FDA tentatively concludes that it is necessary to inform consumers of this fact in sections 201(n) and 403(a) (21 U.S.C. 343) of the act. Under new § 130.10 in the general standard final rule, a product containing an alternative sweetener would be distinguished from the traditional product by naming the product using such nutrient content claims as "reduced sugar" defined in new § 101.60(c)(4) or "reduced calorie" defined in new § 101.60(b)(4), provided that the requirements for the use of these terms on the food label are otherwise met.

FDA also notes that foods that are sweetened with one or more artificial sweeteners, whether nutritive or nonnutritive, are foods for special dietary use under § 105.3(a)(2) (21 CFR 105.3(a)(2). Therefore, they must be labeled to comply with the requirements of § 105.66 (21 CFR 105.66). A final rule revising § 105.66 to conform with the requirements of the 1990 amendments is published elsewhere in this issue of the **Federal Register**. In accordance with new § 105.66, the food may be labeled with terms such as "diet," "dietetic," "artificially sweetened," or "sweetened with nonnutritive sweetener" only if the claim is not false or misleading to consumers, and the food is labeled "low calorie" or "reduced calorie" or bears another comparative caloric claim.

Therefore, to distinguish standardized ice cream products sweetened with alternative sweeteners (i.e., sweeteners other than nutritive carbohydrate sweeteners) from products sweetened with traditional sweeteners (i.e., nutritive carbohydrate sweeteners), FDA is proposing to add a requirement in the ice cream standard in proposed § 135.110(e)(7), and in the goat's milk ice cream standard in proposed § 135.115(c)(2), that the presence of such alternative sweeteners be declared by their common or usual name on the principal display panel of the label as part of the statement of identity in letters of no less than one-half the size of the type used in the product name (e.g., "ice cream") but no smaller than one-sixteenth of an inch.

FDA is also providing in these proposed provisions that, as discussed above, ice cream products sweetened with such sweeteners must comply with the applicable provisions of new § 105.66. Thus, in addition to having to declare the presence of alternative sweeteners as a part of their statements of identity, such products will have to be labeled as "low calorie" or "reduced calorie" or bear another comparative caloric claim in compliance with part 101. The agency notes that modified ice cream products made in conformity with the provisions of new § 130.10 in the general standard final rule will also have to comply with the labeling requirements for sweeteners if they are finalized as in proposed § 135.110(e)(7). New § 130.10(e) requires that the name of a modified version of a standardized food that complies with the general standard in new § 130.10 is the appropriate expressed nutrient content claim e.g., "reduced fat" and the applicable standardized term e.g., "ice cream sweetened with aspartame." The agency specifically requests comments on the need to declare alternative sweeteners in ice cream as discussed above.

C. Skim Milk with Part or All of the Lactose Removed by Alternate Technologies

One comment stated that recently developed technologies will permit increases in the amount of milk protein used in ice cream and related products without the quality problems normally associated with lactose in the dairy ingredients. To address the use of ultrafiltration and other lactose-reduction technologies, the comment requested that FDA revise § 135.110(b) to replace the phrase "skim milk that has been concentrated and from which part of the lactose has been removed by crystallization" with "skim milk [that] may be concentrated and from which part of the lactose has been removed by crystallization, ultrafiltration, or other approved technologies."

FDA tentatively finds that it would be appropriate for the standard to permit addition of concentrated skim milk from which part of the lactose has been removed by ultrafiltration. The agency believes that it should also provide for the removal of part or all of the lactose by any safe and suitable procedure. These actions will give manufacturers the opportunity to use state-of-the-art processing technologies. However, manufacturers must ensure that the nutritional quality of the resulting food is not detrimentally affected. Accordingly, FDA is amending the ice cream standard in proposed § 135.110(b) to provide for the addition of skim milk that may be concentrated, and from which part or all of the lactose has been removed by a safe and suitable procedure, in the food. This approach will minimize the need to revise the standard should other acceptable procedures be developed for lactose reduction or removal at a later date.

D. Goat's Milk Ice Cream and Goat's Milk Ice Milk

In the ANPRM, FDA asked whether the goat's milk ice cream and goat's milk ice milk standards of identity in §§ 135.115 and 135.125 should be amended to achieve consistency with any changes in the ice cream and ice milk standards of identity §§ 135.110 and 135.120. The goat's milk ice cream and goat's milk ice milk standards of identity cross-reference the ice cream and ice milk standards of identity with respect to the use of optional ingredients excluding caseinates, weight per gallon, weight of total food solids, and labeling requirements.

FDA received one comment from a consumer advocacy organization in support of changes in the goat's milk ice cream and goat's milk ice milk standards. The comment stated that, in the interest of consistency and for the same basic reasons given in the petitions, corresponding changes in the standards of identity for goat's milk ice cream and goat's milk ice milk should be proposed.

FDA agrees with this comment. The agency believes that the suggested actions relating to the standards for goat's milk ice milk and goat's milk ice cream will foster uniformity in the labeling of ice cream products. In addition, making changes in the standard for goat's milk ice cream in § 135.115 will permit this product to be formulated similarly to ice cream in § 135.110. Accordingly, the agency is proposing to remove the standard for goat's milk ice milk and to make changes in the standard for goat's milk ice cream similar to the proposed changes in the standard for ice cream and frozen custard, as discussed above.

E. Additional Comments

FDA received several comments on the use of "any safe and suitable dairy ingredient;" the use of safe and suitable milk-derived protein ingredients other than caseinates; the use of vegetable proteins; and the use of fat substitutes, such as microparticulated protein, in ice cream products. As discussed below,

FDA finds that the issues raised by these comments are appropriate for agency consideration. However, as a resource matter, given the demands of the formal rulemaking process, FDA concludes that it is not appropriate for the agency at this time to institute formal rulemaking procedures on most of these matters.

One comment requested that FDA revise § 135.110(b) to provide for "any safe and suitable dairy ingredient." It stated that the listing of optional dairy ingredients by name or by the process by which they are derived effectively prohibits the use of some new or novel materials (e.g., concentrated skim milk with the lactose removed by a process other than crystallization).

In view of the wide range of optional dairy ingredients listed by name or by the process by which they are derived in § 135.110(b) of the standard for ice cream, FDA requests comments on whether the specific names should be deleted from § 135.110(b), and whether the standard should be amended to provide for the use of any safe and suitable dairy ingredients, as suggested by the comment. If a comment supports use of a collective term such as "dairy ingredient," the agency asks that the comment provide a definition of the term so as to facilitate proper interpretation of the regulation.

One comment suggested that FDA provide for safe and suitable milk-derived protein ingredients other than caseinates where the milk solids content minimums required by the standard for ice cream in § 135.110 are otherwise met. The comment stated that these "other milk protein ingredients" include milk protein hydrolysates (enzyme-modified milk protein) and milk protein isolates (caseinates and whey protein co-isolates). The comment maintained that the use of milk proteins other than caseinates contributes to aeration of frozen lowfat dairy desserts, thereby improving the body and texture of these products, and that their use will not reduce the nutritional value of standardized dairy products. It further stated that these ingredients are safe and suitable for use in other nonstandardized foods such as frozen yogurt, coffee whiteners, infant formulas, fortified cereals, and medical foods. The comment requested that the standards proposed in the ANPRM be amended by replacing the optional caseinates with the term "safe and suitable milk-derived proteins."

FDA acknowledges that milk protein hydrolysates are GRAS and are now used in many foods. These hydrolysates vary in the degree of hydrolysis that they have undergone depending on the manufacturing process They also vary in their functional characteristics depending on their intended use. However, before the agency extends the category of milk-derived protein components that may be used in these foods, it would like additional information on the nature of and need for these ingredients in ice cream, the proposed levels of use, and their suitability in performing technical functions in the food, such as aeration, as suggested by the comment, as well as information on any possible adverse effects of their use. If the comments on this issue adequately support the need for such ingredients, FDA will consider providing for their use in the final regulation that results from this proposal.

One comment suggested that the standards provide for the addition of vegetable proteins in addition to milk-derived protein sources. It maintained that vegetable proteins could provide consumers and manufacturers with new nutritional, economic, and quality advantages in these products.

FDA does not agree that the standards for ice cream products should provide for the addition of vegetable proteins. Ice cream and ice milk products are traditionally considered to be dairy products, and, as such, neither vegetable proteins nor vegetable fats or oils are considered to be suitable ingredients of these foods. When vegetable proteins or vegetable fats or oils are used in frozen dessert products resembling ice cream, FDA considers these foods to be nonstandardized substitute foods provided that they are nutritionally equivalent to ice cream or ice milk. As such, these products should bear a common or usual name that is not misleading.

For example, coffee whiteners containing ingredients of vegetable origin do not purport to be cream or dry cream products. Rather, they are products that bear their own common or usual name. In a like manner, the agency believes that frozen dessert products, made in the semblance of ice cream and containing vegetable proteins or vegetable fats or oils, must be properly identified under their own common or usual name. Therefore, FDA is not providing for vegetable proteins in the proposed amendment of the standard of identity for ice cream set forth below. However, the agency notes that nonmilk-derived protein-containing ingredients may be included in frozen dessert products labeled as "mellorine" in § 135.130 (21 CFR 135.130).

One comment from an ingredient supplier asked whether fat substitutes, such as microparticulated protein, could be used in ice cream products. The comment stated that microparticulated protein, prepared from egg white and skim milk (or, alternatively, from whey protein concentrate), is used in products complying with the IICA proposed standards.

A comment from a consumer stated that fat substitutes do not belong in traditional ice cream products covered by standards of identity. The comment stated that these ingredients should be used only in the "frozen desserts" category. The comment contended that the preservation of tradition overrides governmental, medical, and consumer interests in reducing fat intake and providing alternative, healthful products.

FDA does not agree with the consumer comment in its entirety. FDA notes that § 135.110(a) provides for the use of "safe and suitable nonmilk-derived ingredients." In the **Federal Register** of April 12, 1977 (42 FR 19127), in an amendment of the standard for ice cream that provided for "safe and suitable nonmilk derived ingredients," the agency stated that it deems as unsuitable those ingredients that change the basic character of the food or that do not perform an appropriate function in the food. In this regard, the use of fat substitutes to replace milkfat in ice cream is suitable if the minimum compositional levels for milkfat and nonfat milk solids for ice cream in § 135.110(a)(2) are met, and if the fat substitutes are made from ingredients permitted by the standard of identity for ice cream. FDA believes that this approach is reasonable in order to give consumers the option to purchase products that simulate the characteristics of traditional ice cream but that contain less fat.

F. Summary of Proposal

On the basis of the information mentioned above, FDA is proposing to remove the standard of identity for ice milk (§ 135.120) and to make several requested changes in the standard of identity for ice cream. The requested changes in the ice cream standard deal with provisions for: (1) The use of safe and suitable sweeteners; and (2) the use of skim milk that may be concentrated, and from which part or all of the lactose has been removed by a safe and suitable procedure, in the food.

FDA considers it reasonable to propose to remove the standard of identity for ice milk because this action will allow for the use of the "reduced fat" nutrient content claim in conjunction with the name "ice cream." Such use will be consistent with the use of the terms "lowfat" and "nonfat" on ice cream products made in compliance

with new § 130.10. Until the ice milk standard has been removed, frozen desserts that have a milkfat content between 2 and 7 percent and that otherwise comply with the standard in § 135.120 cannot be called "reduced fat ice cream."

FDA also considers it reasonable to amend the standard of identity for ice cream to provide for the use of safe and suitable sweeteners, including alternative sweeteners such as aspartame or saccharin; and to allow for the use of skim milk that may be concentrated, and from which part or all of the lactose has been removed by any safe and suitable procedure, in ice cream. FDA tentatively finds that these changes will permit manufacturers to develop nutritious, wholesome frozen dessert products containing alternative sweeteners or sweetening systems. The proposed amendment of the ice cream standard will increase flexibility and give manufacturers the latitude to develop new, innovative products in response to consumer interest in and desire for lower calorie dairy products.

The goat's milk ice cream (§ 135.115) and goat's milk ice milk (§ 135.125) standards of identity cross-reference the ice cream and ice milk standards of identity. Thus, FDA considers it appropriate to propose comparable changes in the goat's milk ice cream and goat's milk ice milk standards to reflect the proposed changes in the ice cream and ice milk standards. Therefore, the agency is also proposing to remove the goat's milk ice milk standard and to amend the goat's milk ice cream standard with respect to the use of sweeteners and with respect to the use of skim milk with part or all of the lactose removed by any safe and suitable procedure as discussed above for the cross-referenced ice cream standard.

FDA is also making certain minor editorial changes in the standards of identity for ice cream and goat's milk ice cream for clarity.

FDA believes that these actions are necessary to ensure the integrity of these foods, to minimize any confusion regarding the types of acceptable ingredients that may be used in the foods, and to promote honesty and fair dealing in the interest of consumers.

V. Economic Impact

FDA has examined the economic implications of the proposed rule to remove the standards of identity for ice milk and goat's milk ice milk and to amend the standards of identity for ice cream and goat's milk ice cream in part 135 as required by Executive Order 12291 and the Regulatory Flexibility Act. Executive Order 12291 compels Federal agencies to use cost-benefit analysis as a component of decisionmaking. The Regulatory Flexibility Act requires regulatory relief for small businesses where feasible. Because no marginal costs are expected to be incurred to comply with this proposed regulation, the agency finds that this proposed rule is not a major rule as defined by Executive Order 12291. In accordance with the Regulatory Flexibility Act Pub. L. 96–354, FDA has also determined that this proposed rule will not have a significant adverse impact on a substantial number of small businesses.

FDA has tentatively determined that, because the effect of the actions that the agency is proposing is to permit increased flexibility in the processing of frozen desserts and because a reasonable amount of time will be provided to use existing supplies of labels, the proposed actions will not result in a significant impact on a substantial number of small entities. FDA has not received any information or comments on the ANPRM that would cause it to reach a different determination.

FDA considered several options in arriving at this proposal. One option considered was to take no action. Under this option, manufacturers of ice cream products would be limited in the types of skim milk ingredients that may be used in ice cream products. Thus, consumers' choices would also be limited. In addition, removal of the standard of identity for ice milk will provide for more informative labeling of the lower fat ice cream products and help consumers to achieve recommended nutritional goals.

Another option considered was to remove the ice cream standard and goat's milk ice cream standard, as well as the standards for ice milk and goat's milk ice milk, and allow manufacturers to use any combination of types and levels of ingredients in these foods. While this option would appear to provide flexibility in the selection of ingredients, it would not be in the best interest of consumers or manufacturers. In the absence of Federal standards for these foods, the states could establish standards with different requirements which could hinder interstate commerce. Uniform standards protect consumers from unfair trade practices and also enable manufacturers to compete in an equitable manner.

Under the selected option set forth below, i.e., removing the standard of identity for ice milk and amending the standard of identity for ice cream, as requested by the petitioners, as well as removing the goat's milk ice milk standard and amending the goat's milk ice cream standard that cross-references the ice cream standard, manufacturers will be able to provide consumers with ice cream products that reflect the traditional food and that are labeled in a uniform manner. In addition, the removal of the ice milk standard will provide manufacturers with increased flexibility to use names more acceptable to the public in designating ice cream products that contain reduced levels of calories and fat.

If FDA adopts this proposal, firms that produce ice milk products will have to revise their labels. Some firms may also wish to reformulate their ice milk products so as to be able to take advantage of the increased flexibility in product formulation provided for under new § 130.10. However, FDA believes that any additional costs for label changes will be offset by the increased consumer recognition of the benefits of the resulting reduced calorie and reduced fat ice cream products. FDA will also allow an appropriate period of time (1 year) for manufacturers to use up labels so as not to cause a hardship on manufacturers of ice milk products. The proposed amendments to the ice cream and goat's milk ice cream standards will also allow the use of additional optional ingredients. The agency does not anticipate that there will be any increased cost from these changes because there is no requirement that these new optional ingredients be used in ice cream products.

Therefore, FDA finds that marginal costs if any, will be small for the proposed amendment because FDA is providing sufficient time for most ice cream manufacturers to incorporate label changes into normal label stock reordering. Therefore, in accordance with section 605(b) of the Regulatory Flexibility Act, FDA has also determined that this proposed rule will not have a significant adverse impact on a substantial number of small businesses.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24(b)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Effective Date

FDA proposes that any final rule that may issue based on this proposal, unless stayed by the filing of proper objections, become effective 1 year following the date publication of the final rule in the

Federal Register. Because of the formal rulemaking procedures that apply to the amendment and removal of standards for products regulated under part 135, the agency notes that the effective date for any final rule that may issue from this proposal may not coincide with the effective date for the food labeling final rules that were issued in response to the 1990 amendments and that are published elsewhere in this issue of the **Federal Register.** Except as to any provisions that may be stayed by the filing of proper objections, compliance with any final rule that may issue based on this proposal (including any required labeling changes) may begin immediately upon publication of such a final rule in the **Federal Register.** Notice of the filing of objections or lack thereof will be published in the **Federal Register.**

VIII. References

The following information has been placed on file in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. U.S. Department of Agriculture and U.S. Department of Health and Human Services, "Nutrition and Your Health, Dietary Guidelines for Americans," 2d ed., Washington, DC, 1985.

2. U.S. Department of Health and Human Services, "The Surgeon General's Report on Nutrition and Health." DHHS (PHS) Publication No. 88–50210, Washington, DC, U.S. Government Printing Office, GPO Stock No. 017–001–00465–1, 1988.

3. Committee on Technological Options to Improve Nutritional Attributes of Animal Products, Board of Agriculture, National Research Council, "Designing Foods: Animal Product Options in the Marketplace," National Academy Press, Washington, DC, 1988.

IX. Comments

Interested persons may, on or before March 8, 1993, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 135

Food grades and standards, Food labeling, Frozen foods, Ice cream.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, it is proposed that 21 CFR part 135 be amended as follows:

PART 135—FROZEN DESSERTS

1. The authority citation for 21 CFR part 135 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

2. Section 135.110 is amended by revising paragraphs (a)(1) and (b), and by adding paragraph (e)(7) to read as follows:

§ 135.110 Ice cream and frozen custard.

(a) *Description.* (1) Ice cream is a food produced by freezing, while stirring, a pasteurized mix consisting of one or more of the optional dairy ingredients specified in paragraph (b) of this section, and may contain one or more of the optional caseinates specified in paragraph (c) of this section subject to the conditions hereinafter set forth, and other safe and suitable nonmilk-derived ingredients; and excluding other food fats, except such as are natural components of flavoring ingredients used or are added in incidental amounts to accomplish specific functions. Ice cream is sweetened with safe and suitable sweeteners and may or may not be characterized by the addition of flavoring ingredients.

* * * * *

(b) *Optional dairy ingredients.* The optional dairy ingredients referred to in paragraph (a) of this section are: Cream; dried cream; plastic cream (sometimes known as concentrated milkfat); butter; butter oil; milk; concentrated milk; evaporated milk; sweetened condensed milk; superheated condensed milk; dried milk; skim milk; concentrated skim milk; evaporated skim milk; condensed skim milk; superheated condensed skim milk; sweetened condensed skim milk; sweetened condensed part-skim milk; nonfat dry milk; sweet cream buttermilk; condensed sweet cream buttermilk; dried sweet cream buttermilk; skim milk, that may be concentrated, and from which part or all of the lactose has been removed by a safe and suitable procedure; skim milk in concentrated or dried form that has been modified by treating the concentrated skim milk with calcium hydroxide and disodium phosphate; and whey and those modified whey products (e.g., reduced lactose whey, reduced minerals whey, and whey protein concentrate) that have been determined by FDA to be generally recognized as safe (GRAS) for use in this type of food. Water may be added, or water may be evaporated from the mix. The sweet cream buttermilk and the concentrated sweet cream buttermilk or dried sweet cream buttermilk, when adjusted with water to a total solids content of 8.5 percent, has a titratable acidity of not more than 0.17 percent, calculated as lactic acid. The term "milk" as used in this section means cow's milk. Any whey and modified whey products used contribute, singly or in combination, not more than 25 percent by weight of the total nonfat milk solids content of the finished food. The modified skim milk, when adjusted with water to a total solids content of 9 percent, is substantially free of lactic acid as determined by titration with 0.1*N* NaOH, and it has a pH value in the range of 8.0 to 8.3.

* * * * *

(e) * * *

(7) When safe and suitable sweeteners other than nutritive carbohydrate sweeteners are used in the food, their presence shall be declared by their common or usual name on the principal display panel of the label as part of the statement of identity in letters that shall be no less than one-half the size of the type used in the term "ice cream" but in any case no smaller than one-sixteenth of an inch. Further, the use of such sweeteners in the food shall comply with the requirements of § 105.66 of this chapter.

* * * * *

3. Section 135.115 is amended by revising paragraph (a), by redesignating the text of paragraph (c) as paragraph (c)(1), and by adding new paragraph (c)(2) to read as follows:

§ 135.115 Goat's milk ice cream.

(a) *Description.* Goat's milk ice cream is the food prepared in the same manner prescribed in § 135.110 for ice cream, and complies with all the provisions of § 135.110, except that the only optional dairy ingredients that may be used are those in paragraph (b) of this section; caseinates may not be used; and paragraphs (e)(1) and (f) of § 135.110 shall not apply.

* * * * *

(c) * * *

(2) When safe and suitable sweeteners other than nutritive carbohydrate sweeteners are used in the food, their presence shall be declared by their common or usual name on the principal display panel of the label as part of the statement of identity in letters that shall be no less than one-half the size of the type used in the term "goat's milk ice cream" but in any case no smaller than one-sixteenth of an inch. Further, the use of such sweeteners in the food shall

comply with the requirements of § 105.66 of this chapter.

* * * * *

§ 135.120 [Removed]

4. Section 135.120 *Ice milk* is removed from subpart B.

§ 135.125 [Removed]

5. Section 135.125 *Goat's milk ice milk* is removed from subpart B.

Dated: October 23, 1992.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 92-31529 Filed 12-28-92; 8:45 a.m.]

BILLING CODE 4160-01-F

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 1

[Docket No. 921118-2318]

RIN 0651-AA63

Patent Interference Practice Burden of Proof

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Patent and Trademark Office (PTO) proposes to amend its rules of practice in patent interference cases. As a result of issues arising in some recent cases, it is apparent that parties in interference cases would be helped if the interference rules explicitly stated which party has the burden of proof when a motion is filed. There is also some confusion with respect to the nature of the evidence that should be submitted with a preliminary motion, particularly when testimony is needed to support or oppose the preliminary motion. PTO proposes to specify that a party filing a motion has the burden of proof. PTO also proposes to more clearly specify the nature of expert witness and factual witness evidence that must accompany a preliminary motion. Finally, PTO proposes to add a definition of an interlocutory order, as contrasted with a final decision, in order to clarify the meaning of an interlocutory order.

DATES: Comments must be submitted on or before March 8, 1993. A public hearing will not be held.

ADDRESSES: Address written comments to Box 8, Commissioner of Patents and Trademarks, Washington, DC 20231, marked to the attention of Fred E. McKelvey, Solicitor. Written comments will be available for public inspection in suite 918, on the 9th floor of Crystal Park II, located at 2121 Crystal Drive, Arlington, Virginia.

FOR FURTHER INFORMATION CONTACT: Fred E. McKelvey by telephone at (703) 305-9035 or by mail marked to his attention and addressed to Box 8, Commissioner of Patents and Trademarks, Washington, DC 20231.

SUPPLEMENTARY INFORMATION: The PTO conducts interference proceedings to determine who, as between two or more applicants for patent or one or more applicants and one or more patentees, is the first inventor of a patentable invention. In the course of interference proceedings, the Board of Patent Appeals and Interferences enters two kinds of decisions, interlocutory orders and final decisions. There has been some confusion as to what orders are interlocutory orders. The PTO is proposing to add subsection (q) to 37 CFR 1.601 to define an interlocutory order and to contrast interlocutory orders with the final decision. The presumption of correctness of an interlocutory order, which is presently in 37 CFR 1.655(a), is proposed to be moved to proposed new subsection 1.601(q), and to be deleted from § 1.655(a). The definition of interlocutory order would include the decision represented by the notice declaring the interference.

Under the interference rules, a party in an interference is authorized to file motions, including preliminary motions (37 CFR 1.633), motions to correct inventorship (37 CFR 1.634) and miscellaneous motions (37 CFR 1.635). When necessary, a preliminary motion should be accompanied by evidence (37 CFR 1.639). Recently there has been confusion as to who has the burden of proof when a motion is filed. For example, when transmitting papers to the Board for declaration of an interference, the Primary Examiner determines in the first instance the extent, if any, to which a party is entitled to the filing date of an earlier domestic or foreign application. 37 CFR 1.609(b)(4). The interference is then declared by an examiner-in-chief and an indication is given that a party has been accorded the benefit of the filing date of an earlier application. 37 CFR 1.611(c)(5). An opponent, however, is authorized to challenge the initial decision of the Primary Examiner and the examiner-in-chief to accord benefit. The challenge is made through a preliminary motion. 37 CFR 1.633(g). It is the PTO's position that the party filing the motion bears the burden of proof to show that its opponent should not have been accorded the benefit of the filing date of an earlier application. If adopted, the proposed rules would make explicit in 37 CFR 1.637(a) that a party filing a motion has the burden of proving why it is entitled to the relief sought in the motion.

Another difficulty in interference cases has been compliance with 37 CFR 1.639 with respect to evidence that must accompany a preliminary motion. In 1990, a decision was entered in *Hanagan* v. *Kimura*, 16 USPQ2d 1791, 1794 (Comm'r Pat. 1990), that provided the following guidance:

> To the extent it may prove useful, the following guidance is provided. When expert testimony is needed in support of, or in opposition to, a preliminary motion, a party should:
>
> (1) Identify the person whom it expects to call as an expert;
>
> (2) State the field in which the person is alleged to be an expert; and
>
> (3) State in a declaration signed by the person
>
> (a) the subject matter on which the person is expected to testify,
>
> (b) the facts and opinions to which the person is expected to testify, and
>
> (c) a summary of the grounds and basis for each opinion.
>
> If a person is to be called as a fact witness, a declaration by that person stating the facts should be filed.
>
> If the other party is to be called, or if evidence in the possession of the other party is necessary, an explanation of the evidence sought, what it will show, and why it is needed must be supplied.
>
> When inter partes tests are to be performed, a description of the tests stating what they will show must be presented.
>
> The nature of the showing under § 1.639(c) will vary from case to case.

Nothing in the rule change being proposed would alter the need to supply evidence in support of, or in opposition to, a preliminary motion. The rules being proposed would codify the *Hanagan* guidelines. Subsection (c) of § 1.639 is proposed to be amended to refer to "additional evidence in the form of testimony" so as to distinguish the evidence in the form of testimony" so as to distinguish the evidence needed under subsection (c) from that which may be submitted under subsections (a) and (b).

Proposed subsection (d) to 37 CFR 1.639 would specify the nature of evidence that must be submitted when an opinion of an expert is needed. The statement which would be required under proposed subsection (d) would be essentially the same as discovery required under Rule 26(b)(4)(A)(i) of the Federal Rules of Civil Procedures.

Proposed subsection (e) would specify the nature of evidence that must be

submitted when a statement of a fact witness is to be relied upon.

Proposed subsection (f) would specify the nature of a showing which should be made when a statement of an opponent is needed or evidence in possession of an opponent is needed.

Proposed subsection (g) would specify the nature of evidence that must be supplied if inter partes tests are to be conducted.

The party filing the preliminary motion would be expected to supply all necessary evidence with the preliminary motion. Likewise, a party opposing a preliminary motion should supply with the opposition all needed evidence in support of the opposition. Normally, if a party cannot obtain all necessary evidence to support or oppose a preliminary motion, and can show good cause, the party should seek an extension of time to file or oppose the preliminary motion. In an unusual situation, the guidance may not apply in the case of a party opposing a preliminary motion. In a recent interference, an examiner-in-chief deferred to final hearing consideration of a preliminary motion which had been accompanied by considerable evidence. The opponent had requested leave to take testimony. Based on the amount of evidence submitted with the preliminary motion, it was the examiner-in-chief's view that it would have been manifestly unfair to require the opponent to have prepared a full case in opposition to the preliminary motion in the 20-day period set for filing oppositions. As noted by the examiner-in-chief in the instance mentioned above, more leeway as to the evidence, and when it is supplied, can properly be granted to a party opposing a preliminary motion than a party filing a preliminary motion. The party filing the preliminary motion knows what must be proved. A party opposing the preliminary motion may or may not have time to fully respond with evidence accompanying an opposition. If an examiner-in-chief finds in a particular case that a party, during the time allowed for filing an opposition to a preliminary motion, could not reasonably have fully marshalled its evidence for presentation along with the opposition to a preliminary motion, a testimony period may be set. Alternatively, the examiner-in-chief, *sua sponte* or on motion of the opponent, may grant an extension of time to gather and supply the evidence. The action to be taken is a matter within the discretion of the examiner-in-chief.

Present 37 CFR 1.655(a) is proposed to be amended by deleting the last sentence, which would be moved to and be included in the proposed definition of interlocutory order in proposed subsection 1.601(q). The burden of showing error in entry of an interlocutory order is on the party challenging the order. If the order involved a procedural matter, the challenger must show that an examiner-in-chief or a panel abused discretion in entering the order. If the order involved a non-procedural matter (i.e., granting a motion for judgment based on unpatentability), the challenger must show legal error.

In some instances, two or more interlocutory orders may involve the same issue. For example, a notice declaring an interference may accord a party benefit of an earlier application. A preliminary motion may result in the party being denied benefit. When there are two or more interlocutory orders involving the same issue, the latest interlocutory order is presumed to be correct in further proceedings in the interference.

Other Considerations

The proposed rule changes are in conformity with the requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), Executive Orders 12291 and 12612 and the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*

The General Counsel of the Department of Commerce has certified to the Chief Counsel for Advocacy, Small Business Administration, that these proposed rule changes will not have a significant economic impact on a substantial number of small entities (Regulatory Flexibility Act, 5 U.S.C. 605(b)). The principal impact of these proposed changes would be to clarify procedure in patent interference and thereby eliminate any ambiguity which might exist in current rules.

The Office has determined that this proposed rule change is not a major rule under Executive Order 12291. The annual effect on the economy will be less than $100 million. There will be no major increase in costs or prices for consumers; individuals; industries; Federal, state or local government agencies; or geographic regions. There will be no significant effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The Office has also determined that this notice has no Federalism implications affecting the relationship between the National Government and the States as outlined in Executive Order 12612.

The rule change will not impose a burden under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, since no recordkeeping or reporting requirements within the coverage of the Act are placed upon the public.

List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Courts, Inventions and patents.

PART 1—RULES OF PRACTICE IN PATENT CASES

For the reasons set out in the preamble, it is proposed to amend 37 CFR part 1 wherein removals are indicated by brackets ([ ]) and additions by arrows (⧫ ⧫):

1. The authority citation for 37 CFR part 1 would continue to read as follows:

Authority: 35 U.S.C. 6, unless otherwise noted.

2. Section 1.601 is proposed to be amended by adding paragraph (q) to read as follows:

§ 1.601 Scope of rules, definitions.

* * * * *

⧫(q) A *final decision* is a decision awarding judgment as to all counts. An *interlocutory order* is any other action taken by an examiner-in-chief or a panel of the Board in an interference, including the notice declaring an interference. All interlocutory orders shall be presumed to have been correct and the burden of showing error or an abuse of discretion shall be on the party attacking the order. When two or more interlocutory orders involve the same issue, the last entered order shall be presumed to have been correct.⧫

3. Section 1.637 is proposed to be amended by revising paragraph (a) to read as follows:

§ 1.637 Content of motions.

(a) ⧫A party filing a motion has the burden of proof to show that it is entitled to the relief sought in the motion.⧫ Every motion shall include (1) a statement of the material facts in support of the motion, and (3) a full statement of the reasons why the relief requested should be granted.

* * * * *

4. Section 1.639 is proposed to be amended by revising paragraph (c) and by adding paragraphs (d) through (g) as follows:

§ 1.639 Evidence in support of motion, opposition, or reply.

* * * * *

(c) When a party believes that ⧫additional evidence in the form of⧫

testimony is necessary to support or oppose a preliminary motion under § 1.633 or a motion to correct inventorship under § 1.634, the party shall describe the nature of any proposed testimony ⧫in the manner specified in subsections (d) through (g) of this section⧫. If the examiner-in-chief finds that testimony is needed to decide the motion, the examiner-in-chief may grant appropriate interlocutory relief and enter an order authorizing the taking of testimony and deferring a decision on the motion to final hearing.

⧫(d) When the testimony is needed in support of or opposition to a preliminary motion is expert testimony, the moving party or opponent should:

(1) Identify the person whom it expects to call as an expert;

(2) State the field in which the person is alleged to be an expert; and

(3) State:

(i) The subject matter on which the person is expected to testify;

(ii) The facts and opinions to which the person is expected to testify; and

(iii) A summary of the grounds and basis for each opinion.

(e) If a fact witness is to be relied upon, state the facts to which the witness will testify.

(f) If the opponent is to be called, or if evidence in the possession of the opponent is necessary, explain the evidence sought, what it will show, and why it is needed.

(g) When inter partes tests are to be performed, describe the tests stating what they will be expected to show.⧫

5. Section 1.655 is proposed to be amended by removing the last sentence of paragraph (a) as follows:

§ 1.655 Matters considered in rendering a final decision.

(a) In rendering a final decision, the Board may consider any properly raised issue including (1) priority of invention, (2) derivation by an opponent from a party who filed a preliminary statement under § 1.625, (3) patentability of the invention, (4) admissibility of evidence, (5) any interlocutory matter deferred to final hearing, and (6) any other matter necessary to resolve the interference. The Board may also consider whether any interlocutory order was erroneous or an abuse of discretion. (All interlocutory orders shall be presumed to have been correct and the burden of showing manifest error or an abuse of discretion shall be on the party attacking the order.)

* * * * *

Dated: December 30, 1992.

Edward E. Kubasiewicz,

Assistant Commissioner for Patents.

[FR Doc. 93-210 Filed 1-5-93; 8:45 am]

BILLING CODE 3510-16-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 43

[CC Docket No. 92-296; FCC 92-537]

Simplification of the Depreciation Prescription Process

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Federal Communications Commission (the Commission) has adopted a Notice of Proposed Rulemaking (Notice) proposing to simplify its depreciation prescription process. In a continuing effort to reduce unnecessary regulatory burdens and their associated costs, the Commission seeks comment on proposals that would simplify procedures and reduce associated costs in the depreciation prescription process.

DATES: Comments must be filed on or before March 10, 1993 and reply comments must be filed on or before April 13, 1993.

ADDRESSES: Federal Communications Commission, 1919 M St., NW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Sonja J. Rifken or Fatina K. Franklin, Common Carrier Bureau, Accounting and Audits Division, (202) 632-7500.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rulemaking in Simplification of the Depreciation Prescription Process, CC Docket No. 92-296, FCC 92-537, adopted December 10, 1992 and released December 29, 1992. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M St., NW., Washington, DC. The full text will be published in the FCC Record and may also be purchased from the Commission's copy contractor, Downtown Copy Center, (202) 452-1422, 1990 M Street, NW., suite 640, Washington, DC 20036.

Summary

1. In this Notice of Proposed Rulemaking (Notice), we continue our efforts to reduce unnecessary regulatory burdens and their associated costs by undertaking simplification of our depreciation prescription process. Under our current depreciation prescription process, we prescribe depreciation rates by plant account for individual carriers. In this Notice, we seek comment on proposals that would simplify procedures and reduce associated costs in our depreciation prescription process.

2. This Commission determines depreciation rates by using a formula. This formula contains two parameters which must be estimated: future net salvage (FNS) and average remaining life (ARL). Once the parameters are determined, a depreciation rate is computed. The carriers then apply the depreciation rate to the average plant account balance to calculate the depreciation expense for that account. The ultimate purpose of continually estimating depreciation rates is to develop rates, using the most current information, that most accurately allocate plant costs to expense at a rate representative of the actual consumption of the plant.

3. Because the basic factors composing the ARL, projection life and survivor curve, as well as the FNS, are estimates, they are the subject of detailed analyses. Carriers submit detailed studies to prove the merit of their estimates, as required by our rules. A typical carrier submits studies totalling approximately 600 pages and averaging 20-25 pages of analysis per account. It is this part of the depreciation process we seek to simplify in this Notice.

4. In this Notice, we propose four options for simplifying the determination of depreciation expense: the basic factor range option, the range of rates option, the depreciation schedule option, and the price cap carrier option. The first proposal, the basic factor range option, would simplify the depreciation process by establishing ranges for the basic factors that determine the parameters used in the depreciation rate formula; the FNS, and the projection life and survivor curve (the basic factors that determine the ARL). This would eliminate the need for carriers to submit detailed studies in support of their proposed factors. Under this proposal, we would continue to prescribe depreciation rates using the current depreciation rate formula. Carriers would then apply the rates to their plant account balances to determine their depreciation expense.

5. The second proposal, the range of rates options, would simplify the depreciation process by establishing ranges for depreciation rates. Under this option, we would no longer focus on the basic factors used to derive the

parameters for the depreciation rate formula, and more importantly, we would not use the depreciation rate formula to derive depreciation rates. However, carriers would continue to apply depreciation rates to their plant account balances to determine their depreciation expense.

6. The third proposal, the depreciation schedule option, would simplify the depreciation process by establishing a depreciation schedule for each plant account. Essentially, the schedule would be based upon a Commission-specified service life, retirement pattern, and salvage value for a particular account. Carriers would then apply the schedule to their investment by vintage.

7. The final proposal would affect only price cap carriers. The price cap carrier option would simplify the depreciation process by allowing price cap carriers to file depreciation rates with no supporting data, but continuing Commission prescription of depreciation rates. Price cap carriers would file their proposed depreciation rates, and the Commission would issue a Public Notice seeking comment on the proposed rates. The Commission would then prescribe depreciation rates based on the price cap carriers' proposals and the comments submitted thereon.

8. The current depreciation process, and the four simplification options we seek comment on, include net salvage as a part of the depreciation process. In furtherance of simplification, we seek comment on whether we should, independent of those options, change our approach to salvage and not consider it in the depreciation process. This simplification option would require carriers to remove salvage from their depreciation process and require them to book the cost of removal and salvage as current period charges and credits. In addressing this proposal, commenters should quantify the effects this change would have on carriers' income statement and the administrative costs savings associated with the change. Also, we ask whether this changed treatment of salvage would be contrary to Generally Accepted Accounting Principles (GAAP).

9. We certify that the Regulatory Flexibility Act of 1980 does not apply to this rulemaking proceeding because if the proposed rule amendments are promulgated, there will not be a significant economic impact on a substantial number of small business entities, as defined by Section 601(3) of the Regulatory Flexibility Act. 5 U.S.C. 603(a). Because of the nature of local exchange and access service, the Commission has concluded that small telephone companies are dominant in their fields of operation and therefore are not "small entities" as defined by that act. The Secretary shall send a copy of this Notice of Proposed Rulemaking, including the certification, to the Chief Counsel for Advocacy of the Small Business Administration in accordance with section 603(a) of that act.

10. Accordingly, it is ordered that, pursuant to sections 1, 4(i), 4(j), 220, and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 154(j), 220(b), and 403, notice is hereby given of proposed amendments to § 43.43 of the Commission's Rules, 47 CFR 43.43 as described in this Notice of Proposed Rulemaking.

List of Subjects in 47 CFR Part 43

Communications common carriers, Reporting and recordkeeping requirements, Telephone.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 93-104 Filed 1-5-93; 8:45 am]

BILLING CODE 6712-01-M

INTERSTATE COMMERCE COMMISSION

49 CFR Part 1007

[Ex Parte No. 514(B)]

Privacy Act: New System of Records—Exemption; Office of Inspector General Complaint and Investigative Files

AGENCY: Interstate Commerce Commission.

ACTION: Proposed rule.

SUMMARY: The Commission (ICC) proposes here to exempt a new system of records due to the law enforcement nature of those records. That system of records which the Commission today proposed to establish in another proceeding under the Privacy Act of 1974, as amended (5 U.S.C. 552a), will consist of the complaint and investigatory files of the ICC's Office of Inspector General (OIG). This proposed rule amendment is required in order to invoke the relevant exemptions. By relieving the OIG of certain restrictions, the exemption will help ensure that the OIG may efficiently and effectively perform investigations and other authorized duties and activities.

DATES: Comments are due February 5, 1993.

ADDRESSES: An original and two copies of comments, referring to Ex Parte No. 514(B), should be submitted to: Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

FOR FURTHER INFORMATION CONTACT: S. Arnold Smith, Freedom of Information/Privacy Officer, (202) 927-6317 [TDD for hearing impaired: (202) 927-5721].

SUPPLEMENTARY INFORMATION: In the notice section of today's **Federal Register**, the ICC is publishing a notice proposing to establish a new system of records, "Office of Inspector General Complaint and Investigative Files," under the Privacy Act, as amended, 5 U.S.C. 552a. The following proposed amendment of ICC Rule 49 CFR 1007.12 is necessary to exempt the new system of records from certain provisions of the Act. These provisions require, among other things, that the ICC provide notice when collecting information, account for certain disclosures, permit individuals access to their records, and allow them to request that the records be amended. These provisions would interfere with the conduct of OIG investigations if applied to the OIG's maintenance of the proposed system of records.

Accordingly, the ICC proposes to exempt the system of records under sections (j)(2) and (k)(2) of the Privacy Act. Section (j)(2), 5 U.S.C. 552a(j)(2), exempts a system of records maintained by "the agency or component thereof which performs as its principal function any activity pertaining to enforcement of criminal laws * * *" Section (k)(2), 5 U.S.C. 552a(k)(2), exempts a system of records consisting of "investigatory materials compiled for law enforcement purposes," where such materials are not within the scope of the (j)(2) exemption pertaining to criminal law enforcement.

Where applicable, section (j)(2) may be invoked to exempt a system of records from any Privacy Act provision except: 5 U.S.C. 552(b) (conditions of disclosure); (c) (1) and (2) (accounting of disclosures and retention of accounting, respectively); (e)(4) (A) through (F) (system notice requirements); (e) (6), (7), (9), (10), and (11) (certain agency requirements relating to system maintenance); and (i) (criminal penalties). Section (k)(2) may be invoked to exempt a system of records from 5 U.S.C. 552(c)(3) (making accounting of disclosures available to the subject individual); (d) (access to record); (e)(1) (G), (H) and (I) (notice of certain procedures); and (f) (promulgation of certain Privacy Act rules).

The proposed system of records consists of information covered by the (j)(2) and (k)(2) exemptions. The OIG complaint and investigatory files are maintained pursuant to official

investigatory and law enforcement functions of the ICC's OIG under the authority of the Inspector General Act Amendments of 1988, Public Law 100-504, 102 Stat. 251 (amending 5 U.S.C. App. 3 (1978)). Furthermore, the OIG constitutes an ICC component that performs as one of its principal functions activities pertaining to the enforcement of criminal laws. See 5 U.S.C. 552a(j)(2). Information covered under the (j)(2) exemption includes, but is not limited to, information compiled for the purpose of identifying criminal offenders and alleged offenders and consisting of identifying data and notations of arrests, and the nature and disposition of criminal charges, sentencing, confinement, release, and parole and probation status; information compiled for the purpose of a criminal investigation, including reports of informants and investigators, that is associated with an identifiable individual; or reports of enforcement of the criminal laws from arrest or indictment through release from supervision. Information contained in OIG complaint and investigative files under the (k)(2) exemption relates to non-criminal law enforcement matters, such as information pertaining to the investigation of civil, administrative, or regulatory violations and similar wrongdoing.

Access by subject individuals, among others, to this system of records, including the names of persons or agencies to whom the information has been transmitted, would substantially compromise the effectiveness of OIG investigations. Knowledge of such investigations could enable suspects to take action to prevent detection of unlawful activities, conceal or destroy evidence, or escape prosecution. Disclosure of this information could lead to the intimidation of, or harm to, informants, witnesses, and their families and could jeopardize the safety and well-being of investigative and related personnel and their families. The imposition of certain restrictions on the manner in which investigative information is collected, verified, or retained would significantly impede the effectiveness of OIG investigatory activities and, in addition, could preclude the apprehension and successful prosecution or discipline of persons engaged in fraud or other illegal activity.

For these reasons, the ICC proposes to exempt the proposed system of records containing the OIG complaint and investigative files under exemptions (j)(2) and (k)(2) of the Privacy Act by amending 490 CFR 1007.12. Under this rule, the ICC specifies its system of records that are exempt from the Privacy Act.

This proposed rule amendment will become effective 30 days after its final publication in the **Federal Register**. This date may be postponed if the Director of the Office of Management and Budget (OMB) declines, in whole or part, the ICC's request to waive the 60-day period prescribed by OMB for advance notice to OMB and Congress. See OMB Circular No. A-130, App. 1 at 4b.(c)(4).

Regulatory Flexibility Certification

Pursuant to the Regulatory Flexibility Act (RFA), 5 U.S.C. 605(b), the Commission certifies that the proposed amendment to its regulations, if adopted, would not have a significant economic impact on a substantial number of small entities within the meaning of the RFA. The purpose of that amendment, which is proposed pursuant to the Privacy Act, is solely to exempt from disclosure certain files of the ICC's OIG that would be kept in a new system of records within the ICC. The proposed amendment imposes no new regulatory requirements either directly or indirectly on anyone, including small entities. Moreover, because the Privacy Act applies only to "individuals," and the RFA defines "small entities" as having the same meaning as 'small business', 'small organization' and 'small government jurisdiction' as defined in section 601(3), (4) and (5) respectively, the "individuals" who may be affected by the new rule do not appear to come within the meaning of "small entity" as defined by the RFA.

Energy and Environment Considerations

We preliminarily conclude that this action will not significantly affect either the quality of the human environment or the conservation of energy resources.

List of Subjects in 49 CFR Part 1007

Administrative practice and procedure, Privacy.

Decided: December 31, 1992.

By the Commission, Chairman Philbin, Vice Chairman McDonald, Commissioners Simmons and Phillips.

Sidney L. Strickland, Jr.,

Secretary.

For the reasons set forth in the preamble, title 49, chapter X, part 1007 of the Code of Federal Regulations is proposed to be amended as follows:

PART 1007—RECORDS CONTAINING INFORMATION ABOUT INDIVIDUALS

1. The authority citation for part 1007 continues to read as follows:

Authority: 5 U.S.C. 552, 553, and 559.

2. Section 1007.12 is proposed to be amended by adding a new paragraph (c) as follows:

§ 1007.12 Exemptions.

* * * * *

(c) Complaints and investigatory materials compiled by the Commission's Office of Inspector General are exempt from the provisions of 5 U.S.C. 552a and the regulations in this part, pursuant to 5 U.S.C. 552a(j)(2), except subsections (b), (c)(1) and (2), (e)(4) (A) through (F), (e)(6), (7), (9), (10), and (11) and (i) to the extent that the system of records pertains to the enforcement of criminal laws. Complaint and investigatory materials compiled by the Commission's Office of Inspector General for law enforcement purposes also are exempt from the provisions of 5 U.S.C. 5552a and the regulations of this part, pursuant to 5 U.S.C. 552a(k)(2), except subsections (c)(3), (d), (e)(1), (e)(4)(G), (H), (I), and (f).

[FR Doc. 93-250 Filed 1-5-93; 8:45 am]

BILLING CODE 7035-01-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 672

[Docket No. 921226-2326]

Groundfish of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to delay the opening of the second quarter for pollock fishing in the Combined Western and Central Regulatory Areas (W/C) of the Gulf of Alaska (GOA) from the beginning of the second quarterly reporting period (around April 1) until the first day of the weekly reporting period closest to June 1. This action is necessary to increase revenues from the GOA pollock harvest by avoiding a second quarter directed fishery at a time when pollock have recently spawned and flesh yield is low. Additionally, NMFS anticipates this action would reduce discards of undersized pollock, and of incidental bycatch amounts of chinook salmon in the pollock fishery.

By increasing the value of the pollock harvest, this action would foster economic growth. This action is intended to promote the goals and objectives of the North Pacific Fishery Management Council (Council) with respect to groundfish management off Alaska.

DATES: Comments must be received at the following address no later than 4:30 p.m., Alaska local time, February 5, 1993.

ADDRESSES: Comments may be sent to Ronald J. Berg, Chief, Fisheries Management Division, Alaska Region, NMFS, Box 21668, Juneau, AK 99802, Attention: Lori Gravel. Copies of the environmental assessment/regulatory impact review/initial regulatory flexibility analysis (EA/RIR/IRFA) prepared for the proposed action may be obtained from the same address.

FOR FURTHER INFORMATION CONTACT: Jessica A. Gharrett, Fisheries Management Division, (907) 586–7229.

SUPPLEMENTARY INFORMATION:

Background

The domestic and foreign groundfish fisheries in the exclusive economic zone of the GOA are managed by the Secretary of Commerce (Secretary) under the Fishery Management Plan for Groundfish of the GOA (FMP). The FMP was prepared by the Council under the Magnuson Fishery Conservation and Management Act (Magnuson Act) and is implemented by regulations for the foreign fishery at 50 CFR Part 611 and for the U.S. fishery at 50 CFR part 672. General regulations that also pertain to the U.S. fishery appear at 50 CFR part 620.

Under regulations at § 672.20(a)(2)(iv), the total allowable catch (TAC) for pollock in the W/C GOA is apportioned among statistical areas Shumagin (61), Chirikof (62), and Kodiak 63 in proportion to known distribution of the pollock biomass. Each apportionment is divided equally into the four quarterly reporting periods of the fishing year. Under § 672.2, a "quarterly reporting period" means one of four successive 3-month periods during a calendar year. Under § 672.20(c)(1)(ii)(A), directed fishing for pollock in the W/C GOA will commence on dates that coincide with anticipated quarterly reporting periods for 1993. Pollock fishing quarters in the W/C GOA for 1993 commence on the first day of each of the four quarterly reporting periods: January 1, March 29, June 28, and October 4.

At its September 22–27, 1992, meeting, the Council considered an industry proposal to delay the opening of the second quarter pollock fishery in the W/C GOA from the first day of the second quarterly reporting period until the first day of the weekly reporting period nearest June 1. Under § 672.2, a "weekly reporting period" means from 0001 hours Monday morning until 2400 hours the following Sunday night, Alaska local time. For the 1993 fishing year, this date falls on May 31. For the reason given below, the Council found the industry proposal would provide economic benefits to pollock harvesters and processors and recommended that NMFS prepare a proposed rule delaying the opening of the second quarter pollock fishery in the W/C GOA. Pending approval by NMFS, this action would be implemented prior to the start of the second 1993 W/C GOA pollock quarter, currently scheduled for March 29.

The most recent year in which a W/C GOA directed pollock fishery occurred in April was 1990; in 1991 and 1992, the opening of the second quarter was delayed until June. In 1991, the second quarter directed pollock fishery commence on June 13. This change was the result of a delay in approval of the pollock harvest specification to complete additional analyses and a Section 7 consultation for Steller sea lions under the Endangered Species Act (ESA) (56 FR 28112, June 19, 1991). In 1992, the opening of the second quarter was delayed until June 1, under an emergency rule (57 FR 11272, April 2, 1992). This emergency rule was intended to prevent preemption of the inshore component by the offshore component until allocations of pollock under a final rule implementing Amendment 23 to the FMP were effective (57 FR 23321, June 3, 1992). Adoption of this proposed rule would maintain the second quarter pollock fishing and processing seasons as they occurred in 1993 and 1992.

The allocation of pollock into quarters and among several areas has resulted in small quarterly pollock allowances for pollock. Because the domestic groundfish industry has more than adequate capacity to harvest and process the pollock TAC in the W/C GOA, the resultant directed fishery is of short duration; the number of days directed fishing for pollock was open during the second quarter in 1992 was: 2 days for area 61; 16 days for area 62; and 11 days for area 63. This proposed delay is not anticipated to alter effort, and would not be likely to change the length of the directed fishery. The opening of the second quarter directed fishery for pollock would be displaced by approximately 2 months, from the beginning of April to the beginning of June. The opening of the third pollock quarter in the W/C GOA would not be altered by this proposed rule.

The allocation of the W/C GOA pollock TAC to 3 areas will ensure that the harvest remains distributed spatially. Harvesters may be able to fish closer to ports and make shorter trips if searching time to avoid encounters with young and undersized pollock is reduced, and if pollock are not as dispersed as they are in early spring just after spawning.

If the opening of the second quarter pollock fishery is delayed, the same individuals would likely participate in the harvesting and processing of GOA pollock as in 1992, including some processors in close proximity to the Bering Sea and Aleutian Islands Area (BSAI) who also participate in BSAI pollock fisheries. GOA pollock harvesters and processors who participate both in the pollock fishery and in June salmon fisheries may not be able to participate fully in the second quarter fishery if the opening is delayed until June. Participation would depend on the starting dates of the salmon fisheries. In 1992, operators of more than 300 vessels held Federal groundfish permits for trawl gear in the GOA. While this number of vessels is considered substantial, this regulatory measure would only affect the portion of the fleet that participates in the second quarter pollock fishing season. processors who intend to participate in fisheries for pollock as well as other species in the second quarter may experience labor and/or equipment conflicts. These costs, or the extent to which pollock fishing would be foregone, are not quantifiable at this time. Although some processing operations may incur additional labor costs, most operators would realize net benefits resulting from increased yields.

Delaying the opening of the second quarter pollock fishery could result in a fishery that is conducted with pelagic, rather than with non-pelagic, trawl gear, although no additional costs to the industry are anticipated. Under § 672.20(f), an annual halibut bycatch limit is specified for trawl gear. When the limit, or seasonal apportionment thereof, is reached, all GOA groundfish trawl fisheries are closed with the exception of trawling for pollock with pelagic trawl gear. Delay of the opening of the second quarter pollock fishery to around June 1 would increase the likelihood that a seasonable trawl bycatch allowance is taken in other trawl fisheries prior to the start of the second quarter pollock fishery. This situation occurred in the past 2 years and, because trawl closures typically occur in other seasons as well, many

pollock fishermen have acquired pelagic trawl gear. Therefore, any additional costs to harvesters to purchase pelagic nets under the proposed rule are expected to be minimal.

NMFS anticipates that under this proposed action, pollock fishery conducted with pelagic trawl gear would accrue negligible amounts of additional halibut bycatch. Any savings in halibut bycatch experienced by the pollock fishery because of a prohibition on the use of non-pelagic trawl gear may support additional catches of other groundfish species during the second quarter and result in a higher overall groundfish harvest.

NMFS also anticipates that a delayed opening of the second quarter pollock fishery could result in a substantial decrease in the bycatch rates of chinook salmon. Data from 1991 and 1992 indicate that bycatch rates (number of salmon/metric ton (mt) of groundfish) in the pelagic trawl pollock fishery are significantly lower in June than at the end of the first quarter (0.02 and 0.20, respectively). In contract, bycatch rates for salmon other than chinook salmon and for herring may be higher. Bycatch rates of crabs in June are very low and would likely not be different from earlier in the quarter.

The proposed delay of the second quarter opening is anticipated to increase the first wholesale value of the pollock harvest during the second quarter by allowing harvest when recovery of flesh is higher, and to result in potentially higher value products, such as larger fillets and higher grades of surimi. Because the amount of pollock harvest would not be altered under the proposed season delay, an estimate of the increased value is dependent on improved yields, product mix, and wholesale prices. Information on product recovery rates indicates that the increase in flesh yield between pollock harvested in April, when fish have recently spawned, and June, is about 3 percent for fillets, and 4 percent for surimi. Based on 1991 first wholesale values, the value increase would likely be between $2.6 million and $3.6 million for 1993. In addition to increased product value, harvesters and processors also would benefit from decreased fishing, sorting, processing, and storage time, and from decreased disposal of unsuitable fish.

NMFS preliminarily concurs with the Council's recommendation and proposes to delay the opening of the second quarter pollock fishery until the first day of the weekly reporting period nearest June 1.

Classification

The Assistant Administrator for Fisheries, NOAA (Assistant Administrator), has initially determined that this rule is necessary for the conservation and management of the groundfish fishery off Alaska and that it is consistent with the Magnuson Act and other applicable law.

NMFS prepared an EA for this proposed rule that discusses the impact on the environment as a result of this rule. The public may obtain a copy of the EA from the Regional Director (see **ADDRESSES**).

The Assistant Administrator determined that this proposed rule is not a "major rule" requiring a regulatory impact analysis under Executive Order 12291. This determination is based on the socioeconomic impacts discussed in the EA/RIR/IRFA prepared by the NMFS. This proposed rule, if adopted, is not likely to result in an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or a significant adverse effect on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

NMFS prepared an IRFA that concludes that this proposed rule, if adopted, would have significant effects on small entities. In 1992, operators of over 300 vessels were issued permits to fish for GOA groundfish with trawl gear. While this number of vessels is considered substantial, this regulatory measure would affect only the portion of the fleet that participates in the second quarter pollock fishing season. In addition, 14 processors processed pollock during the second quarter pollock fishing of 1992. The proposed action to delay the opening of the second quarter pollock fishery in the W/C GOA is superior to the status quo alternative, because economic benefits will be gained by allowing harvest of pollock when flesh recovery is improved in June as opposed to April. Based on 1991 first wholesale prices, the value increase under the proposed rule is estimated to be between $2.6 and $3.6 million for 1993. Additionally, costs to harvesters and processors may be lower due to decreased time required for fishing, sorting, processing, and product storage. The bycatch and discard of young and undersized pollock, and of chinook salmon, are likely to be lower. Conservation of groundfish and salmon resources would be improved to the extent that these bycatch rates would be reduced. A copy of this analysis is available from the Regional Director (see **ADDRESSES**).

This rule does not include a collection-of-information requirement subject to the Paperwork Reduction Act.

Pursuant to the requirements of the ESA, the Regional Director has determined that this action is not likely to adversely affect any endangered or threatened species or critical habitat within NMFS' jurisdiction.

NFMS has determined that this rule will be implemented in a manner that is consistent to the maximum extent practicable with the approved coastal management program of the State of Alaska. This determination has been submitted for review by the responsible State agency under Section 307 of the Coastal Zone Management Act.

This proposed rule does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under E.O. 12612.

List of Subjects in 50 CFR Part 672

Fisheries, Reporting and recordkeeping requirements.

Dated: December 30, 1992.

Samuel W. McKeen,

Acting Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 672 is proposed to be amended as follows:

PART 672—GROUNDFISH OF THE GULF OF ALASKA

1. The authority citation for 50 CFR part 672 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

2. In § 672.23, paragraph (a) is revised and a new paragraph (f) is added to read as follows:

§ 672.23 Seasons.

(a) Fishing for groundfish in the regulatory areas and districts of the Gulf of Alaska is authorized from 00:01 a.m., Alaska local time (A.l.t), January 1, through 12 midnight, A.l.t., December 31, subject to the other provisions of this part, except as provided in paragraphs (c) through (f) of this section

* * * * *

(f) Directed fishing for pollock in the Western and Central Regulatory Areas of the Gulf of Alaska is authorized from 12 noon, A.l.t., on the first day of each quarterly reporting period through the end of that quarterly reporting period, subject to other provisions of this part, except that directed fishing for pollock during the second quarterly reporting

period is authorized from 12 noon, A.l.t., on the first day of the weekly reporting period closest to June 1, through the end of the second quarterly reporting period, subject to other provisions of this part.

[FR Doc. 93-135 Filed 1-5-93; 8:45 am]

BILLING CODE 3510-22-M

Notices

Federal Register
Vol. 58, No. 3
Wednesday, January 6, 1993

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Meat Import Limitations; First Quarterly Estimate

Public Law 88–482, enacted August 22, 1964, as amended by Public Law 96–177, Public Law 100–418, and Public Law 100–449 (hereinafter referred to as the "Act"), provides for limiting the quantity of fresh, chilled, or frozen meat of bovine, sheep except lamb, and goats; and processed meat of beef or veal (Harmonized Tariff Schedule of the United States subheadings 0201.10.00, 0201.20.20, 0201.20.40, 0201.20.60, 0201.30.20, 0201.30.40, 0201.30.60, 0202.10.00, 0202.20.20, 0202.20.40, 0202.20.60, 0202.30.20, 0202.30.40, 0202.30.60, 0204.21.00, 0204.22.40, 0204.23.40, 0204.41.00, 0204.42.40, 0204.43.40, and 0204.50.00), which may be imported, other than products of Canada, into the United States in any calendar year. Such limitations are to be imposed when the Secretary of Agriculture estimates that imports of articles, other than products of Canada, provided for in Harmonized Tariff Schedule of the United States subheadings 0201.10.00, 0201.20.40, 0201.20.60, 0201.30.40, 0201.30.60, 0202.10.00, 0202.20.40, 0202.20.60, 0202.30.40, 0202.30.60, 0204.21.00, 0204.22.40, 0204.23.40, 0204.41.00, 0204.42.40, 0204.43.40, and 0204.50.00), (hereinafter referred to as "meat articles"), in the absence of limitations under the Act during such calendar year, would equal or exceed 110 percent of the estimated aggregate quantity of meat articles prescribed for calendar year 1993 by section 2(c) as adjusted under section 2(d) of the Act.

In accordance with the requirements of the Act, I have made the following estimates:

1. The estimated aggregate quantity of meat articles prescribed by section 2(c) as adjusted by section 2(d) of the Act for calendar year 1993 is 1,144.7 million pounds.

2. The first quarterly estimate of the aggregate quantity of meat articles which would, in the absence of limitations under the Act, be imported during calendar year 1993 is 1,259.1 million pounds.

Done at Washington, DC this 31st day of December, 1992.

Edward Madigan,

Secretary of Agriculture.

[FR Doc. 93–213 Filed 1–5–93; 8:45 am]

BILLING CODE 3410–10–M

COMMISSION ON CIVIL RIGHTS

Maine State Advisory Committee; Public Meetings

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the Maine State Advisory Committee will be convened at 2 p.m. and adjourn at 5 p.m. on Thursday, January 21, 1993, in suite 212, Civic Center Comfort Inn, 282 Civic Center Drive, Augusta, ME 04330. The purpose of the meeting is (1) to update Committee members and the public on the Commission; (2) to provide an orientation for new Committee members; and (3) to plan future activities.

Persons desiring additional information, or planning a presentation to the Committee, should contact Grayce E. Studley (207–563–3610) or John I. Binkley, Director, ERO (202–376–7533), or TDD (202–376–8116). Hearing impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the regional office at least (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, December 22, 1992.

Carol-Lee Hurley,

Chief, Regional Programs Coordination Unit.

[FR Doc. 93–190 Filed 1–5–93; 8:45 am]

BILLING CODE 6335–01–M

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 619]

Expansion of Foreign-Trade Zone 162; New Haven, Connecticut

Pursuant to its authority under the Foreign-Trade Zones (FTZ) Act of June 18, 1934, as amended (19 U.S.C. 81a–81u) (the Act), and the FTZ Board Regulations (15 CFR part 400), the FTZ Board (the Board) adopts the following Resolution and Order:

Whereas, an application from the Greater New Haven Chamber of Commerce, grantee of Foreign-Trade Zone No. 162, for authority to relocate its general-purpose zone to a larger site at the Port of New Haven, New Haven, Connecticut, within the New Haven Customs port of entry, was filed by the Board on October 31, 1991, and notice inviting public comment was given in the **Federal Register** on November 15, 1991 (Docket 70–91, 56 FR 58030);

Whereas, an examiners committee has investigated the application in accordance with the Board's regulations and recommends approval;

Whereas, the expansion is necessary to improve and expand zone services in the New Haven area; and,

Whereas, the Board has found that the requirements of the Act and the Board's regulations are satisfied, and that approval is in the public interest;

Now, therefore, the Board hereby orders;

That the grantee is authorized to relocate and expand its zone in accordance with the application filed on October 31, 1991, subject to the Act and the Board's regulations (as revised, 56 FR 50790–50808, 10–8–91), including section 400.28.

Signed at Washington, DC, this 29th day of December, 1992.

Alan M. Dunn,

Assistant Secretary of Commerce for Import Administration, Chairman, Committee of Alternatives, Foreign-Trade Zones Board.

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 93–232 Filed 1–5–93; 8:45 am]

BILLING CODE 3510–DS–M

[Order No. 623]

Expansion of Foreign-Trade Zone 101; Clinton County, Ohio

Pursuant to its authority under the Foreign-Trade Zones (FTZ) Act of June 18, 1934, as amended (19 U.S.C. 81a–81u) (the Act), and the FTZ Board Regulations (15 CFR part 400), the FTZ Board (the Board) adopts the following Resolution and Order:

Whereas, an application from the Airborne FTZ, Inc., grantee of Foreign-Trade Zone No. 101, for authority to expand its general-purpose zone at the Airborne Commerce Park in Clinton County, Ohio, adjacent to the Dayton Customs port of entry, was filed by the Board on April 27, 1992, and notice inviting public comment was given in the **Federal Register** on May 7, 1992 (Docket 13–92, 57 FR 19597);

Whereas, an examiners committee has investigated the application in accordance with the Board's regulations and recommends approval;

Whereas, the expansion is necessary to improve and expand zone services in the Clinton County area; and,

Whereas, the Board has found that the requirements of the Act and the Board's regulations are satisfied, and that approval is in the public interest;

Now, therefore, the Board hereby orders:

That the grantee is authorized to expand its zone in accordance with the application filed on April 27, 1992, subject to the Act and the Board's regulations (as revised, 56 FR 50790–50808, 10–8–91), including § 400.28.

Signed at Washington, DC, this 29th day of December, 1992.

Alan M. Dunn,

Assistant Secretary of Commerce for Import Administration, Chairman, Committee of Alternates, Foreign-Trade Zones Board.

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 93–234 Filed 1–5–93; 8:45 am]

BILLING CODE 3510–DS–M

[Order No. 621]

Resolution and Order Approving the Application of the Port of Portland (Oregon) for Special-Purpose Subzone Status for Export Activity Tofle U.S.A., Inc. (Stainless Steel Tubing) Tualatin, OR

Proceedings of the Foreign-Trade Zones Board, Washington, D.C.

Resolution and Order

Pursuant to the authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Resolution and Order:

The Board, having considered the matter, hereby orders:

After consideration of the application of the Port of Portland, grantee of Foreign-Trade Zone 45, filed with the Foreign-Trade Zones (FTZ) Board (the Board) on November 6, 1991, requesting special-purpose subzone status for export activity at the stainless steel tubing plant of Tofle U.S.A., Inc., in Tualatin, Oregon, adjacent to the Portland Customs port of entry, the Board, finding that the requirements of the Foreign-Trade Zones Act and the Board's regulations are satisfied, and that the proposal is in the public interest, approves the application.

The approval is subject to the FTZ Act and the FTZ Board's regulations (as revised, 56 FR 50790–50808, 10–8–91), including Section 400.28. The Secretary of Commerce, as Chairman and Executive Officer of the Board, is hereby authorized to issue a grant of authority and appropriate Board Order.

Whereas, by an Act of Congress approved June 18, 1934, an Act, "To provide for the establishment * * * of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes," as amended (19 U.S.C. 81a–81u) (the Act), the Foreign-Trade Zones Board (the Board) is authorized to grant to corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs ports of entry;

Whereas, the Board's regulations (15 CFR part 400) provide for the establishment of special-purpose subzones when existing zone facilities cannot serve the specific use involved;

Whereas, an application from the Port of Portland (Oregon), grantee of Foreign-Trade Zone 45, for authority to establish a special-purpose subzone for export activity at the stainless steel tubing plant of Tofle U.S.A., Inc., located in Tualatin, Oregon, was filed by the Board on November 6, 1991, and notice was given in the **Federal Register** on November 27, 1992 inviting public comment (FTZ Docket 75–91, 56 FR 60087); and,

Whereas, the Board has found that the requirements of the Act and the Board's regulations are satisfied and that the proposal is in the public interest;

Now, Therefore, the Board hereby authorizes the establishment of a subzone (Subzone 45E) for export activity at the stainless steel tubing plant of Tofle U.S.A., Inc., in Tualatin, Oregon, at the location described in the application, subject to the FTZ Act and the Board's regulations (as revised, 56 FR 50790–50808, 10–8–91), including Section 400.28.

Signed at Washington, DC, this 29th day of December, 1992, pursuant to Order of the Board.

Alan M. Dunn,

Assistant Secretary of Commerce for Import Administration, Chairman, Committee of Alternates Foreign-Trade Zones Board.

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 93–233 Filed 1–5–93; 8:45 am]

BILLING CODE 3510–DS–M

National Oceanic and Atmospheric Administration

Gulf of Mexico Fishery Management Council; Revision to Public Meeting Agenda

AGENCY: National Marine Fisheries Service, NOAA, Commerce.

A notice of, and the agenda for, public meetings of the Gulf of Mexico Fishery Management Council and its Committees were published in the **Federal Register** at 57 FR 61050–61051 on December 23, 1992. Recent actions require a revision to the prior notice as noted below. All other information originally published on December 23, 1992, remains unchanged.

REVISION: Committees: The Budget, Law Enforcement, Habitat and Shrimp Committees will meet on January 18, 1993, from 11 a.m. to 5:30 p.m.

FOR MORE INFORMATION CONTACT: Wayne E. Swingle, Gulf of Mexico Fishery Management Council, 5401 West Kennedy Boulevard, Suite 331, Tampa, FL; telephone: (813) 228–2815.

Dated: December 30, 1992.

Richard H. Schaefer,

Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 93–136 Filed 1–5–93; 8:45 am]

BILLING CODE 3510–22–M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Announcing 1993 Agreement Limits for Certain Cotton, Wool, Man-Made Fiber, Silk Blend and Other Vegetable Fiber Textiles and Textile Products Produced or Manufactured in Hong Kong

December 30, 1992.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Notice.

FOR FURTHER INFORMATION CONTACT: Anne Novak, International Trade

Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

The Bilateral Textile Agreement of August 4, 1986, as amended and extended, and Memoranda of Understanding (MOUs) dated July 29, 1992, August 18, 1992 and November 23, 1992 between the Governments of the United States and Hong Kong establishes limits for the period January 1, 1993 through December 31, 1993. A complete list of the limits is published below.

A copy of the current bilateral agreement is available from the Textiles Division, Bureau of Economic and Business Affairs, U.S. Department of State, (202) 647–3889.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 57 FR 54976, published on November 23, 1992).

Category	Twelve-month limit
Group I	
200–229, 300–326, 360–369, 400–414, 464–469, 600–629 and 665–670, as a group.	212,057,104 square meters equivalent.
Sublevels in Group I	
200	288,725 kilograms.
219	33,488,449 square meters.
218/225/317/326	62,654,035 square meters of which not more than 3,450,739 square meters shall be in Category 218(1)—yarn dyed fabric other than denim and jacquard[1].
226/313	60,071,085 square meters.
314	16,200,451 square meters.
315	8,009,558 square meters.
369(1)[2] (shoptowels)	658,223 kilograms.
604	198,190 kilograms.
611	5,279,905 square meters.
617	3,331,250 square meters.
Group II	
237, 239, 330–359, 431–459, 630–659 and 843/844(1), as a group.	771,903,427 square meters equivalent.
Sublevels in Group II	
237	968,395 dozen.
239	4,439,251 kilograms.
331	3,766,184 dozen pairs.
333/334	259,205 dozen.
335	312,833 dozen.
336	187,035 dozen.
338/339[3] (shirts and blouses other than tank tops and tops, knit).	2,658,990 dozen.
338/339(1)[4] (tank tops and knit tops).	1,997,712 dozen.
340	2,546,264 dozen.
341	2,577,404 dozen.
342	481,971 dozen.
345	394,291 dozen.
347/348	6,086,317 dozen of which not more than 2,995,454 dozen shall be in Category 347; not more than 4,612,442 dozen shall be in Category 348; not more than 6,086,317 dozen shall be in Categories 347–W/348–W[5] of which not more than 4,612,442 dozen shall be in Category 348–W.
350	119,067 dozen.
351	1,088,580 dozen.
352	5,695,971 dozen.
359(1)[6] (coveralls, overalls and jumpsuits).	514,982 kilograms.
359(2)[7] (outer vests)	1,073,329 kilograms.
433	9,090 dozen.
434	9,758 dozen.
435	70,000 dozen.
436	91,170 dozen.
438	748,772 dozen.
442	80,628 dozen.
443	57,523 numbers.
443/444/643/644/843/844(1) (made-to-measure suits).	51,462 numbers.
444	36,508 numbers.
445/446	1,237,621 dozen.
447/448	62,240 dozen.
631	537,473 dozen pairs.
633/634/635	1,162,665 dozen of which not more than 434,862 dozen shall be in Categories 633/634 and not more than 892,796 dozen shall be in Category 635.
636	251,718 dozen.
638/639	4,463,894 dozen.
640	801,977 dozen.
641	771,342 dozen.
642	200,176 dozen.
644	36,455 numbers.
645/646	1,283,443 dozen.
647	447,106 dozen.
648	976,355 dozen of which not more than 976,355 dozen shall be in Category 648–W[8].
649	688,364 dozen.
650	142,351 dozen.
651	272,605 dozen.
652	4,144,252 dozen.
659(1)[9] (coveralls, overalls and jumpsuits).	569,190 kilograms.
659(2)[10] (swimsuits)	227,316 kilograms.
Group III	
831–842, 843/844 (excluding made-to-measure suits), and 847–859, as a group.	43,071,306 square meters equivalent.
Sublevels in Group III	
835	101,129 dozen.
836	138,342 dozen.
840	600,714 dozen.
842	224,421 dozen.
847	322,604 dozen.
Limits not in a group	
845(1)[11] (sweaters made in Hong Kong).	1,100,777 dozen.
845(2)[12] (sweaters assembled in Hong Kong from knit-to-shape component parts knitted elsewhere).	2,634,842 dozen.
846(1)[13] (sweaters made in Hong Kong).	178,006 dozen.
846(2)[14] (sweaters assembled in Hong Kong from knit-to-shape component parts knitted elsewhere).	428,927 dozen.

[1] Category 218(1): The Government of Hong Kong will continue to visa these products as 218.

[2] Category 369(1): only HTS number 6307.10.2005.

[3] Categories 338/339: all HTS numbers except 6109.10.0018, 6109.10.0023, 6109.10.0060, 6109.10.0065, 6114.20.0005 and 6114.20.0010.

[4] Categories 338/339(1): only HTS numbers 6109.10.0018, 6109.10.0023, 6109.10.0060, 6109.10.0065, 6114.20.0005 and 6114.20.0010.

[5] Category 347–W: only HTS numbers 6203.19.1020, 6203.19.4020, 6203.22.3020, 6203.22.3030, 6203.42.4005, 6203.42.4010, 6203.42.4015, 6203.42.4025, 6203.42.4035, 6203.42.4045, 6203.42.4050, 6203.42.4060, 6203.49.3020, 6210.40.2035, 6211.20.1520, 6211.20.3010 and 6211.32.0040; Category 348–W: only HTS numbers 6204.12.0030, 6204.19.3030, 6204.22.3040, 6204.22.3050, 6204.29.4034, 6204.62.3000, 6204.62.4005, 6204.62.4010, 6204.62.4020, 6204.62.4030, 6204.62.4040, 6204.62.4050, 6204.62.4055, 6204.62.4065; 6204.69.3010, 6204.69.9010, 6210.50.2035, 6211.20.1550, 6211.20.6010, 6211.42.0030 and 6217.90.0050.

[6] Category 359(1): only HTS numbers 6103.42.2025, 6103.49.3034, 6104.62.1020, 6104.69.3010, 6114.20.0048, 6114.20.0052, 6203.42.2010, 6203.42.2090, 6204.62.2010, 6211.32.0010, 6211.32.0025 and 6211.42.0010.

[7] Category 359(2): only HTS numbers 6103.19.2030, 6103.19.4030, 6104.12.0040, 6104.19.2040, 6110.20.1022, 6110.20.1024, 6110.20.2030, 6110.20.2035, 6110.90.0044, 6110.90.0046, 6201.92.2010, 6202.92.2020, 6203.19.1030, 6203.19.4030, 6204.12.0040, 6204.19.3040, 6211.32.0070 and 6211.42.0070.

[8] Category 648–W: only HTS numbers 6204.23.0040, 6204.23.0045, 6204.29.2020, 6204.29.2025, 6204.29.4038, 6204.63.2000, 6204.63.3000, 6204.63.3510, 6204.63.3530, 6204.63.3532, 6204.63.3540, 6204.69.2510, 6204.69.2530, 6204.69.2540, 6204.69.2560, 6204.69.3030, 6204.69.9030, 6210.50.1035, 6211.20.1555, 6211.20.6030, 6211.43.0040 and 6217.90.0060.

[9] Category 659(1): only HTS numbers 6103.23.0055, 6103.43.2020, 6103.43.2025, 6103.49.2000, 6103.49.3036, 6104.63.1020, 6104.63.1030, 6104.69.1000, 6104.69.3014, 6114.30.3044, 6114.30.3054, 6203.43.2010, 6203.43.2090, 6203.49.1010, 6203.49.1090, 6204.63.1510, 6204.69.1010, 6210.10.4015, 6211.33.0010, 6211.33.0017 and 6211.43.0010.

[10] Category 659(2): only HTS numbers 6112.31.0010, 6112.31.0020, 6112.41.0010, 6112.41.0020, 6112.41.0030, 6112.41.0040, 6211.11.1010, 6211.11.1020, 6211.12.1010 and 6211.12.1020.

[11] Category 845(1): only HTS numbers 6103.29.2074, 6104.29.2079, 6110.90.0024, 6110.90.0042 and 6117.90.0021.

[12] Category 845(2): only HTS numbers 6103.29.2070, 6104.29.2077, 6110.90.0022 and 6110.90.0040.

[13] Category 846(1): only HTS numbers 6103.29.2068, 6104.29.2075, 6110.90.0020, 6110.90.0038 and 6117.90.0018.

[14] Category 846(2): only HTS numbers 6103.29.2066, 6104.29.2073, 6110.90.0018 and 6110.90.0036.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception of the rulemaking provisions of 5 U.S.C. 553(a)(1).

Donald R. Foote,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 93–162 Filed 1–5–93; 8:45 am]

BILLING CODE 3510–DR–F

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0101]

Clearance Request Regarding Drug-Free Workplace

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for an extension to an existing OMB clearance (9000–0101).

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 35), the Federal Acquisition Regulation (FAR) Secretariat has submitted to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning Drug-Free Workplace.

FOR FURTHER INFORMATION CONTACT: Edward Loeb, Office of Federal Acquisition Policy, GSA (202) 501–4547.

SUPPLEMENTARY INFORMATION:

A. Purpose

Public Law 100–690, the Drug-Free Workplace Act of 1988, mandates that: (1) Government contract employees notify their employer of any criminal drug statute conviction for a violation occurring in the workplace; and (2) Government contractors, after receiving notice of such conviction, must notify the Government contracting officer. These requirements are effective as of March 18, 1989.

The information provided to the Government will be used to determine contractor compliance with the statutory requirements to maintain a drug-free workplace.

B. Annual Reporting Burden

The annual reporting burden is estimated as follows: Respondents, 600; responses per respondent, 1; total annual responses, 600; preparation hours per response, .17; and total response burden hours, 102.

C. Annual Recordkeeping Burden

The annual recordkeeping burden is estimated as follows: Recordkeepers, 600; hours per recordkeeper, .5; and total recordkeeping burden hours, 300.

OBTAINING COPIES OF PROPOSALS: Requester may obtain copies of OMB applications or justifications from the General Services Administration, FAR Secretariat (VRS), room 4037, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB Control No. 9000–0101, Drug-Free Workplace, in all correspondence.

Dated: December 28, 1992.

Beverly Fayson,

FAR Secretariat.

[FR Doc. 93–101 Filed 1–5–93; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0108]

Clearance Request Regarding Bankruptcy

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for an extension to an existing OMB clearance (9000–0108).

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 35), the Federal Acquisition Regulation (FAR) Secretariat has submitted to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning bankruptcy.

FOR FURTHER INFORMATION CONTACT: Edward Loeb, Office of Federal Acquisition Policy, GSA, (202) 501–4547.

SUPPLEMENTARY INFORMATION:

A. Purpose

Under statute, contractors may enter into bankruptcy which may have a significant impact on the contractor's ability to perform its Government contract. The Government often does not receive adequate and timely notice of this event. The subject contract clause requires contractors to notify the contracting officer within five days after the contractor enters into bankruptcy.

B. Annual Reporting Burden

The annual reporting burden is estimated as follows: Respondents, *1,000*; responses per respondent, *1*; total annual responses, *1,000*; preparation hours per response, *1*; and total response burden hours, *1,000*.

C. Annual Recordkeeping Burden

The annual recordkeeping burden is estimated as follows: Recordkeepers, *1,000*; hours per recordkeeper, *.25*; and total recordkeeping burden hours, *250*.

OBTAINING COPIES OF PROPOSALS: Requester may obtain copies of OMB applications or justifications from the General Services Administration, FAR Secretariat (VRS), room 4037, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB Control No. 9000–0108, Bankruptcy, in all correspondence.

Dated: December 28, 1992.

Beverly Fayson,

FAR Secretariat.

[FR Doc. 93–102 Filed 1–5–93; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF ENERGY

Energy Information Administration

Agency Information Collections Under Review by the Office of Management and Budget

AGENCY: Energy Information Administration, DOE.

ACTION: Notice of request submitted for review by the Office of Management and Budget.

SUMMARY: The Energy Information Administration (EIA) has submitted the energy information collection(s) listed at the end of this notice to the Office of Management and Budget (OMB) for review under provisions of the Paperwork Reduction Act (Public Law 96–511, 44 U.S.C. 3501 *et seq.*). The listing does not include collections of information contained in new or revised regulations which are to be submitted under section 3504(h) of the Paperwork Reduction Act, nor management and procurement assistance requirements collected by the Department of Energy (DOE).

Each entry contains the following information: (1) The sponsor of the collection (a DOE component, which term includes the Federal Energy Regulatory Commission); (2) Collection number(s); (3) Current OMB docket number (if applicable); (4) Collection title; (5) Type of request, e.g., new, revision, extension, or reinstatement; (6) Frequency of collection; (7) Response obligation, i.e., mandatory, voluntary, or required to obtain or retain benefit; (8) Affected public (9) An estimate of the number of respondents per report period; (10) An estimate of the number of responses per respondent annually; (11) An estimate of the average hours

per response; (12) The estimated total annual respondent burden; and (13) A brief abstract describing the proposed collection and the respondents.

DATES: Comments must be filed by February 5, 1993. If you anticipate that you will be submitting comments but find it difficult to do so within the time allowed by this notice, you should advise the OMB DOE Desk Officer listed below of your intention to do so, as soon as possible. The Desk Officer may be telephoned at (202) 395–3084. (Also, please notify the EIA contact listed below.)

ADDRESSES: Address comments to the Department of Energy Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, 726 Jackson Place NW., Washington, DC 20503. (Comments should also be addressed to the Office of Statistical Standards at the address below.)

FOR FURTHER INFORMATION AND COPIES OF RELEVANT MATERIALS CONTACT: Jay Casselberry, Office of Statistical Standards (EI–73), Forrestal Building, U.S. Department of Energy, Washington, DC 20585. Mr. Casselberry may be telephoned at (202) 254–5348.

SUPPLEMENTARY INFORMATION: The energy information collection submitted to OMB for review was:

1. Energy Information Administration
2. EIA–1, 3, 3A, 4, 5, 5A, 6, 7A, and 20
3. 1905–0167
4. Coal Program Package
5. Revision
6. Quarterly, Annually, Other (Standby)
7. Mandatory
8. Businesses or other for-profit
9. 6,133 respondents
10. 2.06 responses per respondent
11. 1.53 hours per response
12. 19,390 hours
13. The coal surveys collect data on coal production, consumption, stock prices, imports and exports. Data are published in various EIA publications. Respondents are manufacturing plants, producers of coke, purchasers and distributors of coal, coal mining operators, and coal-consuming electric utilities.

Authority: Sec. 5(a), 5(b), 13(b), and 52, Public Law 93–275, Federal Energy Administration Act of 1974, 15 U.S.C. 764(a), 764(b), 772(b), and 790a.

Issued in Washington DC, December 30, 1992.

Yvonne M. Bishop,

Director, Statistical Standards, Energy Information Administration.

[FR Doc. 93–205 Filed 1–5–93; 8:45 am]

BILLING CODE 6450–01–M

Agency Information Collections Under Review by the Office of Management and Budget

AGENCY: Energy Information Administration.

ACTION: Notice of request submitted for review by the Office of Management and Budget.

SUMMARY: The Energy Information Administration (EIA) has submitted the energy information collection(s) listed at the end of this notice to the Office of Management and Budget (OMB) for review under provisions of the Paperwork Reduction Act (Pub. L. No. 96–511, 44 U.S.C. 3501 *et seq.*). The listing does not include collections of information contained in new or revised regulations which are to be submitted under section 3504(h) of the Paperwork Reduction Act, nor management and procurement assistance requirements collected by the Department of Energy (DOE).

Each entry contains the following information: (1) The sponsor of the collection (a DOE component which term includes the Federal Energy Regulatory Commission (FERC)); (2) Collection number(s); (3) Current OMB docket number (if applicable); (4) Collection title; (5) Type of request, e.g., new, revision, extension, or reinstatement; (6) Frequency of collection; (7) Response obligation, i.e., mandatory, voluntary, or required to obtain or retain benefit; (8) Affected public; (9) An estimate of the number of respondents per report period; (10) An estimate of the number of responses per respondent annually; (11) An estimate of the average hours per response; (12) The estimated total annual respondent burden; and (13) A brief abstract describing the proposed collection and the respondents.

DATES: Comments must be filed by February 5, 1993. If you anticipate that you will be submitting comments but find it difficult to do so within the time allowed by this notice, you should advise the OMB DOE Desk Officer listed below of your intention to do so, as soon as possible. The Desk Officer may be telephoned at (202) 395–3084. (Also, please notify the EIA contact listed below.)

ADDRESSES: Address comments to the Department of Energy Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, 726 Jackson Place NW., Washington, DC 20503. (Comments should also be addressed to the Office of Statistical Standards at the address below.)

FOR FURTHER INFORMATION AND COPIES OF RELEVANT MATERIALS CONTACT: Jay Casselberry, Office of Statistical Standards, (EI–73), Forrestal Building, U.S. Department of Energy, Washington, DC 20585. Mr. Casselberry may be telephoned at (202) 254–5348.

SUPPLEMENTARY INFORMATION: The energy information collection submitted to OMB for review was:

1. Energy Information Administration
2. EIA–800–804, 807, 810–814, 816–818, 819M, 819A, 820, 822A/D, and 825
3. 1905–0165
4. Petroleum Supply Reporting System Surveys
5. Revision
6. On occasion, Weekly, Monthly, Annually, and Triennially
7. Mandatory
8. Businesses or other for-profit
9. 5,350 respondents
10. 10.305 responses per respondent
11. 1.145 hours per response
12. 63,134 hours
13. The Petroleum Supply Reporting System collects information needed for determining the supply and disposition of crude petroleum, petroleum products, and natural gas liquids. These data are published by the EIA. Respondents are producers of oxygenates, operators of petroleum refining facilities, blending plants, bulk terminals, crude oil and product pipelines, natural gas plant facilities, tanker and barge operators, and oil importers.

Authority: Sec. 5(a), 5(b), 13(b), and 52, Public Law 93–275, Federal Energy Administration Act of 1974, 15 U.S.C. 764(a), 764(b), 772(b), and 790a.

Issued in Washington, DC, Dec. 30, 1992.

Yvonne M. Bishop,

Director, Statistical Standards, Energy Information Administration.

[FR Doc. 93–203 Filed 1–5–93; 8:45 am]

BILLING CODE 6450–01–M

Agency Information Collections Under Review by the Office of Management and Budget

AGENCY: Energy Information Administration, DOE.

ACTION: Notice of request submitted for review by the Office of Management and Budget.

SUMMARY: The Energy Information Administration (EIA) has submitted the energy information collection(s) listed at the end of this notice to the Office of Management and Budget (OMB) for review under provisions of the Paperwork Reduction Act (Pub. L. No. 96–511, 44 U.S.C. 3501 *et seq.*). The listing does not include collections of

information contained in new or revised regulations which are to be submitted under section 3504(h) of the Paperwork Reduction Act, nor management and procurement assistance requirements collected by the Department of Energy (DOE).

Each entry contains the following information: (1) The sponsor of the collection (a DOE component, which term includes the Federal Energy Regulatory Commission); (2) Collection number(s); (3) Current OMB docket number (if applicable); (4) Collection title; (5) Type of request, e.g., new, revision, extension, or reinstatement; (6) Frequency of collection; (7) Response obligation, i.e., mandatory, voluntary, or required to obtain or retain benefit; (8) Affected public; (9) An estimate of the number of respondents per report period; (10) An estimate of the number of responses per respondent annually; (11) An estimate of the average hours per response; (12) The estimated total annual respondent burden; and (13) A brief abstract describing the proposed collection and the respondents.

DATES: Comments must be filed by February 5, 1993. If you anticipate that you will be submitting comments but find it difficult to do so within the time allowed by this notice, you should advise the OMB DOE Desk Officer listed below of your intention to do so, as soon as possible. The Desk Officer may be telephoned at (202) 395-3084. (Also, please notify the EIA contact listed below.)

ADDRESSES: Address comments to the Department of Energy Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, 726 Jackson Place NW., Washington, DC 20503. (Comments should also be addressed to the Office of Statistical Standards at the address below.

FOR FURTHER INFORMATION AND COPIES OF RELEVANT MATERIALS CONTACT: Jay Casselberry, Office of Statistical Standards, (EI-73), Forrestal Building, U.S. Department of Energy, Washington, DC 20585. Mr. Casselberry may be telephoned at (202) 254-5348.

SUPPLEMENTARY INFORMATION: The energy information collection submitted to OMB for review was:

1. Federal Energy Regulatory Commission
2. FERC-520
3. 1902-0083
4. Application for Authority to Hold Interlocking Directorate Position
5. Extension
6. On occasion
7. Mandatory
8. Businesses or other
9. 25 respondents
10. 1 response per respondent
11. 51.8 hours per response
12. 1,296 hours
13. The Federal Power Act requires each person that desires to hold public utility interlocking directorate positions to submit an application to the FERC for authority to do so. The supporting information describes the interlocking positions the applicant seeks to hold, the applicant's financial interest, other officers and nature of the business relationships among the firms.

Authority: Sec. 5(a), 5(b), 13(b), and 52, Public Law 93-275, Federal Energy Administration Act of 1974, 15 U.S.C. 764(a), 764(b), 772(b), and 790a.

Issued in Washington, DC., December 30, 1992.

Yvonne M. Bishop,

Director, Statistical Standards, Energy Information Administration.

[FR Doc. 93-204 Filed 1-5-93; 8:45 am]

BILLING CODE 6450-01-M

Federal Energy Regulatory Commission

[Docket Nos. EC93-6-000, et al.]

Cincinnati Gas & Electric Co. and PSI Energy, Inc., et al.; Electric Rate, Small Power Production, and Interlocking Directorate Filings

Take notice that the following filings have been made with the Commission:

1. Cincinnati Gas & Electric Co. and PSI Energy, Inc.

[Docket No. EC93-6-000]

December 28, 1992.

Take notice that on December 23, 1992, Cincinnati Gas & Electric Co. ("CG&E"), on behalf of itself (and its subsidiaries, Union Light, Heat and Power Co. and Miami Power Corp.) and PSI Energy, Inc. (together, "Applicants") filed, pursuant to section 203 of the Federal Power Act and Part 33 of the Commission's regulations, a Joint Application requesting authorization to merge and reorganize Applicants' utility operations and to dispose of Applicants' jurisdictional facilities.

Pursuant to an Agreement and Plan to Reorganization, PSI Resources Inc., PSI Energy and CG&E will merge into a new corporation, CINergy, and PSI Energy and CG&E will operate as separate utility divisions of CINergy. The subsidiaries of CG&E and PSI Resources (excluding PSI Energy, but including PSI Energy's subsidiaries) will become subsidiaries of CINergy. The merger will be effected through an exchange of stock, with PSI Resources and CG&E shareholders exchanging their shares for shares in CINergy.

Applicants have submitted the direct testimony of eleven witnesses who provide, *inter alia*, a description of the merger and the projected benefits for ratepayers and shareholders and an analysis of the effects of the merger on competition in the relevant markets. Applicants also have submitted a *pro forma* open access transmission tariff for Applicants' integrated system, which provides a range of services for a single rate.

Applicants have requested that the Commission expedite consideration of the Joint Application and approve it without an evidentiary hearing.

Comment date: January 27, 1993, in accordance with Standard Paragraph E at the end of this notice.

2. Northern States Power Co.

[Docket No. ER92-551-001]

December 30, 1992.

Take notice that on November 23, 1992, Northern States Power Company tendered for filing its compliance filing in response to a Commission letter order dated October 23, 1992.

Comment date: January 8, 1993, in accordance with Standard Paragraph E at the end of this notice.

3. Ogden Martin Systems of San Bernardino, Inc.

[Docket No. ER93-281-000]

December 30, 1992.

Take notice that on December 15, 1992, Odgen Martin Systems of San Bernardino, Inc. (Ogden-San Bernardino) tendered for filing a Notice of Termination of Rate Schedule FERC No. 1 of Ogden Martin Systems of San Bernardino, Inc. with the Federal Energy Regulatory Commission (FERC or the Commission).

On September 23, 1987, the Commission accepted for filing an electric power purchase agreement between Ogden-San Bernardino and Southern California Edison Company for the sale of capacity and energy from a proposed 42.5 MW solid waste, biomass-fueled small power production facility (the Facility) and designated the agreement as Rate Schedule FERC No. 1. Due to the decision of San Bernardino County, California, to not proceed with the construction of the Facility, Ogden-San Bernardino will not sell capacity and energy to Southern California Edison Company pursuant to Rate Schedule FERC No. 1 and, accordingly, seeks to terminate Rate Schedule FERC No.1.

Comment date: January 13, 1993, in accordance with Standard Paragraph E at the end of this notice.

4. Entergy Power, Inc.

[Docket Nos. ER92-611-000; ER92-664-000; ER92-843-000 and ER93-45-000]

December 30, 1992.

Take notice that on December 17, 1992, Entergy Power, Inc. submitted an amendment to its rate schedule filings originally submitted in the above dockets on June 3, 1992, June 26, 1992, August 14, 1992, September 18, 1992, and October 27, 1992.

The amendment responds to a deficiency letter from the Director of the Division of Applications dated November 17, 1992 and issued in the above referenced proceedings.

Comment date: January 13, 1993, in accordance with Standard Paragraph E at the end of this notice.

5. Gulf States Utilities Co.

[Docket No. ER93-292-000]

December 30, 1992.

Take notice that, pursuant to section 205 of the Federal Power Act and part 35 of the Commission's regulations, Gulf States Utilities Company (Gulf States), on December 22, 1992, tendered for filing rate schedule changes with respect to Gulf States' provision of wholesale and transmission service to Sam Rayburn Dam Electric Cooperative, Inc. (SRDE) and Sam Rayburn Municipal Power Agency (SRMA), and an initial Power Interconnection Agreement between Gulf States and the Vinton Public Power Authority (VPPA). Gulf States states that its filing amends the Power Interconnection Agreement and the Power Supply Agreement among Gulf States, SRDE, and SRMA to account for the sale of SRMA's interest in the jointly-owned Nelson 6 generating station to VPPA.

Gulf States requests a waiver of the prior notice requirements of the Federal Power Act and the Commission's regulations to allow an effective date for its filings of December 18, 1992.

Copies of the filing were served upon SRDE, SRMA, VPPA, the Public Utility Commission of Texas, and the Louisiana Public Service Commission.

Comment date: January 13, 1993, in accordance with Standard Paragraph E at the end of this notice.

6. Florida Power Corp.

[Docket No. ER93-299-000]

December 30, 1992.

Take notice that Florida Power Corporation (Florida Power), on December 24, 1992, tendered for filing a wholesale rate change in its full requirements, partial requirements and transmission rates. The amount of the rate change, either an increase or a decrease, depends on the rates to which the current ones are compared. If compared to the presently effective rates, the filed rates accomplish a rate decrease in the amount of $8.2 million or 5.6% on a 1993 calendar-year basis. If the rates filed herein are compared to the rates negotiated in settlement of Florida Power's last filing, (Consolidated Docket Nos. ER92-436-000 and EL92-29-000), an increase of $8.4 million per year or 6.8% on a 1993 calendar-year basis results.

Florida Power requests that the rate change be permitted to become effective on February 22, 1993, and that it be made effective without suspension if the compliance rates are in effect or be suspended for the minimum one-day period if the settlement rates are in effect. Florida Power states that it has served copies of its filing on the affected customers and the Florida Public Service Commission.

Comment date: January 13, 1993, in accordance with Standard Paragraph E at the end of this notice.

7. Public Service Company of New Mexico

[Docket No. ER93-300-000]

December 30, 1992.

Take notice that on December 28, 1992, Public Service Company of New Mexico (PNM) tendered for filing a Notice of Termination of the Interconnection Agreement (PNM Rate Schedule FPC No. 8 and supplements thereto) between PNM and The Western Colorado Power Company (WCP), as subsequently assigned to WCP's successor, Colorado-Ute Electric Association (CUEA) and since CUEA's bankruptcy to Public Service Company of Colorado (PSCo) and Tri-State Generation and Transmission Association, Inc. (Tri-State).

PNM requests that the Commission's notice requirements be waived to permit the Interconnection Agreement to be terminated effective upon the contract termination date of November 13, 1992.

Copies of the filing have been served upon PSCo, Tri-State and the New Mexico Public Service Commission.

Comment date: January 13, 1993, in accordance with Standard Paragraph E at the end of this notice.

8. Idaho Power Co.

[Docket No. ER93-89-000]

December 30, 1992.

Take notice that on December 22, 1992, Idaho Power Company (IPC) tendered for filing an amendment to its filing of its Agreement for the Sale and Purchase of Firm Energy dated August 31, 1992 with Oregon Trail Electric Consumers Cooperative, Inc.

IPC has requested waiver of the notice provisions § 35.3 of the Commission's regulations in order to permit the Agreement to become effective on January 1, 1993, as requested in the original filing of this Agreement.

Comment date: January 13, 1993, in accordance with Standard Paragraph E at the end of this notice.

9. G. Alex Bernhardt

[Docket No. ID-2541-001]

December 30, 1992.

Take notice that on December 24, 1992, G. Alex Bernhardt (Applicant) tendered for filing a supplemental application under section 305(b) of the Federal Power Act to hold the following positions:

Director Duke Power Company
Director First Union Corporation

Comment date: January 13, 1993, in accordance with Standard Paragraph E at the end of this notice.

10. Entergy Power Development Corp.

[Docket No. EG93-9-000]

December 30, 1992.

Take notice that on December 23, 1992, Entergy Power Development Corporation (Entergy Development) filed an application under section 32 of the Public Utility Holding Company Act of 1935, as amended by section 711 of the Energy Policy Act of 1992, seeking a determination by the Commission that Entergy Development is an exempt wholesale generator. Entergy Development owns an interest in a 250 MW electric generating facility located in Richmond, Virginia.

Comment date: January 19, 1993, in accordance with Standard Paragraph E at the end of this notice.

11. Long Island Lighting Co.

[Docket No. ER93-298-000]

December 30, 1992.

Take notice that on December 24, 1992, Long Island Lighting Company (LILCO) tendered for filing an Agreement between LILCO and the Suffolk County Electrical Agency (SCEA) dated November 12, 1992, for the delivery of certain New York Power Authority power and energy to eligible customers within LILCO's service territory in Suffolk County, New York, together with a supplement thereto which consists of a Letter Agreement between LILCO and the New York Power Authority (NYPA) dated October 29, 1992. LILCO has requested a waiver

so that this filing can become effective on January 1, 1993.

Notice is further given that upon acceptance for filing or approval of the instant filing, LILCO–FERC Rate Schedule No. 42, including Supplement Nos. 1 and 2, and those portions of LILCO–FERC Rate Schedule No. 40 that govern delivery of NYPA economic development power to SCEA's economic development customers are hereby cancelled.

LILCO states that this filing has been served upon the New York State Public Service Commission, NYPA, and SCEA.

Comment date: January 13, 1993, in accordance with Standard Paragraph E at the end of this notice.

12. Richmond Power Enterprise, L.P.

[Docket No. EG93–7–000]

December 30, 1992.

Take notice that on December 23, 1992, Richmond Power Enterprise, L.P. (Richmond Power) filed an application under Section 32 of the Public Utility Holding Company Act of 1935, as amended by section 711 of the Energy Policy Act of 1992, seeking a determination by the Commission that Richmond Power is an exempt wholesale generator. Richmond Power owns and operates a 250 MW electric generating facility located in Richmond, Virginia.

Comment date: January 19, 1993, in accordance with Standard Paragraph E at the end of this notice.

13. Entergy Richmond Power Corp.

[Docket No. EG93–8–000]

December 30, 1992.

Take notice that on December 23, 1992, Entergy Richmond Power Corporation (Entergy Richmond) filed an application under section 32 of the Public Utility Holding Company Act of 1935, as amended by section 711 of the Energy Policy Act of 1992, seeking a determination by the Commission that Entergy Richmond is an exempt wholesale generator. Entergy Richmond owns an interest in a 250 MW electric generating facility located in Richmond, Virginia.

Comment date: January 19, 1993, in accordance with Standard Paragraph E at the end of this notice.

14. Northeast Utilities Service Co.

[Docket No. ER93–297–000]

December 30, 1992.

Take notice that on December 23, 1992, Northeast Utilities Service Company (NUSCO) on behalf of The Connecticut Light and Power Company (CL&P), Western Massachusetts Electric Company (WMECO), and Public Service Company of New Hampshire (PSNH) tendered for filing a Capacity, Transmission and Energy Service Agreement between CL&P and Green Mountain Power Corporation (GMP), a Bulk Power Service Agreement between CL&P and Bozrah Light and Power Company and a Firm Transmission Service Agreement Between CL&P, WMECO, and PSNH and GMP.

NUSCO requests that the Commission waive its standard notice periods and filing regulations to the extent necessary to permit the rate schedule change to become effective as early as January 1, 1993, but no later than February 1, 1993.

NUSCO states that copies of this rate schedule have been mailed or delivered to each of the parties.

NUSCO further states that the filing is in accordance with section 35 of the Commission's regulations.

Comment date: January 13, 1993, in accordance with Standard Paragraph E at the end of this notice.

15. Green Mountain Power Corp.

[Docket No. ER93–296–000]

December 30, 1992.

Take notice that on December 23, 1992, Green Mountain Power Corporation (GMP) tendered for filing a Notice of Cancellation of Power Sales Agreement between GMP and Bozrah Light and Power Company (Bozrah) (GMP Rate Schedule FERC No. 104).

GMP states that the Notice of Cancellation is part of a comprehensive arrangement under which Bozrah will discontinue the purchase of its bulk power requirements from GMP and commence the purchase of its bulk power requirements from The Connecticut Light and Power Company. GMP has requested the Commission to waive any applicable requirements in order to make each of the agreements included in this arrangement effective on January 1, 1993.

Comment date: January 13, 1993, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–230 Filed 1–5–93; 8:45 am]

BILLING CODE 6717–01–M

[Beaver City Canyon, Plant No. 2 Project, FERC No. 1858–002]

Beaver City Corp.; Availability of Environmental Assessment

December 30, 1992.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission's) regulations, 18 CFR part 380 (Order No. 486, 52 FR 47897), the Office of Hydropower Licensing together with the USDA Forest Service (FS) have reviewed the application for new minor license for the existing Beaver City Canyon Plant No. 2 Hydroelectric Project, located on the Beaver River, in Beaver County, near Beaver, Utah, and have prepared a joint environmental assessment (EA) for the relicense proposal. In the EA, the FS and the Commission staff analyze the potential environmental impacts of the project and conclude that approval of the project, with appropriate environmental measures, would not constitute a major federal action significantly affecting the quality of the human environment.

Copies of the EA are available for review in the Public Reference Branch, room 3104, of the Commission's offices at 941 North Capitol Street, NW., Washington, DC 20426.

Lois D. Cashell,

Secretary.

[FR Doc. 93–217 Filed 1–5–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket Nos. CP93–108–000, et al.]

Texas Eastern Transmission Corp., et al.; Natural Gas Certificate Filings

Take notice that the following filings have been made with the Commission:

1. Texas Eastern Transmission Corporation

[Docket No. CP93–108–000]

December 28, 1992.

Take notice that on December 14, 1992, Texas Eastern Transmission Corporation (Texas Eastern), 5400 Westheimer Court, Houston, Texas 77056–5310 filed in Docket No. CP93–

108–000 an application pursuant to section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing it to provide a new incremental firm transportation service pursuant to Rate Schedule FTS–11 and to construct and operate the associated incremental facilities required to perform the proposed transportation service, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Texas Eastern requests authorization to construct, install, own and operate the following facilities required to provide the proposed transportation service:

(a) 3.0 miles of 30-inch diameter pipeline in Warren County, Ohio;

(b) 1.4 miles of 36-inch diameter pipeline in Monroe County, Ohio;

(c) 0.96 mile of 36-inch diameter pipeline loop in Greene County, Pennsylvania;

(d) Replace approximately 1.07 miles of 24-inch diameter pipeline with 36-inch diameter pipeline at the Uniontown Compressor Station discharge in Somerset County, Pennsylvania;

(e) Replace approximately 1.00 mile of 24-inch diameter pipeline with 36-inch diameter pipeline at the Bedford Compressor Station discharge in Fulton County, Pennsylvania; and

(f) Replace approximately 1.21 miles of 20-inch diameter pipeline with 36-inch diameter pipeline at the discharge of Eagle Compressor Station in Bucks County, Pennsylvania.

Texas Eastern indicates that the proposed facilities would be used to render firm incremental transportation service for Staten Island Cogeneration Corporation (Staten Island) from the existing point of interconnection between Texas Eastern and ANR Pipeline Company (ANR) near Lebanon, Ohio to an existing point of interconnection between the facilities of Texas Eastern and the Brooklyn Union Gas Company (BUG) at Goethals Bridge, New York. Texas Eastern proposes to transport and make delivery of up to 11,600 Dth equivalent of natural gas per day to Staten Island.

Texas Eastern states that the estimated total capital cost of the proposed facilities is $14,598,000. Texas Eastern indicates that the proposed facilities will be financed initially by Texas Eastern with funds on hand, borrowing under Texas Eastern's revolving credit arrangements or short-term financing.

Comment date: January 19, 1993, in accordance with Standard Paragraph F at the end of this notice.

2. Arkla Energy Resources a division of Arkla, Inc.

[Docket No. CP93–128–000]

December 29, 1992.

Take notice that on December 22, 1992, Arkla Energy Resources, a division of Arkla, Inc., (AER), P.O. Box 21734, Shreveport, Louisiana 71151, filed in Docket No. CP93–128–000 a request pursuant to §§ 157.205, 157.211 and 157.212 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.211, 157.212) for authorization to construct and operate certain facilities under AER's blanket certificate issued in Docket No. CP82–384–000, *et al.*, pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

AER proposes to:

(1) Construct and operate two new sales taps and related facilities in Coal County, Oklahoma, for delivery of natural gas to Arkansas Louisiana Gas Company (ALG) for resale to two domestic customers, Stephen J. Burge, and Frank Whitt. It is projected that each customer would use approximately 1 Mcf on a peak day and 85 Mcf annually. AER states that each of the tap facilities would cost approximately $1,389.

(2) Operate an existing 1-inch tap on AER's Line OT–23 in Sebastian County, Arkansas, for delivery of natural gas for resale to ALG's domestic customer, Thomas Goodin, who is projected to use 1 Mcf on a peak day and 85 Mcf annually. AER states that this customer would manifold onto an existing tap installed for right-of-way grantor Terrell Jones in 1974.

AER states that the facilities would be financed with internally generated capital.

Comment date: February 12, 1993, in accordance with Standard Paragraph G at the end of this notice.

3. Northern Natural Gas Company

[Docket No. CP93–88–000]

December 29, 1992.

Take notice that on December 3, 1992, Northern Natural Gas Company (Northern), 1111 South 103rd Street, Omaha, Nebraska 68124–1000, filed in Docket No. CP93–88–000 an application pursuant to section 7(b) of the Natural Gas Act for permission and approval to abandon six individually certificated transportation and exchange agreements between Northern and EL Paso Natural Gas Company (EL Paso), all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Specifically, Northern proposes to abandon its Rate Schedules T–1, T–3, T–25, X–21, X–58 and X–68 contained in its FERC Gas Tariff, Original Volume No. 2. Northern indicates that proper notice was given by Northern and El Paso for the termination of the service under these agreements are no longer required and the abandonment requested will not impact the remaining service of Northern of EL Paso. Finally, Northern states that EL Paso has received authorization from the Commission to abandon the certificates issued to EL Paso for two of these agreements and is filing in a separate application to abandon its certificates issued for the remaining four agreements.

Comment date: January 19, 1993, in accordance with Standard Paragraph F at the end of this notice.

4. Panhandle Eastern Pipe Line Co.

[Docket No. CP93–110–000]

December 30, 1992.

Take notice that on December 14, 1992, Panhandle Eastern Pipe Line Company (Panhandle), P.O. Box 1642, Houston, Texas 77251–1642, filed in Docket No. CP93–110–000 a request under Section 7(b) of the Commission's Regulations under the Natural Gas Act for a certificate permitting and approving abandonment of sales service provided to the City of Hazelton, Kansas (Hazelton), an existing jurisdictional customer under Panhandle's Rate Schedule SSS–3, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

Panhandle states that it is requesting authorization to abandon firm sales service provided to Hazelton under Rate Schedule SSS–3, effective January 1, 1993, as a result of Hazelton's election to terminate its firm sales service with Panhandle effective January 1, 1993. Panhandle states that Hazelton will convert to firm transportation service provided under Panhandle's Rate Schedule SCT effective January 1, 1993. No facilities are proposed to be abandoned herein.

Comment date: January 21, 1993, in accordance with Standard Paragraph F at the end of this notice.

5. Panhandle Eastern Pipe Line Co.

[Docket No. CP93–115–000]

December 30, 1992.

Take notice that on December 17, 1992, panhandle Eastern Pipe Line Company (Panhandle), P.O. Box 1642, Houston, Texas 77251–1642, filed in Docket No. CP93–115–000 a request under section 7(b) of the Commission's

Regulations under the Natural Gas Act for a certificate permitting and approving abandonment of sales services provided to Associated Natural Gas Company (Associated), under Panhandle's Rate Schedules SSS–2 to be effective January 1, 1993, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

Panhandle states it is requesting authorization to abandon firm sales service provided to Associated under Rate Schedule SSS–2, effective January 1, 1993, as a result of Associated's election to terminate its firm sales service with Panhandle effective January 1, 1993. Panhandles states that Associated will convert to firm transportation service provided under Panhandle's Rate Schedule SCT effective January 1, 1993. No facilities are proposed to be abandoned herein.

Comment date: January 21, 1993, in accordance with Standard Paragraph F at the end of this notice.

6. Panhandle Eastern Pipe Line Co.

[Docket No. CP93–112–000]

December 30, 1992.

Take notice that on December 15, 1992, Panhandle Eastern Pipe Line Company (Panhandle), P.O. Box 1642, Houston, Texas 77251–1642, filed in Docket No. CP93–112–000 a request under section 7(b) of the Commission's Regulations under the Natural Gas Act for a certificate permitting and approving abandonment of transportation and sales services provided to Kansas-Nebraska Natural Gas Company (KN), under Panhandle's Rate Schedules T–41, T–61, and TT–1 to be effective October 31, 1992, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

Panhandle states that by letters dated October 19, 1992, Panhandle and KN have mutually agreed to terminate Rate Schedules TT–1, T–41 and T–61 effective October 31, 1992. Panhandle further states that the existing interconnections with KN will continue to be available for open access transportation service. No facilities are proposed to be abandoned herein.

Comment date: January 21, 1993, in accordance with Standard Paragraph F at the end of this notice.

7. United Gas Pipe Line Co.

[Docket No. CP93–131–000]

December 30, 1992.

Take notice that on December 2, 1992, United Gas Pipe Line Company (United), P.O. Box 1478, Houston, Texas 77251–1478, filed a request with the Commission in Docket No. CP93–131–000 pursuant to § 157.205 of the Commission's Regulations under the Natural Gas Act (NGA) for authorization of facilities previously constructed under section 311(a) of the Natural Gas Policy Act (NGPA) and § 284.3(c) of the Commission's regulations, under United's blanket certificate issued in Docket No. CP88–6–000, all as more fully set forth in the request which is open to public inspection.

United states that the proposed facilities will enable United to provide transportation services under its blanket transportation certificate through all of its facilities to all current and potential shippers. United also states that it has sufficient capacity to provide the proposed service without detriment to its other existing customers.

Comment date: February 16, 1993, in accordance with Standard Paragraph G at the end of this notice.

Standard Paragraphs

F. Any person desiring to be heard or make any protest with reference to said file with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this filing if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for the applicant to appear or be represented at the hearing.

G. Any person or the Commission's staff may, within 45 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 93–229 Filed 1–5–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket Nos. TA93–1–20–000 and TM93–8–20–000]

Algonquin Gas Transmission Co.; Notice of Proposed Changes in FERC Gas Tariff

December 30, 1992.

Take notice that Algonquin Gas Transmission Company ("Algonquin") on December 23, 1992, tendered for filing proposed changes in its FERC Gas Tariff, Third Revised Volume No. 1, as set forth in the revised tariff sheets:

Proposed to be effective February 1, 1993

6 Rev Sheet No. 63

Proposed to be effective March 1, 1993

2 Rev 16 Rev Sheet No. 21
2 Rev 16 Rev Sheet No. 22
2 Rev 16 Rev Sheet No. 25
2 Rev 16 Rev Sheet No. 26
2 Rev 16 Rev Sheet No. 27
2 Rev 16 Rev Sheet No. 28
2 Rev 16 Rev Sheet No. 29

Algonquin states that the revised tariff Sheet Nos. 21 through 29, listed above, are being filed as part of Algonquin's regularly scheduled Annual Purchased Gas Adjustment ("PGA") and Transportation Cost Adjustment ("TCA") to reflect the standby service costs to be charged by Texas Eastern Transmission Corporation ("Texas Eastern"), Transportation and Compression by Others' Costs ("T&C Costs") from Texas Eastern and Transcontinental Gas Pipe Line Corporation and purchased gas costs to be charged by its various suppliers.

Algonquin states that the effect of the change in rates in the listed sheets is to

decrease the demand charges by $0.4400 per MMBtu and to decrease the commodity charges by $0.4373 per MMBtu under all of Algonquin's firm sales rate schedules from those rates contained in Algonquin's last quarterly PGA and TCA filing, made October 29, 1992 in Docket Nos. TQ93-2-20-001 and TM93-5-20-000 and revised December 9, 1992 per Commission Letter Order of November 24, 1992.

Algonquin states that the proposed effective date for the listed tariff sheets is March 1, 1993 with the exception of 6 Rev Sheet No. 63.

Algonquin further states that it is filing Sheet No. 63 to concurrently track the change made by Texas Eastern in the underlying rates. Pursuant to section 4.2(c) of Rate Schedule ATAP, the proposed effective date of Sheet No. 63 is February 1, 1993 to coincide with the effective date of Texas Eastern's filing. The effect of the revision in rates in Rate Schedule ATAP is to decrease the demand rate by $0.7600 per MMBtu and decrease the maximum commodity rates by $0.0241 per MMBtu.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with sections 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before January 15, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 93-221 Filed 1-5-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP93-53-000]

Carnegie Natural Gas Co.; Petition for Temporary Waiver of Regulations and Tariff, and for Expedited Action

December 30, 1992.

Take notice that on December 23, 1992, Carnegie Natural Gas Company (Carnegie) filed a petition for waiver of § 154.305(i) (1) (iii) of the Commission's regulations and Section 23.9 of the General Terms and Conditions of Carnegie's FERC Gas Tariff to permit Carnegie to retain the balance in the refund subaccount of its Account No. 191 until such time as the Account No. 191 settlement proposal filed in Carnegie's restructuring proceeding in Docket No. RS92-30-000 becomes subject to a final Commission order.

Carnegie requests that the Commission grant temporary waiver of the requirement that it disburse to its customers within 90 days, or before January 30, 1993, the demand portion of the refund received by Carnegie from Texas Eastern Transmission Corporation (Texas Eastern) on October 30, 1992. Carnegie states that waiver is requested only for the limited period pending the outcome of the issues in Docket No. RS92-30-000 concerning the treatment upon restructuring of Carnegie's remaining unrecovered gas costs.

Carnegie states that copies of the filing have been served upon all affected customers of Carnegie and interested state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with 18 CFR 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before January 7, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Lois D. Cashell,

Secretary.

[FR Doc. 93-216 Filed 1-5-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TM93-8-4-000]

Granite State Gas Transmission, Inc.; Notice of Proposed Changes in Rates

December 30, 1992.

Take notice that on December 28, 1992, Granite State Gas Transmission, Inc. (Granite State), 300 Friberg Parkway, Westborough, Massachusetts 01581 filed Sixth Revised Sheet No. 24 in its FERC Gas Tariff, Second Revised Volume No. 1, proposing changes in rates for effectiveness on January 28, 1993.

According to Granite State, its filing is submitted to passthrough to its customers the take-or-pay buydown and buyout costs directly billed to Granite State by Tennessee Gas Pipeline Company (Tennessee).

Granite State states that, on December 1, 1992, Tennessee filed revised tariff sheets to recover additional transition costs in Docket Nos. RP93-37-000 and TM93-2-9-000. According to Granite State, its tariff sheet reflects the changes in Tennessee's allocation of take-or-pay costs to Granite State and also complies with the requirements of the reallocation of costs to small customers pursuant to Order No. 528-A.

According to Granite State the proposed rate changes are applicable to its jurisdictional sales services rendered to Bay State Gas Company and Northern Utilities, Inc. and to a sale to a direct customer, Pease Air Force Base. Granite State further states that copies of its filing were served upon its customers and the regulatory commissions of the States of Maine, New Hampshire and Massachusetts.

Any person desiring to be heard or to make any protest with reference to said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426 in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before January 7, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party to the proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93-218 Filed 1-5-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TM93-7-4-000]

Granite State Gas Transmission, Inc.; Notice of Proposed Changes in Rates

December 30, 1992.

Take notice that on December 28, 1992, Granite State Gas Transmission, Inc. (Granite State) 300 Friberg Parkway, Westborough, Massachusetts 01581 tendered for filing the revised tariff sheets listed below in its FERC Gas Tariff, Second Revised Volume No. 1,

containing changes in rates for effectiveness on December 1, 1992:

Eighteenth Revised Sheet No. 25
Second Revised Sheet No. 66

According to Granite State, it provides storage services for Bay State Gas Company and Northern Utilities, Inc., under its Rate Schedule S–1 with storage capacity provided in a facility operated by Penn-York Energy Corporation (Penn-York) pursuant to Penn-York's Rate Schedule SS–1.

Granite State further states that Penn-York filed proposed changes in its rates for storage service under Rate Schedule SS–1 in Docket No. RP92–161–000 which were suspended until December 1, 1992. According to Granite State, Penn-York moved its suspended rate changes into effect on December 1, 1992.

Granite State states that its filing tracks in its Rate Schedule S–1 the revised rates made effective on December 1, 1992 by the motion filed by Penn-York in Docket No. RP92–161–000.

Granite State states that copies of its filing were served on its storage service customers, Bay State Gas Company and Northern Utilities, Inc. and also on the regulatory commissions of the states of Maine, Massachusetts and New Hampshire.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with sections 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before January 7, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–222 Filed 1–5–93; 8:45 am]

BILLING CODE 6717–01–M

[Project No. 1855–006]

New England Power Co.; Notice Dismissing Complaint

December 29, 1992.

New England Power Company is the licensee for the Bellows Falls Project No. 1855, located on the Connecticut River in Cheshire and Sullivan Counties, New Hampshire, and in Windham and Windsor Counties, Vermont.[1] Horace A. and Betty B. Bezanson, and their daughter Marcia S. Calloway (collectively, the Bezansons), own property within the project boundary over which New England Power has flowage rights.[2] On December 28, 1989, the Bezansons filed a complaint [3] alleging that New England Power [4] intended to convey certain property rights with respect to land within the project boundary and adjacent to the Bezansons' to facilitate the construction of a wood chip storage and transfer facility adjacent to the Bezanson's property. The wood chip facility was to be developed by Woodland Fiber, Inc. on land owned by Cersosimo Lumber Company over which New England Power has flowage rights.

On October 7, 1992, the Director, Division of Project Compliance and Administration (Director), sent a status request letter to the parties. The letter noted that during its preliminary investigation of the complaint the Commission staff had received informal indications that Woodland Fiber, Inc. may no longer be planning to construct the contemplated wood chip storage and transfer facility, such that the complaint may be moot. The letter asked the parties to advise the Commission of the current status of the matter, including any recommendations the parties might have with respect to future proceedings on the complaint.

Both parties responded to the Director's letter.[5] Marcia Calloway, on behalf of the Bezansons, responded first, indicating that she is "not privy to the plans" of either Woodland Fiber, Inc. or Cersosimo Lumber Company, and is "therefore unable to tell you the exact status of their intention * * *." Her letter refers to a recent application by Cersosimo for an access right-of-way permit, from which "complainants can only assume that the Woodland Fiber project is still viable." Accordingly, "complainants request the Commission to consider this matter as open and continue the proceeding pending definite withdrawal of the Woodland Fiber, Inc. wood chip storage and transfer facility project."

New England Power contends, in its response to the Director, that the complaint has been rendered moot and should therefore be dismissed. New England Power's response includes a letter to New England Power [6] from Ramsey, McLaren, the firm that had been retained by Woodland Fiber, Inc. to secure the permits and approvals necessary for the construction of the wood chip facility. That letter describes the current status of the proposed wood chip facility as follows:

3. In May 1991 the property owner advised Woodland Fiber that no further land lease extensions would be granted and that the purchase option had to be exercised if Woodland Fiber wanted to continue with its permit and approval process. Woodland Fiber did not exercise the purchase option.

4. The state Land Use Permit application was terminated at that time and the local site plan and zoning approvals subsequently expired due to an absence of activity within the statutory time period.

5. To the best of our knowledge, Woodland Fiber has no intention of resuming any activities necessary for the establishment of a wood fiber storage and transfer facility at this site and we have therefore closed the file. [Emphasis in original.]

New England sent a copy of its response to Marcia Calloway. No response to New England Power's letter was filed.

Based on the above-described correspondence in the record, there appears to be no present plans to construct and operate the proposed wood chip storage and transfer facility. Inasmuch as the complaint was predicated on the development of that facility, the complaint does not present a current controversy. Therefore, the complaint is dismissed, but without prejudice to refiling in the event that the proposal to construct the wood chip facility is revived.

This notice constitutes final agency action. Requests for rehearing by the Commission may be filed within 30

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[1] 8 FERC ¶61,122 (1979).

[2] The Bellows Falls Project includes a 2,804-acre reservoir that extends approximately 26 miles upstream from the project's dam. The project boundary includes land along the shoreline that New England Power needs for the operation and maintenance of the project. New England Power has title in fee to only a small portion of this land, and has flowage easements over the rest.

[3] Notice of the complaint was published in the Federal Register (55 *FR* 19979, May 14, 1990).

[4] The complaint was filed against New England Power Service Company, an affiliate of New England Power Company, which is the licensee. New England Power filed an answer on June 13, 1990.

[5] See letter from Marcia S. Calloway, dated October 14 and filed October 19, 1992, and letter from Mark E. Slade, attorney for New England Power, dated November 6 and filed November 9, 1992, both addressed to the Commission's Secretary.

[6] See letter from Hal J. Wilkins to Mark Slade, dated November 4, 1992.

days of the issuance of this notice, pursuant to 18 CFR 385.713.

Lois D. Cashell,

Secretary.

[FR Doc. 93-109 Filed 1-5-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP93-52-000]

Northern Natural Gas Co.; Notice of Proposed Changes in FERC Gas Tariff

December 30, 1992.

Take notice that Northern Natural Gas Company (Northern) on December 23, 1992, tendered for filing to become part of Northern's FERC Gas Tariff, the following tariff sheets, proposed to become effective January 1, 1993:

Fourth Revised Volume No. 1

Third Revised Sheet No. 56
Third Revised Sheet No. 57
Third Revised Sheet No. 58
Substitute Third Revised Sheet No. 56
Substitute Third Revised Sheet No. 57
Substitute Third Revised Sheet No. 58

Original Volume No. 2

One Hundred Twenty-Third Revised Sheet No. 1C
Substitute 123 Revised Sheet No. 1C

Northern states that the filing of the revised tariff sheets reflects notice to Northern's customers of the potential shifting of costs from the IGIC to the PGA. The Northern Distributor Group has challenged the inclusion of certain Pre-July 1991 costs in the IGIC and alleged that those costs should be more appropriately recovered through the PGA. Pursuant to this filing, Northern's Reconciliation Adjustment would increase $.057 to $.118. Northern states that it would defer collection of the $.057 increase pending resolution of the Northern Distributor Group's protest of Northern's IGIC Reconciliation Report filed April 30, 1992. Northern requests, at a minimum, that the Commission find the filing constitutes sufficient legal notice to the customers that if the Pre-July 1991 IGIC costs are to be recovered in the PGA, then the Reconciliation Adjustment will be modified accordingly.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 214 and 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.214 and 385.211). All such petitions or protests must be filed on or before January 7, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93-220 Filed 1-5-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP93-51-000]

Northwest Pipeline Corp.; Petition for Limited Waiver of Tariff Provisions

December 30, 1992.

Take notice that on December 21, 1992, Northwest Pipeline Corporation (Northwest) petitions the Commission for a limited waiver of the Commission's first-come, first-served policy as reflected in Section 1 of Northwest's TF-1 Rate Schedule and in the Priority Date provisions of section 12 of First Revised Volume 1-A of Northwest's FERC approved tariff, in order to allow the permanent assignment of firm transportation capacity presently held by Kern River Gas Supply Corporation (KRGS) to KRGS' producer-suppliers who have entered into "buy/sell" agreements with KRGS.

Northwest seeks waiver of the Commission's first-come, first-served policy in order to implement replacement firm transportation agreements with Petro-Canada, Salmon, CHMI, and WRI, who will each succeed to a portion of KRGS' interests under the Transportation Agreement pursuant to proposed assignments.

Northwest states that by providing firm transportation service directly to Salmon, Petro-Canada, CHMI, and WRI instead of indirectly through KRGS, simply eliminates KRGS as an unnecessary conduit in these suppliers securing transportation services on the Northwest system.

Northwest requests that the Commission grant any necessary waivers of the Commission's first-come, first-served policy and Northwest's applicable tariff provisions to permit KRGS' permanent assignment of its firm capacity on Northwest to Salmon, Petro-Canada, CHMI, and WRI.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with 18 CFR 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before January 7, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Lois D. Cashell,

Secretary.

[FR Doc. 93-215 Filed 1-5-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP89-137-010]

Northwest Pipeline Corp.; Notice of Compliance Filing

December 30, 1992.

Take notice that on December 8, 1992, Northwest Pipeline Corporation (Northwest) made a filing to comply with Ordering Paragraph (B) of Federal Energy Regulatory Commission order issued September 24, 1992, in the above docket. Northwest provided justification of Order No. 500/528 recovery of a certain amount associated with transportation discounts included in five of Northwest's take-or-pay buyout/buydown settlements.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before January 7, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93-219 Filed 1-5-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP92-120-000]

Panhandle Eastern Pipe Line Co.; Informal Settlement Conference

December 30, 1992.

Take notice that an informal settlement conference will be convened in this proceeding on Wednesday, January 13, 1993, at 10 a.m. The conference will be held at the offices of the Federal Energy Regulatory Commission, 810 First Street, NE.,

Washington, DC, for the purpose of exploring the possible settlement of all issues raised in the above-referenced docket.

Any party, as defined in 18 CFR 385.102(c) or any participant, as defined in 18 CFR 385.102(b) is invited to attend. Persons wishing to become a party must move to intervene and receive intervenor status pursuant to the Commission's regulations, 18 CFR 385.214.

For additional information, contact Carmen Gastilo at (202) 208-2182 or Joanne Leveque at (202) 208-5705.

Lois D. Cashell,

Secretary.

[FR Doc. 93-214 Filed 1-5-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP93-23-001]

Transcontinental Gas Pipe Line Corp.; Notice of Proposed Change in FERC Gas Tariff

December 30, 1992.

Take notice that Transcontinental Gas Pipe Line Corporation (TGPL) on December 21, 1992, tendered for filing a certain tariff sheets to Third Revised Volume No. 1 of its FERC Gas Tariff (Tariff). The proposed effective date of the revised tariff sheets is December 13, 1992.

On November 12, 1992, TGPL filed Third Revised Sheet No. 62 to the Tariff to permit TGPL to discount its Commodity Producer Settlement Payment (PSP) charge for quantities of gas received and redelivered by TGPL in its Rate Zones 1, 2 or 3 under its Rate Schedules IT and FT. By order issued on December 11, 1992 in the referenced proceeding (Order), the Commission accepted and suspended effective December 13, 1992 Third Revised Sheet No. 62 subject to refund and subject to modifications and conditions.

Specifically, the Order required TGPL to file tariff sheets including language permitting TGPL to discount all of its take-or-pay commodity surcharges, including those for transportation in Zones 4, 5 and 6, in a non-discriminatory manner. The Order further required TGPL's filing to include the appropriate rate sheets reflecting maximum and minimum rates for all of TGPL's take-or-pay surcharges not already filed. TGPL states that the purpose of the instant filing is to comply with the Order.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before January 7, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93-223 Filed 1-5-93; 8:45 am]

BILLING CODE 6717-01-M

Office of Fossil Energy

[FE Docket No. 92-159-NG]

CanWest Gas Supply U.S.A., Inc.; Order Granting Blanket Authorization To Import and Export Natural Gas From and to Canada

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of order.

SUMMARY: The Office of Fossil Energy of the Department of Energy gives notice that it has issued an order granting CanWest Gas Supply U.S.A., Inc. blanket authorization to import and/or export a cumulative maximum of 400 Bcf of natural gas from and to Canada over a two-year term beginning on the date of the first import or export after February 28, 1993.

A copy of this order is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F-056, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586-9478. The docket room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, December 29, 1992.

Charles F. Vacek,

Deputy Assistant Secretary for Fuels Programs, Office of Fossil Energy.

[FR Doc. 93-202 Filed 1-5-93; 8:45 am]

BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY

[FRL-4552-7]

Agency Information Collection Activities Under OMB Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected cost and burden.

DATES: Comments must be submitted on or before February 5, 1993. For further information, or to obtain a copy of this ICR, contact Sandy Farmer at EPA (202) 206-2740.

SUPPLEMENTARY INFORMATION:

Office of Pesticides and Toxic Substances

Title: Section 12(b) Notification of Chemical Exports (EPA ICR No.: 0795.07; OMB No.: 2070-0030). This is a reinstatement of a previously approved collection.

Abstract: Under section 12(b)(2) of the Toxic Substances Control Act (TSCA), those who export or intend to export federally regulated chemical substances (or mixtures) must notify the EPA Administrator annually of the export or intent to export. EPA will then notify the government of the importing country of the Agency's action concerning the regulated chemical. Respondents submit to EPA one annual notice per chemical, or list of chemicals, for each country to which they are intending to export. A notice consists of: the name and the address of the exporter, the name (or list) of the chemical(s) to be exported, the country of import, the date of export, and the citation of the TSCA section (4, 5, 6, or 7) requiring the chemicals to be reviewed for export.

Burden Statement: The estimated public reporting burden for this collection of information is 38 hours per respondent annually. On average a respondent will prepare 74 export notices each requiring 0.5 hour. This estimate includes the time to read the instructions, gather existing information, prepare the chemical lists and submit the annual notice.

Respondents: Exporters of TSCA 12(b) chemicals.

Estimated No. of Respondents: 162.

Estimated No. of Responses per Respondent: 74.

Estimated Total Annual Burden on Respondents: 6,162 hours.

Frequency of Collection: Annually and on occasion.

Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden to: Sandy Farmer, U.S. Environmental Protection Agency, Information Policy

Branch (PM 223Y), 401 M Street, SW, Washington, DC 20460.

and

Matthew Mitchell, Office of Management and Budget, Office of Information and Regulatory Affairs, 725 17th Street, NW., Washington, DC 20503.

Dated: December 30, 1992.

Paul Lapsley,

Director, Regulatory Management Division.

[FR Doc. 93-197 Filed 1-5-93; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Requirements Submitted to Office of Management and Budget for Review

December 28, 1992.

The Federal Communications Commission has submitted the following information collection requirements to OMB for review and clearance under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507).

Copies of these submissions may be purchased from the Commission's copy contractor, Downtown Copy Center, 1990 M Street, NW., suite 640, Washington, DC 20036, (202) 452-1422. For further information on these submissions contact Judy Boley, Federal Communications Commission, (202) 632-7513. Persons wishing to comment on these information collections should contact Jonas Neihardt, Office of Management and Budget, room 3235 NEOB, Washington, DC 20503, (202) 395-4814.

OMB Number: 3060-0054.

Title: Application for Exemption From Ship Station Requirements

Form Number: FCC Form 820

Action: Revision of a currently approved collection

Respondents: Individuals or households and business or other for-profit (including small businesses)

Frequency of Response: On occasion reporting

Estimated Annual Burden: 200 responses; 1.166 hours average burden per response; 233 hours total annual burden

Needs and Uses: Applicants are required to complete FCC Form 820 to apply for exemption from radio provisions of statute, treaty, or international agreement. The forms is being revised to remove data elements that are no longer necessary and to re-word and reformat questions to simplify completion of the form.

OMB Number: 3060-0184.

Title: Section 73.1740, Minimum Operating Schedule

Action: Extension of a currently approved collection

Respondents: Businesses or other for-profit (including small businesses)

Frequency of Response: On occasion reporting

Estimated Annual Burden: 330 responses; 0.5 hours average burden per response; 165 hours total annual burden

Needs and Uses: Section 73.1740 requires licensees of commercial broadcast stations to notify the FCC in Washington, DC when events beyond their control make it impossible to continue operation or to adhere to the required operating schedules set forth in this section. In addition, the FCC must be notified when normal operation is resumed. No further authority is needed for limited operation or discontinued operation for a period not exceeding 30 days. Should events beyond the licensees control make it impossible for compliance within the required 30-day time period, an informal written request shall be submitted to the FCC requesting the amount of additional time that the licensee deems necessary. The data are used by FCC staff to authorized temporarily a limited operation or a discontinuance of operation.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 93-103 Filed 1-5-93; 8:45 am]

BILLING CODE 6712-01-M

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA-966-DR]

Florida; Amendment to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Florida (FEMA-966-DR), dated October 8, 1992, and related determinations.

EFFECTIVE DATE: November 23, 1992.

FOR FURTHER INFORMATION CONTACT: Pauline C. Campbell, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-3606.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this disaster is closed effective October 4, 1992.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

Grant C. Peterson,

Associate Director, State and Local Programs and Support.

[FR Doc. 93-185 Filed 1-5-93; 8:45 am]

BILLING CODE 6718-02-M

[FEMA-975-DR]

Massachusetts; Amendment to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Massachusetts (FEMA-975-DR), dated December 21, 1992, and related determinations.

EFFECTIVE DATE: December 23, 1992.

FOR FURTHER INFORMATION CONTACT: Pauline C. Campbell, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-3606.

SUPPLEMENTARY INFORMATION: The notice of a major disaster for the State of Massachusetts, dated December 21, 1992, is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of December 21, 1992:

The counties of Duke, Nantucket, Norfolk, and Worcester for Public Assistance.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

Grant C. Peterson,

Associate Director, State and Local Programs and Support.

[FR Doc. 93-184 Filed 1-5-93; 8:45 am]

BILLING CODE 6718-02-M

[FEMA-973-DR]

New Jersey; Amendment to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of New Jersey (FEMA-973-DR), dated December 18, 1992, and related determinations.

EFFECTIVE DATE: December 22, 1992.

FOR FURTHER INFORMATION CONTACT: Pauline C. Campbell, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-3606.

SUPPLEMENTARY INFORMATION: The notice of a major disaster for the State of New Jersey, dated December 18, 1992, is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of December 18, 1992:

The counties of Essex, Hudson, Middlesex, Somerset, and Union for Individual Assistance and Public Assistance.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

Grant C. Peterson,

Associate Director, State and Local Programs and Support.

[FR Doc. 93-186 Filed 1-5-93; 8:45 am]

BILLING CODE 6718-02-M

[FEMA-973-DR]

New Jersey; Amendment to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of New Jersey (FEMA-973-DR), dated December 18, 1992, and related determinations.

EFFECTIVE DATE: December 18, 1992.

FOR FURTHER INFORMATION CONTACT: Pauline C. Campbell, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-3606.

SUPPLEMENTARY INFORMATION: The notice of a major disaster for the State of New Jersey, dated December 18, 1992, is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of December 18, 1992:

The counties of Bergen, Cape May, and Cumberland for Individual Assistance and Public Assistance.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

Grant C. Peterson,

Associate Director, State and Local Programs and Support.

[FR Doc. 93-187 Filed 1-5-93; 8:45 am]

BILLING CODE 6718-02-M

[FEMA-974-DR]

New York; Amendment to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of New York (FEMA-974-DR), dated December 21, 1992, and related determinations.

EFFECTIVE DATE: December 21, 1992.

FOR FURTHER INFORMATION CONTACT: Pauline C. Campbell, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-3606.

SUPPLEMENTARY INFORMATION: The notice of a major disaster for the State of New York, dated December 21, 1992, is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of December 21, 1992:

The counties of Rockland and Westchester for Individual Assistance and Public Assistance.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

Grant C. Peterson,

Associate Director, State and Local Programs and Support.

[FR Doc. 93-183 Filed 1-5-93; 8:45 am]

BILLING CODE 6718-02-M

FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

Appraisal Subcommittee; Interim Order Granting Commonwealth of the Northern Mariana Islands Emergency Temporary Waiver Relief and Request for Comments

[Docket No. AS92-5]

AGENCY: Appraisal Subcommittee, Federal Financial Institutions Examination Council.

ACTION: Interim order granting Commonwealth of the Northern Mariana Islands ("CNMI") emergency temporary waiver relief from State appraiser certification and licensure requirements and request for comments.

SUMMARY: The Appraisal Subcommittee ("ASC") of the Federal Financial Institutions Examination Council ("FFIEC"), with the FFIEC's approval, is issuing an interim Order granting CNMI emergency temporary waiver relief under section 1119(b)[1] of title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 ("FIRREA"), as amended.[2] This interim relief will run from January 1, 1993, until the effective date of the ASC's final Order on this matter. The ASC also is soliciting comments from interested members of the public regarding CNMI's temporary waiver request.

DATES: Effective date of interim Order is January 1, 1993. Written comments on this Notice must be submitted on or before the close of business on February 5, 1993.

ADDRESSES: Copies of the request for temporary waiver relief and supporting documentation are available for public inspection at: Appraisal Subcommittee, 2100 Pennsylvania Avenue, NW., suite 200, Washington, DC 20037. Written comments may be mailed to the Appraisal Subcommittee at this location, and those comments also will be made available for public inspection.

FOR FURTHER INFORMATION CONTACT: Edwin W. Baker, Executive Director, or Marc L. Weinberg, General Counsel, at (202) 634-6520, Appraisal Subcommittee, 2100 Pennsylvania Avenue, NW., suite 200, Washington, DC 20037.

SUPPLEMENTARY INFORMATION:

I. Background

After December 31, 1992, all federally regulated financial institutions must use State licensed or certified appraisers, as appropriate, in federally related transactions.[3] Thus, each State should have in place at that time its entire regulatory scheme for certifying, licensing and supervising real estate appraisers.

Section 1119(b) of title XI provides the ASC and the States with a degree of flexibility in dealing with extraordinary circumstances that may occur at any time at December 31st. This Section enables the ASC to waive, on a temporary basis and with the FFIEC's approval,[4] any State certification or licensing requirement on a written finding that: (1) "There is a scarcity of certified or licensed appraisers to perform appraisals in connection with federally related transactions"; and (2) that the scarcity is "leading to significant delays in the performance of such appraisals." Either a State in compliance with title XI or the ASC can make a written "scarcity/delay" finding. A State, however, cannot grant or deny a waiver under section 1119(b); that authority belongs only to the ASC.

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[1] 12 U.S.C. 3348(b).

[2] Public Law 101-73, 103 Stat. 183 (1989), as amended by Public Law 102-233, 105 Stat. 1761, 1792 (1991), Public Law 102-242, 105 Stat. 2330, 2386 (1991), Public Law 102-550, 106 Stat. 3672 (1992), and Public Law 102-485, 106 Stat. 2771 (1992).

[3] See Section 1119(a) of title XI, 12 U.S.C. 3348(a).

[4] On December 30, 1992, the Chairman of the FFIEC has approved this action pursuant to authority delegated by the Council.

Congress intended that the ASC exercise this waiver authority "cautiously."[5] Temporary waivers terminate when the ASC "determines that such * * * delays have been eliminated."

In April 1992, the ASC adopted rules governing the handling of temporary waiver requests.[6] In order for a waiver request to be received by the ASC for processing, ASC Rule 1102.2 requires a State appraiser regulatory agency to include in its request:

(a) * * * a written, duly authorized determination by the * * * Agency that there is a scarcity of State licensed or State certified appraisers leading to significant delays in obtaining appraisals in federally related transactions;

(b) The requirement or requirements of State law from which relief is being sought;

(c) A description of all significant problems currently being encountered in efforts to comply with title XI;

(d) The nature of the scarcity of certified or licensed appraisers (including supporting documentation);

(e) The extent of the delays anticipated or experienced in obtaining the services of certified or licensed appraisers (including supporting documentation);

(f) The reasons why the requester believes that the requirement or requirements are causing the scarcity of certified or licensed appraisers and the service delays; and

(g) A specific plan for expeditiously alleviating the scarcity and the service delays.

Rule 1102.4 requires the ASC to publish a notice promptly in the **Federal Register** respecting the received request which must "contain a concise general statement of the nature and basis for the action and (must) give interested persons 30 calendar days from its publication in which to submit written data, views and arguments." The ASC then, under Rule 1102.5, must "either grant or deny a waiver in whole, in part, and upon specified terms and conditions" within "45 calendar days of the date of publication of the notice * * * in the **Federal Register**." The ASC retains significant flexibility in the case of an emergency. If the ASC determines that an emergency exists, "the ASC may issue an interim approval Order simultaneously with its action" publishing the Rule 1102.4 notice in the **Federal Register**.

II. CNMI's Request

On December 21, 1992, the ASC received a letter dated December 16, 1992, from Lorenzo I. De Leon Guerrero, the Governor of CNMI. The letter requested a one-year waiver, i.e., from January 1 through December 31, 1993, from the requirement to use certified or licensed real estate appraisers within CNMI. CNMI stated that, while it has made "substantial, documented progress," it continues "to encounter significant problems in [its] efforts to comply with Title XI" and has "a serious shortage of [certified or licensed] appraisers."

More specifically, CNMI stated that only four appraisers in CNMI "theoretically qualify for appraisal work" and that, "[d]espite good faith efforts * * *, we still can't qualify the people we have available. In practice, we have only one person who might be able to meet Title XI requirements. This person must complete required courses." However, no appraisal education providers are situated on CNMI, and the closest educational provider is on the island of Guam, 120 miles south by air. CNMI concluded that "[e]ducation is our dilemma. It relates directly to our present scarcity of appraisers."

CNMI further represented that this scarcity of appraisers causes "inordinate delays in connection with federally related transactions. Six retail banks operate in CNMI.* * * Many people seek federally guaranteed home loans. Business loan applications are brisk. We have significant appraiser business and presently no local qualified appraisers to serve it." CNMI concedes that appraisers who are licensed or certified in Guam are willing to come to CNMI to perform appraisals. The use of such appraisers, however, "means delay" and "significant and burdensome costs to loan applicants."

CNMI noted that it has a specific plan for resolving the scarcity and delays. A one-year waiver will "allow our local appraisers time to finish the required appraisal courses. At least one of our local appraisers has started the course work, presently only available on Guam." CNMI also is "working on getting the qualified Guam instructors to come to the CNMI to teach appraisal courses." In sum, CNMI promised to "work hard to make the plan a success."

III. Finding of an Emergency Under Rule 1102.5

On the basis of the foregoing representations of CNMI's Governor, the ASC finds that an emergency exists in CNMI. Absent emergency interim relief, CNMI's appraisers who have not been licensed or certified would be unable to perform appraisals in connection with federally related transactions for federally regulated lenders during the period of January 1, 1993, until the time that the ASC makes a final determination respecting CNMI's temporary waiver request under Rule 1102.5. Those lenders would be forced to fly into CNMI State certified or licensed appraisers from elsewhere, *e.g.*, Guam, Hawaii or the United States mainland. In the worst case, such appraisers would not be available and real estate loans in federally related transactions could not be made in compliance with federal law. And, in the best case, significant delays and additional costs would likely result.

IV. Order

On the basis of the foregoing and with the concurrence of the FFIEC, the ASC finds that an emergency exists in CNMI under section 1119(b) of title XI and 12 CFR part 1102, subpart A, thereunder, and orders temporary interim waiver relief under those provisions for CNMI for the period beginning on January 1, 1993, through the date on which the ASC will make a final determination respecting CNMI's temporary waiver request, not to exceed February 22, 1993. Thus, during the time that this Order is effective within CNMI, the federally regulated lenders specified in section 1120 of Title XI[7] may use appraisers who are not licensed or certified so long as appraisals are performed in a manner that is consistent with the appraisal regulations, requirements, guidelines and standards of the appropriate federal financial institution regulatory agency.[8] By the Appraisal Subcommittee of the Federal Financial Institutions Examination Council.

Dated: December 30, 1992.

Fred D. Finke,

Chairman.

[FR Doc. 93–182 Filed 1–5–93; 8:45 am]

BILLING CODE 6210–01–M

[5] House Comm. on Banking, Finance and Urban Affairs, Report Together With Additional, Supplemental, Minority, Individual, and Dissenting Views, Financial Institutions Reform, Recovery, and Enforcement Act of 1989, H.R. Rep. No. 101–54 Part 1, 101st Cong., 1st Sess., at 482–83.

[6] 12 CFR part 1102, subpart A (57 FR 10979 (April 1, 1992)).

[7] 12 U.S.C. 3349.

[8] These agencies are the Board of Governors of the Federal Reserve System ("FRS"), the Federal Deposit Insurance Corporation ("FDIC"), the Office of the Comptroller of the Currency ("OCC"), the Office of Thrift Supervision ("OTS"), and the National Credit Union Administration ("NCUA"). *See* section 1122(6) of title XI, 12 U.S.C. 3350(6). Their appraisal regulations can be found at 12 CFR: part 225, subpart G (FRS); part 323 (FDIC); part 34 (OCC); part 564 (OTS); and part 722 (NCUA).

FEDERAL RESERVE SYSTEM

Barnett Merger Corp., et al.; Acquisitions of Companies Engaged in Permissible Nonbanking Activities

The organizations listed in this notice have applied under § 225.23(a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23(a)(2) or (f)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated for the application or the offices of the Board of Governors not later than January 26, 1993.

A. Federal Reserve Bank of Atlanta (Zane R. Kelley, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. Barnett Merger Corp., Jacksonville, Florida; to acquire Barnett Banks Trust Company, N.A., Jacksonville, Florida, and thereby engage in trust company functions pursuant to § 225.25(b)(3) of the Board's Regulation Y.

2. Main Street Banks Incorporated, Covington, Georgia; to acquire First Federal Savings Bank of Georgia, and thereby engage in operating a savings association pursuant to § 225.25(b)(9) of the Board's Regulation Y.

B. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. Union Planters Corporation, Memphis, Tennessee; to acquire First Federal Savings Bank of Maryville, Maryville, Tennessee, and thereby engage in operating a savings association pursuant to § 225.25(b)(9); and in the sale of credit life, accident, and health insurance as principal, agent, or broker, directly related to the extensions of credit by First Federal and limited to assuring the repayment of the outstanding balance due on the extension of credit in the event of the death, disability, or involuntary unemployment of the debt pursuant to § 225.25(b)(8)(i) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, December 30, 1992.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93-164 Filed 1-5-93; 8:45 am]

BILLING CODE 6210-01-F

Robert H. and Norma J. Garwood, et al.; Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than January 20, 1993.

A. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. Robert H. and Norma J. Garwood, Miami, Oklahoma; to acquire 100 percent of the voting shares of Nine Tribes Bancshares, Inc., Quapaw, Oklahoma, and thereby indirectly acquire The Bank of Quapaw, Quapaw, Oklahoma.

2. Dr. James M. Plate, Kimball, Nebraska; to acquire an additional 26.49 percent of the voting shares of Banner County Ban Corporation, Harrisburg, Nebraska, for a total of 36.42 percent and thereby indirectly acquire Banner County Bank, Harrisburg, Nebraska.

3. Donald L. Sturm, Omaha, Nebraska; to acquire up to 100 percent of the voting shares of Bank of Laramie, Laramie, Wyoming.

Board of Governors of the Federal Reserve System, December 30, 1992.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93-165 Filed 1-5-93; 8:45 am]

BILLING CODE 6210-01-F

Merchants New York Bancorp, Inc., et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than January 26, 1993.

A. Federal Reserve Bank of New York (William L. Rutledge, Vice President) 33 Liberty Street, New York, New York 10045:

1. Merchants New York Bancorp, Inc., New York, New York; to become a bank holding company by acquiring 100 percent of the voting shares of The Merchants Bank of New York, New York.

B. Federal Reserve Bank of Atlanta (Zane R. Kelley, Vice President) 104

Marietta Street, N.W., Atlanta, Georgia 30303:

1. F & M Bancorporation, Birmingham, Alabama; to become a bank holding company by acquiring 100 percent of the voting shares of The Farmers & Merchants Bank, Centre, Alabama.

C. Federal Reserve Bank of Chicago (David S. Epstein, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. Minowa Bancshares, Inc., Decorah, Iowa; to acquire 100 percent of the voting shares of Minnesota Bank, National Association, Caledonia, Minnesota.

D. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. Citizens Financial Corporation and Citizens Financial Corporation Employee Stock Ownership Plan, Belzoni, Mississippi; to acquire 100 percent of the voting shares of Flora Financial Corporation, Flora, Mississippi, and thereby indirectly acquire Bank of Flora, Flora, Mississippi.

2. West Tennessee Financial Corporation, Selmer, Tennessee; to become a bank holding company by acquiring 100 percent of the voting shares of Community Bank of West Tennessee, Selmer, Tennessee, through the conversion of the existing savings association, First Federal Savings Bank of West Tennessee, Selmer, Tennessee.

E. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 400 South Akard Street, Dallas, Texas 75222:

1. LNB Financial Corporation, Austin, Texas; to become a bank holding company by acquiring 100 percent of the voting shares of LNB Financial-Delaware, Inc., Wilmington, Delaware, and thereby indirectly acquire Liberty National Bank, Austin, Texas. In connection with this application, LNB Financial-Delaware, Inc., Wilmington, Delaware, has applied to become a bank holding company by acquiring 100 percent of the voting shares of Liberty National Bank, Austin, Texas.

F. Federal Reserve Bank of San Francisco (Kenneth R. Binning, Director, Bank Holding Company) 101 Market Street, San Francisco, California 94105:

1. American Marine Bank Employee Stock Ownership Plan, Bainbridge Island, Washington; to become a bank holding company by acquiring 48.58 percent of the voting shares of American Marine Bank, Winslow, Washington.

Board of Governors of the Federal Reserve System, December 30, 1992.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93-166 Filed 1-5-93; 8:45 am]

BILLING CODE 6210-01-F

U.S. Trust Corporation, et al.; Notice of Applications to Engage de novo in Permissible Nonbanking Activities

The companies listed in this notice have filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 20, 1993.

A. Federal Reserve Bank of New York (William L. Rutledge, Vice President) 33 Liberty Street, New York, New York 10045:

1. U.S. Trust Corporation, New York, New York; to engage *de novo* through its subsidiary, U.S. Trust Company of Connecticut, Stamford, Connecticut, in trust company activities, including activities of a fiduciary, investment advisory, agency and custodial nature pursuant to §§ 225.25(b)(3) and (b)(4) of the Board's Regulation Y.

B. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 400 South Akard Street, Dallas, Texas 75222:

1. Victoria Bankshares, Inc., Victoria, Texas; to engage *de novo* through its subsidiary, Victoria Securities Corporation, Victoria, Texas, in full service brokerage activities and advisory services pursuant to §§ 225.25(b)(4) and (b)(15) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, December 30, 1992.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93-167 Filed 1-5-93; 8:45 am]

BILLING CODE 6210-01-F

FEDERAL TRADE COMMISSION

[Dkt 9254]

Alliant Techsystems Inc.; Proposed Consent Agreement With Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent agreement, accepted subject to final Commission approval, would require, among other things, a Minnesota-based defense systems contractor that provides ammunition, for a 10-year period, to obtain Commission approval before: acquiring the assets or stock of any company engaged in systems contracting for certain tank or lightweight ammunition; or selling or transferring Alliant's stock or assets to a company engaged in systems contracting for certain types of ammunition. In addition, the respondent would be required to terminate its proposed acquisition of Olin.

DATES: Comments must be received on or before March 8, 1993.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, room 159, 6th St. and Pa. Ave., NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Laura Wilkinson, FTC/S-2308, Washington, DC 20580. (202) 326-2830.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C.

46 and § 3.25(f) of the Commission's Rules of Practice (16 CFR 3.25(f)), notice is hereby given that the following consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with § 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii)).

Agreement Containing Consent Order

In the matter of Alliant Techsystems Inc., a corporation.

The agreement herein, by and between Alliant Techsystems Inc. ("Alliant"), a corporation, by its duly authorized officer and its attorney, and counsel for the Federal Trade Commission ("the Commission"), is entered into in accordance with the Commission's Rule governing consent order procedures. In accordance therewith the parties hereby agree that:

1. Alliant is a corporation organized, existing and doing business under the laws of the State of Delaware, with its office and principal place of business located at 5901 Lincoln Drive, Edina, Minnesota 55436.

2. Alliant has been served with a copy of the complaint issued by the Federal Trade Commission charging it with violations of section 7 of the Clayton Act, as amended, and section 5 of the Federal Trade Commission Act, as amended. Alliant denies said charges.

3. Alliant admits all the jurisdictional facts set forth in the Commission's complaint in this proceeding.

4. Alliant waives:

a. Any further procedural steps;

b. The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law;

c. All rights to seek judicial review or otherwise challenge or contest the validity of the Order entered pursuant to this agreement; and,

d. All rights under the Equal Access to Justice Act.

5. This agreement shall not become part of the public record unless and until it is accepted by the Commission. If this agreement is accepted by the Commission, it will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify Alliant, in which event it will take such action as it may consider appropriate, or issue and serve its decision, in disposition of the proceeding.

6. This agreement is for settlement purposes only and does not constitute an admission by Alliant that the law has been violated as alleged in the complaint issued by the Commission.

7. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of § 3.25(f) of the Commission's Rules, the Commission may, without further notice to Alliant, 1) issue its decision containing the following Order in disposition of the proceeding, and 2) make information public with respect thereto. When so entered, this Order shall have the same force and effect, and may be altered, modified or set aside in the same manner and within the same time provided by statute for other orders. This Order shall become final upon service. Delivery by the U.S. Postal Service of the decision containing the agreed to Order to Alliant's address as stated in this agreement shall constitute service. Alliant waives any right it may have to any other manner of service. The complaint may be used in construing the terms of this Order, and no agreement, understanding, representation or interpretation not contained in the Order or this agreement may be used to vary or contradict the terms of the Order.

8. Alliant has read the complaint and Order contemplated hereby. Alliant understands that it may be liable for civil penalties in the amount provided by law for each violation of the Order after it becomes final.

Order

I.

For purposes of this Order, the following definitions shall apply:

"Alliant" means Alliant Techsystems Inc., as well as its directors, officers, employees, representatives, agents, parents, divisions, subsidiaries, successors, and assigns, as well as the directors, officers, employees and agents of its parents, divisions and subsidiaries, successors, and assigns.

"Olin" means Olin Corporation, as well as its directors, officers, employees, representatives, agents, parents, divisions, subsidiaries, successors, and assigns, as well as the directors, officers, employees and agents of its parents, divisions and subsidiaries, successors, and assigns.

"Systems contractor for 30mm lightweight ammunition or 120mm tank ammunition" means any company that supplies or has supplied completed rounds of 30mm lightweight ammunition or completed rounds of 120mm tank ammunition to any customer in the United States, including but not limited to the United States Army, or that is developing completed rounds of 30mm lightweight ammunition or completed rounds of 120mm tank ammunition for any customer in the United States, including but not limited to the United States Army.

II.

It is ordered That, for a period commencing on the date this Order becomes final and continuing for ten (10) years, Alliant shall not, without the prior approval of the Commission, directly or indirectly, through subsidiaries or otherwise, acquire: (1) Any interest in the whole or any part of the stock, share capital, or equity of any systems contractor for 33mm lightweight ammunition or 120mm tank ammunition; or (2) any assets of a systems contractor for 30mm lightweight ammunition or 120mm tank ammunition. *Provided,* however, that this Paragraph II shall not apply to the acquisition of products or services in the ordinary course of business.

III.

It is further ordered That, for a period commencing on the date this Order becomes final and continuing for ten (10) years, Alliant shall not, without the prior approval of the Commission, directly or indirectly, through subsidiaries or otherwise, sell or otherwise transfer to any systems contractor for 30mm lightweight ammunition or 120mm tank ammunition: (1) Any interest in or any part of the stock, share capital, or equity of Alliant, or (2) any assets used for or previously used for (and still suitable for use for) systems contracting of 30mm lightweight ammunition or 120mm tank ammunition. *Provided,* however, that this Paragraph III shall not apply to the sale of products or services in the ordinary course of business.

IV.

It is further ordered That, for a period commencing on the date this Order becomes final and continuing for ten (10) years, Alliant shall notify the Commission at least thirty (30) days prior to any proposed change in the corporation that may affect compliance obligations arising out of the Order, such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or

dissolution of any subsidiary engaged as systems contractor for 30mm lightweight ammunition or 120mm tank ammunition, or any other change that may affect compliance obligations arising out of the Order.

V.

It is further ordered That, unless Alliant has already done so, it will, not later than fourteen (14) days after this Order becomes final: (1) Terminate any agreement that provides for or contemplates the acquisition of, or exchange of stock for, Olin's Ordnance Division and/or its Physics International Subsidiary, including but not limited to the transaction agreement signed on or about August 4, 1992; (2) return or destroy all documents containing or recording confidential information provided to Alliant by Olin in connection with acquisition negotiations or agreements; and (3) recover from Olin or have Olin destroy all documents containing or recording confidential information provided by Olin by Alliant in connection with acquisition negotiations or agreements. Nothing herein contained shall relieve Alliant from any obligation of confidentiality imposed by agreement among Alliant and Olin.

VI.

It is further ordered That Alliant shall, within sixty (60) days after the date this Order becomes final, file with the Commission a report, in writing, setting forth in detail the manner and form in which it has complied with this Order. Within one year after the Order becomes final, and annually for the next nine years. Alliant shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, or has complied with the Order.

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission ("Commission") has accepted provisionally an agreement containing a proposed consent order from Alliant Techsystems Inc. ("Alliant"), concerning Alliant's proposed acquisition of Olin Corporation's ("Olin") Ordnance Division and Physics International Company. Olin is Alliant's only competitor in systems contracting for 120mm tank ammunition and 30 mm lightweight ammunition in the United States. The proposed order requires Alliant to seek prior approval for certain mergers or acquisitions for a period of ten (10) years.

The proposed consent order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

On or about August 4, 1992, Alliant and Olin signed a definitive agreement under which Olin would exchange its Ordnance Division and Physics International subsidiary for approximately 2.82 million shares of newly issued Alliant common stock plus Alliant's assumption of $65 million of Olin debt. On November 6, 1992, the Federal Trade Commission filed a preliminary injunction action against Alliant in the United States District Court for the District of Columbia to enjoin the proposed acquisition. The Commission won a preliminary injunction on November 18, 1992; the district court's supplemental opinion supporting the injunction was issued on November 23, 1992. The court found that the merger would preclude the Army from conducting a competitive bid for an upcoming multiyear contract, and that the anticompetitive effects of the merger were not counterbalanced by competing efficiency and other considerations alleged by defendants. *FTC* v. *Alliant Techsystems Inc.*, Civ. Action No. 92-2499-LFO, Supplemental Memorandum at 6-7, 21-22, 25-28 (November 23, 1992).

On December 7, 1992, the Commission issued an administrative complaint against Alliant which alleges that Alliant's proposed acquisition of Olin violates section 5 of the Federal Trade Commission Act, 15 U.S.C. 45, as amended, and that, if consummated, such acquisition would violate section 7 of the Clayton Act, 15 U.S.C. 18, as amended, and section 5 of the Federal Trade Commission Act, 15 U.S.C. 45, as amended. The complaint alleges that both Alliant and Olin are competitors in systems contracting for 120mm tank ammunition and 30mm lightweight ammunition in the United States. The complaint alleges that these markets are highly concentrated and that entry into the markets is difficult or unlikely. The complaint alleges that the effect of the proposed acquisition may be substantially to lessen competition or tend to create a monopoly in the relevant markets in the United States.

The first paragraph of the proposed order defines the terms "Alliant," "Olin" and "system contractor for 30mm lightweight ammunition or 120mm tank ammunition" as used in the order. Paragraph II bans Alliant from acquiring, directly or indirectly, without the prior approval of the Federal Trade Commission, any stock or assets of any company engaged in systems contracting for 30mm lightweight or 120mm tank ammunition in the United States. Paragraph III bans Alliant from selling or transferring its stock or assets to a company engaged in systems contracting for 30mm lightweight or 120mm tank ammunition without the prior approval of the Federal Trade Commission. These bans last for a period of ten (10) years from the date the order becomes final.

Paragraph IV of the proposed order requires that Alliant notify the Commission at least thirty (30) days prior to any proposed change in the corporation, such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of any subsidiary engaged in systems contracting for 30mm lightweight or 120mm tank ammunition in the United States, or any other change that may affect compliance obligations arising out of the Order.

Paragraph V of the proposed order requires that within fourteen (14) days after the order becomes final, Alliant must terminate its proposed acquisition of Olin. Additionally, Alliant must return or destroy any documents containing confidential information obtained from Olin and recover or have Olin destroy any confidential documents Alliant supplied to Olin.

Paragraph VI of the proposed order requires Alliant to file with the Commission, within sixty (60) days after service of the order, a report, in writing, setting for in detail the manner and form in which it has complied with this order. Alliant is also required to file with the Commission annual reports detailing its compliance with the order.

The agreement is for settlement purposes only and does not constitute an admission by Alliant that the law has been violated as alleged in the complaint issued by the Commission.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 93-115 Filed 1-5-93; 8:45 am]

BILLING CODE 6750-01-M

[Docket C-3406]

American Psychological Association; Prohibited Trade Practices, and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Consent order.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent order prohibits, among other things, a Washington, DC association from restricting the dissemination of truthful, non-deceptive information by its members. In addition, the respondent is prohibited from banning payments by psychologists to patient-referral services. Finally, the respondent must cease its affiliation with any state, regional or other psychological association that imposes similar restrictions.

DATES: Complaint and Order issued December 16, 1992. [1]

FOR FURTHER INFORMATION CONTACT: Elizabeth R. Hilder, FTC/S-3115, Washington, DC 20580. (202) 326-2545.

SUPPLEMENTARY INFORMATION: On Tuesday, October 6, 1992, there was published in the **Federal Register**, 57 FR 46028, a proposed consent agreement with analysis In the Matter of American Psychological Association, for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions or objections regarding the proposed form of the order.

No comments having been received, the Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered an order to cease and desist, as set forth in the proposed consent agreement, in disposition of this proceeding.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45)

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 93-112 Filed 1-5-93; 8:45 am]

BILLING CODE 6750-01-M

[1] Copies of the Complaint and the Decision and Order and the separate statement of Commissioner Mary L. Azcuenaga, concurring in part and dissenting in part, are available from the Commission's Public Reference Branch, H-130, 6th Street & Pennsylvania Avenue, NW., Washington, DC 20580.

[File No. 902 3145]

CC Pollen Company, et al.; Proposed Consent Agreement With Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: In settlement of alleged violations of Federal law prohibiting unfair acts and practices and unfair methods of competition, this consent agreement, accepted subject to final Commission approval, would prohibit, among other things, a Phoenix-based firm, and its owners, from making false claims about the effect consumption of their bee pollen products has in regard to allergies, aging, impotence, sexual disfunction, weight loss and antibiotic treatment, and require that they have scientific evidence to support any other health-benefit claims they make about any food or other product for human consumption, in the future. In addition, the respondents would be prohibited from producing or distributing any advertisement that is represented to be something other than a paid ad, and required to prominently disclose in all future infomercials they create that the programs are paid ads. Finally, the respondents would be required to pay $200,000 as disgorgement of profits.

DATES: Comments must be received on or before March 8, 1993.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, room 159, 6th St. and Pa. Ave., NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Brinley Williams, Cleveland Regional Office, Federal Trade Commission, 668 Euclid Avenue, Suite 520-A, Cleveland, OH 44114, (216) 522-4210.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and § 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the following consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with § 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii)).

Agreement Containing Consent Order To Cease and Desist

The Federal Trade Commission having initiated an investigation of certain acts and practices of C C Pollen Company, a corporation, and Bruce R. Brown, Carol M. Brown, and Royden Brown, individually and as officers of said corporation, hereinafter sometimes referred to as proposed respondents, and it now appearing that proposed respondents are willing to enter into an agreement containing an Order to Cease and Desist from the use of the acts or practices being investigated.

It is hereby agreed by and between proposed respondents and their attorney and counsel for the Federal Trade Commission that:

1. Proposed respondents C C Pollen Company, a corporation, and Bruce R. Brown, Carol M. Brown, and Royden Brown, individually and as officers of said corporation, have an office or principal place of business located at 3627 East Indian School Road, Suite 209, Phoenix, Arizona 85018.

2. Proposed respondents admit all the jurisdictional facts set forth in the draft Compliant here attached.

3. Proposed respondent waive:

(a) Any further procedural steps;

(b) The requirement that the Commission's Decision contain a statement of findings of fact and conclusions of law;

(c) All rights to seek judicial review or otherwise to challenge or contest the validity of the Order entered pursuant to this Agreement; and

(d) All claims under the Equal Access to Justice Act.

4. This Agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this Agreement is accepted by the Commission, it, together with the draft Complaint contemplated thereby, will be placed on the public record for a period of sixty (60) days and information with respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this Agreement and so notify proposed respondents, in which event it will take such action as it may consider appropriate, or issue and serve its Complaint (in such form as the circumstances may require) and Decision, in disposition of the proceeding.

5. This Agreement is for settlement purposes only and does not constitute an admission by proposed respondents of facts other than jurisdictional facts, or of violations of law as alleged in the draft Complaint here attached.

6. This Agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of § 2.34 of the

Commission's Rules, the Commission may, without further notice to proposed respondents, (1) issue its Complaint corresponding in form and substance with the draft Complaint and its Decision containing the following Order to Cease and Desist in disposition of the proceeding, and (2) make information public with respect thereto. When so entered, the Order to Cease and Desist shall have the same force and effect and may be altered, modified, or set aside in the same manner and within the same time provided by statute for other orders. The Order shall become final upon service. Delivery by the United States Postal Service of the Complaint and Decision containing the agreed-to Order to proposed respondents' address as stated in this Agreement shall constitute service. Proposed respondents waive any right they may have to any other manner of service. The Complaint attached thereto may be used in construing the terms of the Order. No agreement, understanding, representation, or interpretation not contained in the Order or the Agreement may be used to vary or contradict the terms of the Order.

7. Proposed respondents have read the proposed Complaint and Order contemplated hereby. They understand that once the Order has been issued, they will be required to file one or more compliance reports showing that they have fully complied with the Order. Proposed respondents further understand that they may be liable for civil penalties in the amount provided by law for each violation of the Order after it becomes final.

Order

The following definition shall apply throughout this Order:

Bee pollen product means any product(s) intended for human consumption or use consisting in whole or in part of bee pollen, bee propolis, and/or royal jelly in any form.

I

It is Ordered That respondents CC Pollen Company, a corporation, and Bruce R. Brown, Carol M. Brown, and Royden Brown, individually and as officers of said corporation, their successors and assigns, and their officers, agents, representatives and employees, directly or through any partnership, corporation, subsidiary, division or other device in connection with the advertising, packaging, labeling, promotion, offering for sale, sale or distribution of any product or service in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from creating, producing, selling or disseminating:

(A) Any advertisement that misrepresents, directly or by implication, that is not a paid advertisement; and

(B) Any commercial or other video advertisement fifteen (15) minutes in length or longer, or intended to fill a broadcasting or cablecasting time slot of fifteen (15) minutes in length or longer, that does not display visually, in a clear and prominent manner and for a length of time sufficient for an ordinary consumer to read, within the first thirty (30) seconds of the commercial and immediately before each presentation of ordering instructions for the product or service, the following disclosure:

The program you are watching is a paid advertisement for [the product or service].

Provided that, for the purposes of this provision, the oral or visual presentation of a telephone number or address for viewers to contact to place an order for the product or service shall be deemed a presentation of ordering instructions so as to require the display of the disclosure provided herein.

Provided further That should the Federal Trade Commission adopt a trade regulation rule requiring different disclosures or a different frequency of making such disclosures than that required by subpart I(B), above, compliance with such trade regulation rule shall be deemed compliance with subpart I(B).

II

It is further ordered That respondents C C Pollen Company, a corporation, and Bruce R. Brown, Carol M. Brown, and Royden Brown, individually and as officers of said corporation, their successors and assigns, and their officers agents, representatives and employees, directly or through any partnership, corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of any bee pollen product in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing, directly or by implication, that:

(A) Consumption of any been pollen product cannot or will not result in an allergic reaction;

(B) Consumption of any bee pollen product will permanently alleviate all pollen allergy symptoms;

(C) Consumption of any bee pollen product slows or prevents or reverse the aging process;

(D) Consumption of any bee pollen product can cure, or prevent, or alleviate impotence and/or sexual dysfunction;

(E) Consumption of any been pollen product can cause weight loss;

(F) Any bee pollen product is an effective antibiotic for human use.

Provided, however, That use of any statement approved by the United States Food and Drug Administration ("FDA") for inclusion on the above label of the product will be deemed not to violate this part when its use is consistent with the FDA approval.

III

It is further ordered That respondents C C Pollen Company, a corporation, and Bruce R. Brown, Carol M. Brown, and Royden Brown, individually and as officers of said corporation, their successors and assigns, and their officers, agents, representatives and employees, directly or through any partnership, corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of any product or service for human consumption or use, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing, directly or by implication, that any such product or service will have any effect on the user's health or physical condition unless, at the time of making such representation, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation. For purposes of this Order, "competent and reliable scientific evidence" shall mean tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted by others in the profession to yield accurate and reliable results.

IV

It is further ordered That respondents, their successors and assigns, shall pay Two Hundred Thousand Dollars ($200,000) to the United States Treasury as disgorgement. Such payment shall be by two cashier's checks or certified checks made payable to the Treasurer of the United States, the first such check, in the amount of One Hundred Thousand Dollars ($100,000), to be tendered within five (5) days of the date of service of this Order, and the second, also in the amount of One Hundred Thousand Dollars ($100,000), to be tendered no later than one year to the day after this Agreement becomes final. Respondents shall provide security for the second payment in a manner agreed to by the parties before provisional acceptance of this Order by the Federal Trade Commission. In the event of any default in payment, which default continues for more than ten (10) days beyond the due date of payment, respondents shall also pay interest as computed under 28 U.S.C. 1961, which shall accrue on the unpaid balance from the date of default until the date the balance is fully paid.

V

It is further ordered That for a period of three (3) years from the date that a representation covered by this Order is last disseminated, respondents shall maintain and upon request make available to the Federal Trade Commission for inspection and copying:

(A) All materials that were relied upon by respondents in disseminating any representation covered by this Order; and

(B) All reports, tests, studies, surveys, demonstrations or other evidence in any respondent's possession or control that contradict, qualify or call into question such representation or the basis upon which respondents relied for such representation, including complaints from consumers.

VI

It is further ordered That respondent CC Pollen Company shall:

(A) Within thirty (30) days after service of this Order, provide a copy of this Order to each of respondent's current principals,

officers, directors and managers, and provide a complete copy of Parts I through III of this Order to all personnel, agents and representatives having advertising or policy responsibility with respect to the subject matter of this Order, and to each employee of CC Pollen Company who is engaged in the sale of CC Pollen products; and

(B) For a period of seven (7) years from the date of entry of this Order, provide a copy of this Order to each of respondent's principals, officers, directors and managers, and provide a complete copy of Parts I through III of this Order to all personnel, agents and representatives having advertising or policy responsibility with respect to the subject matter of this Order, and to each employee of CC Pollen Company who is engaged in the sale of CC Pollen products, within three (3) days after the person assumes his or her position.

VII

It is further ordered That respondent CC Pollen Company shall notify the Commission at least thirty (30) days prior to the effective date of any proposed change in the corporate respondent such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in the corporation which may affect compliance obligations arising out of this Order.

VIII

It is further ordered That respondents Bruce R. Brown, Carol M. Brown, and Royden Brown shall, for a period of seven (7) years from the date of entry of this Order, notify the Federal Trade Commission within thirty (30) days of the discontinuance of his or her present business or employment and of his or her affiliation with any new business or employment. Each notice of affiliation with any new business or employment shall include the respondent's new business address and telephone number, current home address, and a statement describing the nature of the business or employment and his or her duties and responsibilities.

IX

It is further ordered That respondents shall, for at least three (3) years after service of this Order, maintain and make available to the Federal Trade Commission upon request, for inspection and copying, complete records regarding respondents' compliance with this Order.

X

It is further ordered That respondents shall, within sixty (60) days after service of this Order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this Order.

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, an agreement to a proposed Consent Order from C C Pollen Company and its principals, Royden Brown, Bruce Brown and Carol Brown.

The proposed Consent Order has been placed on the public record for sixty (60) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement and take other appropriate action, or make final the proposed Order contained in the agreement.

This matter concerns two program-length television advertisements for C C Pollen's bee pollen products, *TV Insiders* and *The Search for the Fountain of Youth*, as well as C C Pollen's print advertisements for these products.

The Complaint alleges that C C Pollen Company engaged in deceptive advertising in violation of section 5 of the Federal Trade Commission Act by falsely claiming that the television advertisements were not paid-for advertisements but rather were independent and objective documentary or news programs.

The Complaint also alleges that C C Pollen violated sections 5 and 12 of the FTC Act by making false and unsubstantiated claims that consumption of any bee pollen product cannot result in an allergic reaction; that consumption of C C Pollen Company's bee pollen products will permanently alleviate all of the consumer's pollen allergy symptoms; that consumption of bee pollen products slows or prevents or reverses the aging process; that consumption of bee pollen products can cure, or prevent, or alleviate impotence and/or sexual dysfunction; that consumption of bee pollen products causes weight loss; and that bee pollen projects, such as those advertised by C C Pollen Company, are an effective antibiotic for human use.

The Complaint further alleges that C C Pollen falsely implied that it had a reasonable basis for each of these claims. According to the Complaint, C C Pollen did not have a reasonable basis for making these claims.

The Consent Order contains provisions designed to prevent future misrepresentations concerning the nature of C C Pollen's program-length advertisements. Paragraph I of the Order prohibits C C Pollen and the three named officers of the company from misrepresenting that any advertisement is an independent program, and not an advertisement. Paragraph I also provides that any television advertisement 15 minutes or more in length must contain a clear and prominent visual message which states that the program is a paid advertisement. The disclosure must be made at the beginning of the advertisement and prior to any ordering instructions.

Paragraph II of the Order prohibits respondents from claiming that consumption of any bee pollen product cannot or will not result in an allergic reaction; that consumption of any bee pollen product will permanently alleviate all pollen allergy symptoms; that consumption of any bee pollen product slows or prevents or reverses the aging process; that consumption of any bee pollen product can cure, or prevent, or alleviate impotence and/or sexual dysfunction; that consumption of any bee pollen product can cause weight loss; and that any bee pollen product is an effective antibiotic for human use.

Paragraph III requires substantiation consisting of competent and reliable scientific evidence for all future claims concerning any product for human use or consumption having any effect on the user's health or physical condition.

Paragraph IV requires the respondents to pay to the United States Treasury Two Hundred Thousand Dollars ($200,000) as disgorgement, with $100,000 to be paid within five days of the date of service of the Order and the remaining $100,000 to be paid within one year after the Order becomes final.

The remainder of the Order contains standard record-retention and notification provisions.

The purpose of this analysis is to facilitate public comment on the proposed Order. It is not intended to constitute an official interpretation of the agreement and proposed Order or to modify in any way their terms.

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 93-119 Filed 1-5-93; 8:45 am]

BILLING CODE 6750-01-M

[File No. 922 3155]

Alan V. Phan, d/b/a Harcourt Companies; Proposed Consent Agreement With Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent agreement, accepted subject to final Commission approval, would prohibit,

among other things, a California marketer of "Jazz cigarettes", a non-tobacco product, from representing that smoking such products poses no health risk, that smoking such products does not pose any of the health risks associated with smoking cigarettes, and that the smoke contains no tar. In addition, the respondent would be prohibited from making any representations about the comparative or absolute health or safety attributes, benefits or risks of any cigarette or smoking product, unless it is substantiated by reliable scientific evidence.

DATES: Comments must be received on or before March 8, 1993.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, room 159, 6th St. and Pa. Ave., NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Jeffrey Klurfeld or Kerry O'Brien, San Francisco Regional Office, Federal Trade Commission, 901 Market St., Suite 570, San Francisco, CA 94103. (415) 744–7920.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and § 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the following consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with § 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii)).

Agreement Containing Consent Order To Cease and Desist

In the Matter of Alan V. Phan, a/k/a Alan V. Pasqualle, an individual trading and doing business as Harcourt Companies.

The Federal Trade Commission having initiated an investigation of certain acts and practices of Alan V. Phan, an individual trading and doing business as Harcourt Companies ("proposed respondent"), and it is now appearing that proposed respondent is willing to enter into an agreement containing an order to cease and desist from the acts and practices being investigated,

It is hereby agreed By and between Alan V. Phan and counsel for the Federal Trade Commission that:

1. Proposed respondent Alan V. Phan is the owner of Harcourt Companies, a California sole proprietorship. His principal office and place of business is located at 10915 Bloomfield Avenue, Los Alamitos, CA 90720.

2. Proposed respondent admits all the jurisidictional facts set forth in the draft complaint here attached.

3. Proposed respondent waives:

a. Any further procedural steps;

b. The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law;

c. All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement; and

d. All claims under the Equal Access to Justice Act, 5 U.S.C. 504.

4. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission, it, together with the draft of complaint contemplated thereby, will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify the proposed respondent, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision, in disposition of the proceeding.

5. This agreement is for settlement purposes only and does not constitute an admission by proposed respondent of facts, other than jurisdictional facts, or of violations of law as alleged in the draft of complaint here attached.

6. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of § 2.34 of the Commission's Rules, the Commission may, without further notice to proposed respondent, (a) issue its complaint corresponding in form and substance with the draft of complaint here attached and its decision containing the following order to cease and desist in disposition of the proceeding and (b) make information public in respect thereto. When so entered, the order to cease and desist shall have the same force and effect and may be altered, modified or set aside in the same manner and within the same time provided by statute for other orders. The order shall become final upon service. Delivery by the U.S. Postal Service of the complaint and decision containing the agreed-to order to proposed respondent's address as stated in this agreement shall constitute service. Proposed respondent waives any right he may have to any other manner of service. The complaint may be used in construing the terms of the order, and no agreement, understanding, representation, or interpretation not contained in the order or the agreement may be used to vary or contradict the terms of the order.

7. Proposed respondent has read the proposed complaint and order contemplated hereby. Proposed respondent understands that once the order has been issued, he will be required to file one or more compliance reports showing that he has fully complied with the order. Proposed respondent further understands that he may be liable for civil penalties in the amount provided by law for each violation of the order after it becomes final.

Order

I.

It is ordered That respondent Alan V. Phan, an individual trading and doing business as Harcourt Companies, and his successors and assigns, in connection with the manufacturing, labelling, advertising, promotion, offering for sale, sale, or distribution of Jazz or any product containing substantially similar ingredients, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing, in any manner, directly or by implication, that:

A. Smoking such product poses no health risk for the user.

B. Smoking such product does not pose any of the health risks associated with smoking tobacco cigarettes.

C. Such product's smoke contains no "tar."

It is further ordered That respondent Alan V. Phan, an individual trading and doing business as Harcourt Companies, and his successors and assigns, in connection with the manufacturing, labelling, advertising, promotion, offering for sale, sale, or distribution of any smoking product, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from making any misrepresentation, in any manner, directly or by implication, regarding the display of health warnings required by the Federal Cigarette Labeling and Advertising Act.

III.

It is further ordered That respondent Alan V. Phan, an individual trading and

doing business as Harcourt Companies, and his successors and assigns, in connection with the manufacturing, labelling, advertising, promotion, offering for sale, sale, or distribution of any cigarette, as defined in 15 U.S.C. 1332, or any other smoking product, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing, in any manner, directly or by implication, the comparative or absolute health or safety attributes, benefits, or risks associated with smoking such product, unless such representation is true and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation. For purposes of this Order, "competent and reliable scientific evidence" shall mean tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

IV.

It is further ordered That respondent Alan V. Phan, an individual trading and doing business as Harcourt Companies, and his successors and assigns, in connection with the manufacturing, labelling, advertising, promotion, offering for sale, sale, or distribution of any product in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing, in any manner, directly or by implication, that using such product is effective in aiding people to quit smoking tobacco products, unless, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

V.

It is further ordered That respondent shall:

A. Within thirty (30) days from the date of service of this Order, distribute a copy of the Complaint and Order to each past or present distributor of Jazz.

B. Distribute a copy of the Complaint and Order to each new distributor of Jazz within thirty (30) days of the date that individual or entity becomes a distributor;

C. Distribute a copy of the Complaint and Order to each future purchaser of Jazz, or any other transferee, who acquires, with or without valuable consideration, more than thirty (30) cartons of Jazz.

D. For ten (10) years from the date of service of this Order, distribute a copy of the Complaint and Order to each managerial employee of respondent, and to each salesperson of respondent's products, whether they are independent sales agents or employees of respondent.

E. Within ten (10) days from the date of service of this Order, distribute a copy of the Complaint and Order to any individual or entity who is involved in the preparation and placement of advertisements or promotional materials, or communicates with customers or prospective customers regarding the efficacy or safety of any product covered by this Order.

VI.

It is further ordered That for five (5) years after the last date of dissemination of any representation covered by this Order, respondent, or his successors and assigns, shall maintain and upon request make available to the Federal Trade Commission for inspection and copying:

A. All materials that were relied upon in disseminating such representation; and

B. All test, reports, studies, surveys, demonstrations or other evidence in his possession or control that contradict, qualify, or call into question such representation, or the basis relied upon for such representation, including complaints from consumers.

VII.

It is further ordered That respondent shall, for a period of ten (10) years after the date of service of this Order upon him, promptly notify the Commission, in writing, of his discontinuance of his present business or employment and of his affiliation with a new business or employment. For each such new affiliation, the notice shall include the name and address of the new business or employment, a statement of the nature of the new business or employment, and a description of respondent's duties and responsibilities in connection with the new business or employment.

VIII.

It is further ordered That respondent shall, within sixty (60) days from the date of service of this Order upon them, and at such other times as the Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this Order.

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted an agreement, subject to final approval, to a proposed consent order from respondent Alan V. Phan, an individual trading and doing business as Harcourt Companies.

The proposed consent order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement and take other appropriate action or make final the agreement's proposed order.

This matter concerns the advertising of "Jazz Cigarettes" ("Jazz"), a nontobacco product. Because Jazz does not contain tobacco, it is not a "cigarette," as that term is defined in the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. 1332. The Commission's complaint charges that respondent's advertising contained false and unsubstantiated representations concerning the health risks associated with smoking Jazz, and Jazz's efficacy in helping people to quit smoking tobacco products.

Specifically, the complaint alleges that respondent falsely represented that: (1) Smoking Jazz poses no health risk for the user; (2) smoking Jazz does not pose any of the health risks associated with smoking tobacco cigarettes; (3) Jazz smoke contains no tar; and (4) Jazz packages do not display the Surgeon General's health warnings because smoking Jazz does not pose the health and safety risks that have been associated with smoking tobacco cigarettes. The complaint also alleges that respondent lacked substantiation for his claim that smoking Jazz is effective in aiding people to quit smoking tobacco products.

The proposed consent order contains provisions designed to remedy the violations charged and to prevent the respondent from engaging in similar acts and practices in the future.

Part I of the proposed order prohibits respondent from representing that (1) smoking Jazz poses no health risk for the user; (2) smoking Jazz does not pose any of the health risks associated with smoking tobacco cigarettes; and (3) Jazz's smoke contains no tar. Part I of the proposed order also covers these representations when made about a product that contains substantially similar ingredients as those contained in Jazz.

Part II of the proposed order prohibits respondent from making any misrepresentation regarding the display of health warnings required by the Federal Cigarettes Labeling and Advertising Act on any smoking product.

As fencing-in relief, Part III of the proposed order provides that if respondent represents that comparative or absolute health or safety attributes, benefits, or risks associated with smoking any cigarette or any other smoking product, the representation must be true and respondent must possess competent and reliable scientific evidence that substantiates the representation.

Part IV of the proposed order provides that if respondent represents that a product helps people to quit smoking tobacco products, respondent must possess competent and reliable scientific evidence that substantiates the representation.

The proposed order also requires respondent to maintain materials relied upon to substantiate claims covered by the order, to distribute copies of the order to past, present and future distributors of Jazz, to distribute copies of the order to certain future purchasers of Jazz, to notify the Commission of certain changes in respondent's business or employment, and to file one or more reports detailing compliance with the order.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 93–114 Filed 1–5–93; 8:45 am]

BILLING CODE 6750–01–M

[Docket No. 9247]

Phone Programs, Inc.; Prohibited Trade Practices, and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Consent order.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent order prohibits, among other things, a New York corporation from misrepresenting the ease with which a premium is obtainable and the content of any telephone information service message to children aged twelve and under. In addition, the respondent is required to include a clear statement at the beginning of each children's message giving the child a chance to hand up without charge, and is required to provide a means for parents to prevent, or not be charged for, unauthorized calls by their children.

DATES: Complaint issued May 7, 1991. order issued December 10, 1992.[1]

FOR FURTHER INFORMATION CONTACT: Richard Cleland, FTC/S–4002, Washington, DC 20580. (202) 326–3088.

SUPPLEMENTARY INFORMATION: On Tuesday, September 29, 1992, there was published in the **Federal Register**, 57 FR 44744, a proposed consent agreement with analysis In the Matter of Phone Programs, Inc., for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions or objections regarding the proposed form of the order

No comments having been received, the Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered an order to cease and desist, as set forth in the proposed consent agreement, in disposition of this proceeding.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45)

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 93–113 Filed 1–5–93; 8:45 am]

BILLING CODE 6750–01–M

[File No. 931 0023]

S.C. Johnson & Son, Inc.; Proposed Consent Agreement with Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent agreement, accepted subject to final Commission approval, would require, among other things, a Wisconsin-based manufacturer of home care products to divest its assets used in the production, manufacture and sale of continuous action and aerosol air freshener products and furniture care products, in order to acquire certain assets of the Drackett Company, a subsidiary of Bristol-Myers Squibb Company. In addition, for a 10-year period, Johnson must obtain Commission approval before acquiring any interest in any air freshener or furniture care product manufacturer or distributor.

DATES: Comments must be received on or before March 8, 1993.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, room 159, 6th St. and Pa. Ave., NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Steven A. Newborn, FTC/S–2308, Washington, DC 20580. (202) 326–2682.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and Section 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the following consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with § 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii)).

Agreement Containing Consent Order

In the matter of S.C. Johnson & Son, Inc. a corporation.

The Federal Trade Commission ("Commission") having initiated an investigation of the proposed acquisition by S.C. Johnson & Son, Inc. ("Johnson"), a corporation, of all the voting securities of The Drackett Company ("Drackett"), from Bristol-Myers Squibb Company ("BMS"), a corporation, and certain assets of BMS relating to Drackett's international business, and it now appearing that Johnson, hereinafter sometimes referred to as "proposed respondent", is willing to enter into an Agreement Containing Consent Order ("Agreement") to divest certain assets, to cease and desist from certain acts, and to provide for certain other relief.

It is Hereby Agreed by and between Johnson, by its duly authorized officers and its attorneys, and counsel for the Commission that:

1. Proposed respondent Johnson is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Wisconsin, with its office and principal place of business located at 1525 Howe Street, Racine, Wisconsin 53403–5011.

2. BMS is a corporation, organized, existing, and doing business under and by virtue of the laws of the State of

[1] Copies of the Complaint and the Decision and Order are available from the Commission's Public Reference Branch, H–130, 6th Street & Pennsylvania Avenue, NW., Washington, DC 20580.

Delaware, with its office and principal place of business located at 345 Park Avenue, New York, New York 10154–0037.

3. Drackett is a corporation, organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 201 East Fourth Street, Cincinnati, Ohio 45202.

4. Proposed respondent admits all the jurisdictional facts set forth in the draft of complaint here attached.

5. Proposed respondent waives:

(a) Any further procedural steps;

(b) The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law;

(c) All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this Agreement; and

(d) Any claim under the Equal Access to Justice Act.

6. This Agreement shall not become part of the public record of the proceedings unless and until it is accepted by the Commission. If this Agreement is accepted by the Commission it, together with the draft of complaint contemplated thereby, will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this Agreement and so notify the proposed respondent, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision, in disposition of the proceeding.

7. This Agreement is for settlement purposes only and does not constitute an admission by proposed respondent that the law has been violated as alleged in the draft of complaint here attached.

8. This Agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Section 2.34 of the Commission's Rules, the Commission may, without further notice to proposed respondent, (1) issue its complaint corresponding in form and substance with the draft of complaint here attached and its decision containing the following order to divest and cease and desist, and for other relief in disposition of the proceeding, and (2) make information public with respect thereto. When so entered, the order shall have the same force and effect and may be altered, modified, or set aside in the same manner and within the same time provided by statute for other orders. The order shall become final upon service. Delivery by the United States Postal Service of the complaint and decision containing the agreed-to order to proposed respondent's address as stated in this Agreement shall constitute service. Proposed respondent waives any right it may have to any other manner of service. The complaint may be used in construing the terms of the order, and no agreement, understanding, representation, or interpretation not contained in the Agreement or the order may be used to vary or contradict the terms of the order.

9. Proposed respondent has read the proposed complaint and order contemplated hereby. Johnson understands that once the order has been issued, it will be required to file one or more compliance reports showing it has fully complied with the order. Proposed respondent further understands that it may be liable for civil penalties in the amount provided by law for each violation of the order after it becomes final.

Order

I.

As used in this order, the following definitions shall apply:

A. "Johnson" means S.C. Johnson & Son, Inc., its predecessors, successors and assigns, divisions, subsidiaries, affiliates, companies, groups, partnerships and joint ventures that S.C. Johnson & Son, Inc. controls, directly or indirectly, and their directors, officers, employees, agents and representatives, and their respective successors and assigns.

B. "BMS" means Bristol-Myers Squibb Company, its predecessors, successors and assigns, divisions, subsidiaries, affiliates, companies, groups, partnerships and joint ventures that Bristol-Myers Squibb Company controls, directly or indirectly, and their directors, officers, employees, agents and representatives, and their respective successors and assigns.

C. "Drackett" means The Drackett Company, its predecessors, successors and assigns, divisions, subsidiaries, affiliates, companies, groups, partnerships and joint ventures that The Druckett Company controls, directly or indirectly, the their directors, officers, employees, agents and representatives, and their respective successors and assigns.

D. "Acquisition" means the acquisition by Johnson from BMS of all the voting securities of Drackett, a wholly-owned subsidiary of BMS, and certain assets of BMS relating to Drackett's international business.

E. "Air freshener products" means products designed to combat and eliminate offensive odors in the home that are applied by aerosol spray, or in liquid, solid, wick or other forms and that are distributed to consumers primarily through grocery, drug, and mass merchandise stores.

F. "Furniture care products" means household polishes and dusting aids designed to clean, shine, and protect furniture and other household surfaces, which are applied by aerosol spray or in cream, paste, liquid and other forms and that are distributed to consumers primarily through grocery, drug, and mass merchandise stores.

G. "Renuzit Assets" means all of Drackett's rights, title and interest in and to:

(1) Air freshener products, including, but not limited to, the brands and trademarks "Renuzit", "Renuzit Adjustable", "Renuzit Roommate", "Renuzit Freshell", "Renuzit Fragrance Jar", "Renuzit Aerosol", and "Renuzit Fresh 'n Dry";

(2) Furniture care products, including, but not limited to, the brands and trademarks "Endust" and "Behold", but excluding the brand and trademark "Jr. Muscle" outside the United States; and

(3) All of Drackett's assets and businesses associated with the development, production, distribution, and sale for resale of air freshener products and furniture care products and as further delineated in the subparagraphs of Schedule A, attached hereto and made a part hereof.

II.

It is ordered That:

A. Johnson shall divest, absolutely and in good faith, within twelve (12) months of the date this order becomes final, the Renuzit Assets; provided, however, Johnson is not required to divest any of the Renuzit Assets identified in Schedule A, Part 2, if such assets are not needed by the acquirer or acquirers ("acquirer(s)") in connection with the development, production, distribution, and sale for resale of air freshener products or furniture care products.

B. Johnson shall divest the Renuzit Assets only to an acquirer or acquirers ("acquirer(s)") that receive the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission. The purpose of the divestiture of the Renuzit Assets is to ensure the continuation of the assets as an ongoing, viable enterprise engaged in the same businesses in which the Renuzit Assets

presently are employed, and to remedy the lessening of competition resulting from the proposed Acquisition as alleged in the Commission's complaint.

C. At the time of divestiture, Johnson shall make available to the acquirer(s) such Johnson personnel, assistance and training as the acquirer(s) might reasonably need to transfer Drackett technology and know-how included in the Renuzit Assets, and shall continue providing such personnel, assistance and training at Johnson's cost for a period of time (not to exceed six (6) months) sufficient to satisfy the acquirer(s)' management that its personnel are appropriately trained in the technology and know-how. At the time of divestiture, Johnson shall also divest any additional, incidental assets of Drackett and make any further arrangements for administrative services within the first six (6) months after divestiture that may be reasonably necessary to assure the viability and competitiveness of the Renuzit Assets.

D. Johnson shall ensure that substantially the same services that BMS agreed to provide Johnson pursuant to the Acquisition Agreement dated October 26, 1992, between Johnson and BMS covering Johnson's acquisition of Drackett ("Acquisition Agreement"), shall be provided to the acquirer(s), upon the acquirer's request and on the same terms as such services are provided to Johnson, during the period that BMS has agreed to provide Johnson such services pursuant to the Acquisition Agreement.

E. Johnson will provide and ensure that BMS also provides reasonable cooperation and assistance to the acquirer(s) in obtaining approvals for the transfer of all registrations, leases, licenses, certifications, permits, or similar documents relating to the Renuzit Assets.

F. Johnson shall comply with all terms of the Agreement to Hold Separate, attached hereto and made a part hereof. The Agreement to Hold Separate shall continue in effect until such time as Johnson has divested the Renuzit Assets or until such other time as the Agreement to Hold Separate provides.

G. Johnson shall take such actions as are necessary to maintain the viability and marketability of the Renuzit Assets and to prevent the destruction, removal, wasting, deterioration or impairment of any of the Renuzit Assets except in the ordinary course of business and except for ordinary wear and tear that does not affect the viability and marketability of the Renuzit Assets.

III.

It is further ordered That:

A. If Johnson has not divested, absolutely and in good faith and with the Commission's prior approval, the Renuzit Assets within twelve (12) months of the date this order becomes final, Johnson shall consent to the appointment by the Commission of a trustee to divest the Renuzit Assets. In the event the Commission or the Attorney General brings an action pursuant to section 5(1) of the Federal Trade Commission Act, 15 U.S.C. 45(1), or any other statute enforced by the Commission, Johnson shall consent to the appointment of a trustee in such action. Neither the appointment of a trustee nor a decision not to appoint a trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed trustee, pursuant to section 5(1) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Johnson to comply with this order.

B. If a trustee is appointed by the Commission or a court pursuant to Paragraph III.A. of this order, Johnson shall consent to the following terms and conditions regarding the trustee's power, duties, authorities, and responsibilities:

1. The Commission shall select the trustee, subject to the consent of Johnson, which consent shall not be unreasonably withheld. The trustee shall be a person with experience and expertise in acquisitions and divestitures.

2. The trustee shall, subject to the prior approval of the Commission, have the exclusive power and authority to divest the Renuzit Assets, and in addition, after a period of six (6) months, to divest the trademark "Vanish" along with the Renuzit Assets, together with any additional, incidental assets of Johnson, including those relating to the "Vanish" trademark, and make any further arrangements for administrative services that may be reasonably necessary to assure the viability and competitiveness of the Renuzit Assets and the "Vanish" trademark.

3. The trustee shall have twelve (12) months from the date the Commission approves the trust agreement described in Paragraph B.8. to accomplish the divestiture. If, however, at the end of the twelve-month period, the trustee has submitted a plan of divestiture or believes that divestiture can be accomplished within a reasonable time, the divestiture period may be extended by the Commission or by the court (in the case of a court-appointed trustee). Provided, however, the Commission may only extend the divestiture period two (2) times.

4. The trustee shall have full and complete access to the personnel, books, records, and facilities related to the Renuzit Assets, or any other relevant information, as the trustee may reasonably request. Johnson shall develop such financial or other information as such trustee may reasonably request and shall cooperate with any reasonable request of the trustee. Johnson shall take no action to interfere with or impede the trustee's accomplishment of the divestiture. Any delays in divestiture caused by Johnson shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or the court for a court-appointed trustee.

5. Subject to Johnson's absolute and unconditional obligation to divest at no minimum price and the purpose of the divestiture as stated in Paragraph II.B. of this order, the trustee shall use his or her best efforts to negotiate the most favorable price and terms available with each acquirer for the divestiture. The divestiture shall be made in the manner set out in Paragraph II; provided, however, if the trustee receives bona fide offers from more than one acquirer, and if the Commission determines to approve more than one such acquirer, the trustee shall divest to the acquirer(s) selected by Johnson from among those approved by the Commission.

6. The trustee shall serve, without bond or other security, at the cost and expense of Johnson, on such reasonable and customary terms and conditions as the Commission or a court may set. The trustee shall have authority to employ, at the cost and expense of Johnson, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are reasonably necessary to carry out the trustee's duties and responsibilities. The trustee shall account for all monies derived from the sale and all expenses incurred. After approval by the Commission and, in the case of a court-appointed trustee, by the court, of the account of the trustee, including fees for his or her services, all remaining monies shall be paid at the direction of Johnson and the trustee's power shall be terminated. The trustee's compensation shall be based at least in significant part on a commission arrangement contingent on the trustee's divesting the Renuzit Assets.

7. Johnson shall indemnify the trustee and hold the trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the trusteeship, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of any claim, whether or not resulting in any liability, except to the extent that such liabilities, claims, or expenses result from misfeasance, negligence, willful or wanton acts, or bad faith by the trustee.

8. Within thirty (30) days after appointment of the trustee, and subject to the prior approval of the Commission and, in the case of a court-appointed trustee, of the court, Johnson shall execute a trust agreement that transfers to the trustee all rights and powers necessary to permit the trustee to effect the divestiture required by this order.

9. If the trustee ceases to act or fails to act diligently, a substitute trustee shall be appointed in the same manner as provided in Paragraph III.A. of this order.

10. The Commission or, in the case of a court-appointed trustee, the court, may on its own initiative or at the request of the trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this order.

11. The trustee shall have no obligation or authority to operate or maintain either the Renuzit Assets or those assets associated with the "Vanish" trademark.

12. The trustee shall report in writing to Johnson and to the Commission every thirty (30) days concerning the trustee's efforts to accomplish divestiture.

IV.

It is further ordered That Johnson shall maintain the viability and marketability of the "Vanish" trademark together with any additional, incidental assets of Johnson relating to the "Vanish" trademark, and shall not sell, transfer, encumber (other than in the normal course of business), or otherwise impair their marketability or viability, pending divestiture without the prior approval of the Commission.

V.

It is further ordered That, within sixty (60) days after the date this order becomes final and every sixty (60) days thereafter until Johnson has fully complied with the provisions of Paragraphs II and III of this order, Johnson shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, or has complied with those provisions. Johnson shall include in its compliance reports, among other things that are required from time to time, a full description of all substantive contacts or negotiations for the divestiture, including the identity of all parties contacted. Johnson also shall include in its compliance reports copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning divestiture.

VI.

It is further ordered That, for a ten (10) year period commencing on the date this order becomes final, Johnson shall cease and desist from acquiring, without the prior approval of the Federal Trade Commission, directly or indirectly, through subsidiaries, partnerships or otherwise.

(1) Any equity or other interest in, or the whole or any part of the stock or share capital of, any person or business that is engaged in the development, production, distribution, and sale for resale of air freshener products or furniture care products in the United States; provided, however, that individual employees of Johnson and each pension, benefit or welfare plan or trust controlled by Johnson may acquire, for investment purposes only, an interest of not more than two (2) percent of the stock or share capital of such person or business;

(2) Any equity or other interest in, or the whole or any part of the stock or share capital of, any person or business that owns or licenses a brand or trademark used in connection with the sale of air freshener products or furniture care products in the United States; provided, however, that individual employees of Johnson and each pension, benefit or welfare plan or trust controlled by Johnson may acquire, for investment purposes only, an interest of not more than two (2) percent of the stock or share capital of such person or business; or

(3) Any assets used or previously used (and still suitable for use) in the manufacture or production of air freshener products or furniture care products; provided, however, that Johnson may, in the ordinary course of business, make purchases of used equipment suitable for manufacturing air freshener products and/or furniture care products totalling not more than $1 million per year.

One (1) year from the date this order becomes final and annually thereafter for nine (9) years on the anniversary date of this order, Johnson shall file with the Secretary of the Federal Trade Commission a verified written report of its compliance with this Paragraph.

VII.

It is further ordered That, for the purposes of determining or securing compliance with this order, and subject to any legally recognized privilege, upon written request and on reasonable notice to Johnson, Johnson shall permit any duly authorized representatives of the Commission:

A. Access, during office hours and in the presence of counsel, to inspect and copy all books, ledgers, accounts, correspondence, memoranda and other records and documents in the possession or under the control of Johnson relating to any matters contained in this consent order; and

B. Upon five (5) days notice to Johnson, and without restraint or interference from Johnson, to interview officers or employees of Johnson, who may have counsel present, regarding such matters.

VIII.

It is further ordered That Johnson shall notify the Commission at least thirty (30) days prior to any change that may affect compliance obligations arising out of the order, including but not limited to, any change in Johnson such as dissolution, assignment, or sale resulting in the emergency of a successor, the creation or dissolution of subsidiaries, or any other change.

Schedule A

Johnson shall divest all of the Renuzit Assets pursuant to the terms of this order. The associated assets identified in Paragraph I.G.(3) of this order shall include all assets, properties, business and goodwill, tangible and intangible, utilized by Drackett in the development, production, distribution and sale of air freshener products and furniture care products, including, without limitation, the following:

Part 1

(1) All customer lists, vendor lists, catalogs, sales promotion literature, advertising materials, marketing information, product development information, research materials, technical information, management information systems, software, inventions, trade secrets, technology, know-how, specifications, designs, drawings, processes and quality control data;

(2) Intellectual property rights, patents and patent applications and the

formulas, copyrights, trademarks and trade names, service marks:

(3) All rights, title and interest in and to the contracts entered in the ordinary course of business with customers (together with associated bid and performance bonds), suppliers, sales representatives, brokers and distributors, agents, inventors, product testing and laboratory research institutions, providers of electronic data exchange services, personal property lessors, personal property lessees, licensors, licensees, consignors and consignees;

(4) All rights under warranties and guarantees, express or implied;

(5) All books, records, files, financial statements and supporting documents;

(6) All items of prepaid expense.

Part 2

(1) The Franklin, Kentucky plant, all machinery, fixtures, equipment, vehicles, furniture, tools and all other tangible personal property;

(2) Inventory;

(3) Accounts and notes receivable;

(4) All Environmental Protection Agency and all other federal and state regulatory agency registrations and applications, and all documents related thereto; and

(5) All rights, title and interest in and to owned or leased real property, together with appurtenances, licenses and permits.

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission ("Commission") has accepted provisionally a proposed Consent Order and Agreement to Hold Separate from S.C. Johnson & Son, Inc. ("SCJ").

The proposed Consent Order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

On October 26, 1992, SCJ entered into an agreement with Bristol-Myers Squibb Company ("BMS") to buy all of the voting securities of the Drackett Company ("Drackett"), a wholly-owned subsidiary of BMS, and certain assets of BMS relating to Drackett's international business. The proposed complaint alleges that the proposed acquisition, if consummated, would constitute a violation of section 7 of the Clayton Act, as amended, 15 U.S.C. 18 and section 5 of the FTC Act, as amended, 15 U.S.C. 45 in the markets for the manufacturer and sale of air freshener products and furniture care products in the United States.

The proposed Consent Order provides that SCJ shall divest all of the assets relating to Drackett's air freshener products and furniture care products businesses (the "Renuzit Assets") within twelve (12) months of the Order becoming final. If the divestiture is not completed within twelve (12) months, the Commission will appoint a trustee to complete the divestiture. If the Renuzit Assets are not divested by the trustee after an additional six (6) months, the proposed Order provides that all of the assets relating to Drackett's toilet bowl cleaning products the "Vanish Assets", shall also be divested with the Renuzit Assets.

The Hold Separate Agreement provides that pending divestiture, the Renuzit Assets shall be operated independently of SCJ. Under the provisions of the proposed Order, SCJ is also required to provide the Commission with a report of its compliance with the divestiture provisions of the Order within sixty (60) days following the date this Order becomes final, and every sixty (60) days thereafter until SCJ has completely divested the Renuzit Assets. The proposed Order will also require SCJ to cease and desist for ten (10) years from acquiring, without Federal Trade Commission approval, any interest in assets suitable for the manufacture, sale, or distribution of air freshener products or furniture care products in the United States. SCJ will also be required to file with the Commission annual reports of its compliance with the Order.

The purpose of this analysis is to facilitate public comment on the proposed Order, and it is not intended to constitute an official interpretation of the agreement and proposed Order or to modify in any way their terms.

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 93-117 Filed 1-5-93; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 92N-0448]

Boehringer Ingelheim Animal Health, Inc., Withdrawal of Approval of NADA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) held by Boehringer Ingelheim Animal Health, Inc. The NADA provides for the use of True Antibiotic 10 Lactating Cow Mastitis Treatment (procaine penicillin G). The firm requested the withdrawal of approval. In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the regulations by removing the entry that reflects the approval.

EFFECTIVE DATE: January 19, 1993.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV-216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-295-8749.

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Animal Health, Inc., 2621 North Belt Highway, St. Joseph, MO 64506, is the sponsor of NADA 65-466 which provides for the use of True Antibiotic 10 Lactating Cow Mastitis Treatment. In its letter dated August 10, 1992, the sponsor requested the withdrawal of approval of the NADA.

Therefore, under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADA 65-466 and all supplements and amendments thereto is hereby withdrawn, effective January 19, 1993.

In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending 21 CFR 526.1696a(f) to reflect the withdrawal of approval of this NADA.

Dated: December 16, 1992.

Gerald B. Guest,

Director, Center for Veterinary Medicine.

[FR Doc. 93-94 Filed 1-5-93; 8:45 am]

BILLING CODE 4160-01-F

[Docket Nos. 91N-0429 and 91P-0325]

Alpha Therapeutic Corp.; Revocation of U.S. License No. 744-071

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the establishment license (U.S. License No. 744-071) and the product license issued to Alpha

Therapeutic Corp. (doing business as Alpha Plasma Center) for the manufacture of Source Plasma. Alpha Therapeutic Corp. has multiple Centers at various locations under its licenses. Only the Alpha Plasma Center in Odessa, TX, is affected by this revocation. A notice of opportunity for a hearing (NOOH) on a proposal to revoke the licenses was published in the **Federal Register** of January 21, 1992 (57 FR 2281). On February 14, 1992, Alpha Therapeutic Corp. requested a hearing. On March 20, 1992, Alpha Therapeutic Corp. withdrew its request for a hearing. On March 20, 1992, Alpha Therapeutic Corp. also withdrew a petition (Docket No. 91P–0325) requesting reconsideration of FDA's decision to institute proceedings for the revocation of U.S. License No. 744–071.

DATES: The revocation of the above establishment and product license is effective on January 6, 1993.

FOR FURTHER INFORMATION CONTACT: JoAnn M. Minor, Center for Biologics Evaluation and Research (HFB–132), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892, 301–295–8188.

SUPPLEMENTARY INFORMATION: FDA is revoking the establishment license (U.S. License No. 744–071) and the product license issued to Alpha Therapeutic Corp., doing business as Alpha Plasma Center, located at 2100 Andrews Hwy., Odessa, TX 79761, for the manufacture of Source Plasma. Other locations under the Alpha Therapeutic Corp. license are not affected by this revocation.

By letter dated April 26, 1991, FDA advised Alpha Therapeutic Corp. that FDA intended to initiate proceedings to revoke the licenses. In the **Federal Register** of January 21, 1992 (57 FR 2281), FDA published a NOOH on the proposed revocation of the licenses pursuant to 21 CFR 12.21(b), as provided in 21 CFR 601.5(b). As described in the NOOH, the grounds for the proposed license revocation included the following: (1) The results of the most recent FDA inspections of Alpha Plasma Center in February 1991, (2) the results of an FDA investigation of Alpha Plasma Center conducted concurrently with the February 1991 inspections, (3) a determination by FDA that the deviations documented during the February 1991 inspections and investigation of Alpha Plasma Center showed significant and continued noncompliance with the applicable Federal regulations and the provisions of the establishment's license, and (4) a determination by FDA that the violations at the Alpha Plasma Center were significant and willful. FDA noted that documentation in support of the proposed revocations had been placed on file for public examination with Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

The NOOH provided 30 days for Alpha Therapeutic Corp. to submit any written request for a hearing, as specified in 21 CFR 12.21(b), and 60 days to submit any written data justifying a hearing. The NOOH further provided 60 days for other interested persons to submit written comments on the proposed revocations. FDA advised Alpha Therapeutic Corp., by telephone, that the NOOH had been published, and forwarded a copy of the NOOH to Alpha Therapeutic Corp., by facsimile transmission, on February 3, 1992.

Alpha Therapeutic Corp. responded to the NOOH by letter dated February 14, 1992. The letter requested a hearing concerning the proposal to revoke the establishment and the product licenses issued for the Alpha Plasma Center location. The letter also stated that data justifying a hearing would be submitted by March 23, 1992. By letter dated March 20, 1992, the firm informed FDA that after further consideration, and in light of the financial impact, Alpha Therapeutics Corp. was withdrawing its request for a hearing. By a separate letter dated March 20, 1992, Alpha Therapeutic Corp. also withdrew a petition (Docket No. 91N–0325) that requested reconsideration of FDA's decision to institute proceedings for the revocation of U.S. License No. 744–071.

No other written comments on the proposed revocations were received within the prescribed 60 days specified in the NOOH. Accordingly, under 21 CFR 12.38(a)(1), 601.7, 601.8, and the Public Health Service Act (sec. 351 (42 U.S.C. 262)), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director and Deputy Director, Center for Biologics Evaluation and Research (21 CFR 5.67(d)), the establishment license (U.S. License No. 744–071) and the product license issued to Alpha Therapeutic Corp. for the manufacture of Source Plasma are revoked, effective January 6, 1993.

Dated: December 15, 1992.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 93–96 Filed 1–5–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 92N–0501]

Lyphomed, et al.; Withdrawal of Approval of 30 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 30 abbreviated new drug applications (ANDA's). The holders of the ANDA's notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

EFFECTIVE DATE: February 5, 1993.

FOR FURTHER INFORMATION CONTACT: Lola E. Batson, Center for Drug Evaluation and Research (HFD–360), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–295–8038.

SUPPLEMENTARY INFORMATION: The holders of the ANDA's listed in the table in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications. The applicants have also, by their request, waived their opportunity for a hearing.

ANDA No.	Drug	Applicant
70–522	Aminocaproic Acid Injection, USP, 250 milligrams (mg)/milliliters (mL)	Lyphomed, 2045 North Cornell Ave., Melrose Park, IL 60160–1002.
70–652	Methyldopate Hydrochloride Injection, USP, 50 mg/mL	Do.
70–661	Naloxone Hydrochloride Injection, USP, 0.02 mg/mL	Do.
83–136	Niacin Tablets, 500 mg	Bolar Pharmaceutical Co., Inc., 33 Ralph Ave., P.O. Box 30, Coplague, NY 11726–0030.
83–150	Propoxyphene Hydrochloride Capsules, 65 mg	Do.
83–172	Butabarbital Sodium Tablets, 15 mg	Do.
83–204	Promethazine Hydrochloride Tablets, 25 mg	Do.
83–636	Phentermine Hydrochloride Tablets, 8 mg	Do.
83–645	Butabarbital Sodium Tablets, 100 mg	Do.

ANDA No.	Drug	Applicant
83-646	Butabarbital Sodium Tablets, 30 mg	Do.
83-797	Diphenhydramine Hydrochloride Capsules, 25 and 50 mg	Do.
84-911	Chlorpromazine Hydrochloride Injection, 25 mg/mL	Lyphomed, 2045 North Cornell Ave., Melrose Park, IL 60160-1002.
84-964	Sulfasalazine Tablets, 500 mg	Bolar Pharmaceutical Co., Inc., 33 Ralph Ave., P.O. Box 30, Copiague, NY 11726-0030.
85-485	Chlorothiazide Tablets, 250 mg	Eon Labs Manufacturing, Inc., 227-15 North Conduit Ave., Laurelton, NY 11413.
86-761	Lidocaine Hydrochloride Injection, 1 percent and 2 percent	Lyphomed, 2045 North Cornell Ave., Melrose Park, IL 60160-1002.
88-290	Nandrolone Decanoate Injection, USP	Do.
88-317	Nandrolone Decanoate Injection, USP	Do.
89-143	Methylprednisolone Sodium Succinate for Injection, USP, 40 mg/mL	Do.
89-144	Methylprednisolone Sodium Succinate for Injection, USP, 125 mg/mL	Do.
89-187	Methylprednisolone Sodium Succinate for Injection, USP, 500 mg/5 mL	Do.
89-189	Methylprednisolone Sodium Succinate for Injection, USP, 1,000 mg/10 mL	Do.
89-194	Cyclophosphamide for Injection, USP, 100 mg/vial	Do.
89-195	Cyclophosphamide for Injection, USP, 200 mg/vial	Do.
89-196	Cyclophosphamide for Injection, USP, 500 mg/vial	Do.
89-263	Methotrexate Sodium Injection, USP, 25 mg/mL	Do.
89-322	Methotrexate Sodium Injection, USP, 25 mg/mL	Do.
89-323	Methotrexate Sodium Injection, USP, 2.5 mg/mL	Do.
89-373	Calcium Gluceptate Injection, USP, 90 mg Calcium/5 mL	Do.
89-415	Procainamide Hydrochloride Injection, USP, 100 mg/mL	Do.
89-416	Procainamide Hydrochloride Injection, USP, 500 mg/mL	Do.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the ANDA's listed above, and all amendments and supplements thereto, is hereby withdrawn, effective February 5, 1993.

Dated: December 16, 1992.

Carl C. Peck,

Director, Center for Drug Evaluation and Research.

[FR Doc. 93-174 Filed 1-5-93; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 91E-0491]

Determination of Regulatory Review Period for Purposes of Patent Extension; Pravachol®; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the notice of its determination of the regulatory review period for purposes of patent term extension for Pravachol® (pravastatin sodium) that appeared in the Federal Register of March 10, 1992 (57 FR 8461). The notice incorrectly identified the applicant for patent term extension as "E. R. Squibb & Sons, Inc." The notice should have identified the applicant as "Sankyo Co., Ltd." In addition, the notice incorrectly stated: "[T]he applicable regulatory review period for Pravachol® is 2,189 days. Of this time, 1,040 days occurred during the testing phase of the regulatory review period, while 1,149 days occurred during the approval phase." The notice should have stated: "[T]he applicable regulatory review period for Pravachol® is 2,191 days. Of this time, 1,187 days occurred during the testing phase of the regulatory review period, while 1,004 days occurred during the approval phase." A correction to the March 10, 1992, notice was published in the Federal Register of April 24, 1992 (57 FR 15090); the latter notice contained errors and should be disregarded.

FOR FURTHER INFORMATION CONTACT: John S. Ensign, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

1. In FR Doc. 92-5596, appearing on page 8461 in the Federal Register of Tuesday, March 10, 1992, the following corrections are made:

On page 8462, in the first column, under the caption "SUPPLEMENTARY INFORMATION:", in the third complete paragraph, in line 14, "E. R. Squibb & Sons, Inc." is corrected to read "Sankyo Co., Ltd."; on the same page, in the second column, in the first complete paragraph, in line 3, "2,189" is corrected to read "2,191"; in line 4, "1,040" is corrected to read "1,187"; and in line 6, "1,149" is corrected to read "1,004".

Dated: December 17, 1992.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 93-97 Filed 1-5-93; 8:45 am]

BILLING CODE 4160-01-F

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

MEETING: The following advisory committee meeting is announced:

Vaccines and Related Biological Products Advisory Committee

Date, time, and place. January 26, 1993, 8:30 a.m., Conference rms. D and E, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5 p.m.; Jack Gertzog, Center for Biologics Evaluation and Research (HFB-5), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8226.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of vaccines intended for use in the diagnosis, prevention, or treatment of human diseases.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before January 20, 1993, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed

participants, and an indication of the approximate time required to make their comments.

Open committee discussion. The committee will discuss: (1) The influenza virus vaccine formulation for the 1993 through 1994 influenza season, (2) a live oral cholera vaccine (Swiss Serum and Vaccine Institute), and (3) the reorganization of the Center for Biologics Evaluation and Research.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting will be available from the Freedom of Information Office (HFI-35), Food and Drug Administration, rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting will be available from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: December 21, 1992.

Jane E. Henney,

Deputy Commissioner for Operations.

[FR Doc. 93-98 Filed 1-5-93; 8:45 am]

BILLING CODE 4160-01-F

Indian Health Service

National Environmental Policy Act; Categorical Exclusions

AGENCY: Indian Health Service (IHS), HHS.

ACTION: List of IHS program actions that are categorically excluded from the requirement to conduct further evaluation under the National Environmental Policy Act (NEPA).

SUMMARY: This notice provides a list of classes of IHS actions that normally do not have a significant impact on the environment and, therefore, do not require environmental impact statements (EIS) or environmental assessments (EA) under Council on Environmental Quality (CEQ) regulations (40 CFR parts 1500-1508) or Department of Health and Human Services (HHS) procedures (HHS General Administration Manual Part 30). All actions involving construction are reviewed to determine if extraordinary or exceptional circumstances exist that prevent the action from meeting the criteria established for this listing.

EFFECTIVE DATE: January 6, 1993.

FOR FURTHER INFORMATION CONTACT: Director, Division of Environmental Health (DEH), Office of Environmental Health and Engineering (OEHE), IHS, Public Health Service (PHS), HHS, room 5A-39, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; or telephone (301) 443-1043.

SUPPLEMENTARY INFORMATION: Regulations of the CEQ at 40 CFR parts 1500-1508 require Federal agencies to adopt procedures to supplement and implement their regulations. The HHS, by giving notice in the **Federal Register** (45 FR 76519), has adopted such procedures and included them in the HHS General Administration Manual Part 30. The CEQ approved the HHS procedures on October 2, 1980. Paragraphs 1507.3 and 1508.4 of the CEQ regulations provide for the definition of categories of actions that do not individually or cumulatively have a significant effect on the human environment and therefore, do not require the preparation of an EIS or an EA. Paragraph 30-20-40 of the HHS General Administration Manual establishes categories of exclusion for Departmental actions and provides for the listing of actions by Operating Divisions within the Department. The IHS, as an agency of the PHS, hereby gives notice of its listing of actions which normally can be categorically excluded from further environmental review.

If a proposed action belongs to an excluded category but one or more extraordinary or exceptional circumstances (as defined in Part K) apply, then an EA must be prepared for the purpose of determining whether an EIS is warranted.

The IHS provides comprehensive health care services to more than 1 million American Indians and Alaska Natives. The goal of the IHS program is to raise the health status of American Indians and Alaska Natives to the highest level possible. In carrying out this goal, the program has three main objectives: (1) To deliver the highest quality health services possible; (2) to assist tribes and native corporations to develop their capacity to manage health programs; and (3) to serve as an advocate for American Indians and Alaska Natives in health related matters.

The IHS program is carried out through a health services delivery system, designed to provide a broad mix of preventive, curative, rehabilitative, and environmental services. The type of health services delivery system

employed varies from Area to Area. Population, health indices, and facilities and services available from sources other than the IHS are evaluated to determine the methods IHS uses to provide services.

The IHS program consists of two major systems: (1) A Federal health care delivery system, administered by Federal employees, and (2) a tribal health delivery system, administered by tribes and tribal groups under grants, contracts or cooperative agreements. The categorical exclusions apply to IHS program actions whether carried out directly by the IHS, or funded or otherwise sponsored by the IHS. The IHS contracts, grants, and cooperative agreements are actions defined in NEPA and are subject to the IHS review procedures established to ensure NEPA compliance, including provisions covering extraordinary and exceptional circumstances. The NEPA compliance for the tribal health care delivery system is ensured through IHS administrative procedures for contracts, grants, and cooperative agreements.

The selection of IHS program actions to list as categorical exclusions has been determined, in part, by agency experience in complying with NEPA, during the past 10 years. Actions required to provide health care services will not have significant impact on the environment except when exceptional or extraordinary circumstances exist. The IHS has categorically excluded these actions, since enactment of NEPA; however, actions involving construction normally have required completion of an environmental review/assessment.

The IHS administers programs for the construction of domestic sanitation facilities (water, wastewater, and solid waste) for Indian homes and communities, construction of new or replacement health care facilities and staff quarters, and renovations to existing health care facilities and quarters units.

Environmental reviews/assessments of construction projects undertaken during the past 10 years have concluded that an EIS was not required for any of them. Approximately 2,300 sanitation facilities construction projects and fewer than 60 health care facilities/staff quarters construction projects have been approved during this time.

The type of program and procedures employed to administer the construction of sanitation facilities for Indian homes and communities, and the consistent determinations that these projects do not have a significant impact on the environment, are the basis for the decision to list most sanitation facilities projects are categorically excluded. Factors considered in making this determination include:

1. Projects are undertaken to improve health and/or environment.
2. Projects are untaken at the request and with approval of the tribal governing body, which provides for discussion and evaluation of the project and its impacts.
3. Projects are normally constructed on tribally owned or individually owned tribal land within reservation boundaries.
4. Projects are constructed to comply with all current applicable environmental regulations and plans and specifications are submitted to State and Federal agencies as necessary for review and comment.
5. Projects are constructed to provide utilities (water, sewer, solid waste) either for existing American Indian or Alaska Native homes or for new homes constructed with Federal, tribal, State or other resources. New homes are constructed at sites and locations approved by the Tribal Governing Board. Utilities are not provided for future development or undeveloped parcels, and capacity provided is limited to that routinely provided by standard engineering practice for the current design population.
6. The IHS projects fall into the category of minor construction projects based on cost. During the last 10 years, 85 of the 2,300 projects exceeded $1 million, and the average estimated cost was $250,000.
7. Standard IHS procedures require documentation of an environmental review of each construction project to identify any exceptional or extraordinary circumstances and to ensure compliance with all environmental laws, regulations, and executive orders; e.g., those concerning floodplains, wetlands, endangered species, etc. This review is required early in the project planning process.

The categorical exclusion for construction of health care facilities and staff quarters has been limited to renovation or new construction at existing health care delivery sites, and construction or development of relatively small facilities at new locations. The procedures noted in item 7 above for sanitation facilities construction projects also apply to all health care facility and staff quarters construction projects. Most health care facility and staff quarters renovation projects can be classified as minor construction projects based on cost. Fewer than 200 major renovation projects have been undertaken and only a few were funded at a level exceeding $1 million.

Categorical Exclusions

A. Health Services

Direct delivery of medical, dental, nursing, and other related health services; e.g., patient care/counseling administered from hospitals, health centers, health stations, satellite clinics, and in private homes by IHS staff or contract providers to authorized recipients.

B. Research

Research activities that are consistent with the mission of IHS including: (a) Biological and behavioral studies conducted in laboratories, clinics, and the field; (b) studies on the development and delivery of prevention and treatment services and their administration and financing; and (c) evaluations of prevention and treatment.

C. Pesticides

Application of pesticides which are not classified for restricted use under provisions of the Federal Insecticide, Fungicide and Rodenticide Act when used for routine pest control purposes.

D. Contracts, Grants, and Cooperative Agreements

Contracts, grants, and cooperative agreements and continuations, supplements, extensions, and amendments of these documents for IHS programs or actions that are categorically excluded. (Includes Self-Determination Act contracts, Contract Health Care contracts, etc.)

E. Technical Assistance

Action involving the provision of technical assistance to American Indian and Alaska Native tribes and groups, other Federal agencies, State and local governments, and non-profit organizations are excluded. These actions include but are not limited to:

1. The provision of technical assistance to American Indian and Alaska Native tribes and groups for the purpose of developing management capabilities needed to enable eventual tribal assumption of health program operation;
2. The provision of technical assistance to American Indian and Alaska Native tribes and groups for the purpose of developing capabilities in the areas of epidemiology, disease reduction, injury prevention, environmental improvement, and the operation and maintenance of sanitation facilities; and
3. The assignment of IHS personnel to agencies/organizations for the purpose of providing technical expertise (e.g.,

investigation, diagnosis, consultation, counseling) in health programs.

F. Management and Administrative Support

Routine management and administrative support actions.

G. Training, Education, and Manpower Development

The award of training grants, scholarships, and the provision of other types of training and educational assistance are excluded. These actions include:

1. Support for development of professional and paraprofessional health competencies;
2. Support for development of American Indian and Alaskan Natives health management capabilities;
3. Support for development of tribal and community capabilities in the areas of environmental improvement, disease reduction, injury control, and operation and maintenance of sanitation facilities;
4. Support for training and education of IHS personnel necessary for the efficient accomplishment of the IHS program; and
5. Educational activities including development of disease prevention and treatment and presentation of such material to American Indian and Alaskan Natives.

H. Statistics, Data Processing, and Information Gathering

Actions associated with statistics and information collection and dissemination are excluded. These actions typically involve:

1. Collection of demographic or morbidity data and analysis for program management and budget justification purposes;
2. Epidemiologic studies;
3. Environmental surveillance activities (e.g., sample collection, analysis, and monitoring of air, food, water, and wastewater) to determine quality as a basis for ensuring necessary corrective action;
4. Engineering studies and investigations including soil boring and test well drilling to gather data for the purpose of determining engineering feasibility and to permit facility design;
5. Updating existing data bases and data processing;
6. Printing and distributing reports; and
7. Developing new/redesignating existing data systems to meet specific program needs.

I. Indian Health Service Owned and Leased Facilities

Actions related to the IHS owned and leased facilities, or actions funded by IHS at tribally owned (or leased) and managed facilities as listed below, are excluded:

1. Maintenance and day-to-day operation of the physical plant and repairs to plant and equipment, or replacement-in-kind of utilities and building components;
2. Acquisition of equipment, provided all requirements for permits, registrations, and licenses are met, and provided the equipment involves use of generally accepted technology;
3. Building alteration or renovation that does not substantially change the function or general appearance of existing buildings;
4. Construction or lease of new facilities (including portable facilities and trailers) where such lease or construction:

(a) Is at the site of an existing health care facility and the facility capacity is not substantially increased,

(b) Is for buildings of less than 12,000 square feet of useable space when less than five acres of surface land area are involved at a new site, or

(c) Is for projects other than buildings when less than five acres of surface land area are involved at a new site;

5. Facility planning and design including funding of such activities;
6. Acquisition of space by lease, use agreement, transfer, gift or similar arrangement for which:

(a) The intended use of the space is consistent with the functional design of the building, and

(b) The acquisition is consistent with an applicable master plan, if such plan exists;

7. The acquisition, sale, release, abandonment, closure or transfer of real property, provided the action:

(a) Is consistent with any applicable master plan, if such a plan exists,

(b) Conforms to local zoning and land use ordinances, if such ordinances exist,

(c) Is consistent with the functional design of the facility,

(d) Would not violate applicable Federal, State, or local environmental protection or historic preservation laws, and

(e) Satisfies the requirements of applicable comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) section 120 (h) provisions.

J. Construction of Sanitation Facilities

Actions associated with construction of sanitation facilities to serve Indian homes and communities, except that the following actions are not excluded:

(1) Construction of a sanitary landfill at a new solid waste disposal site, and

(2) Construction of a new wastewater treatment facility with direct discharge of treated sewage to surface waters.

K. Extraordinary or Exceptional Circumstances

Under extraordinary circumstances, the normally excluded actions described above may have a significant environmental effect; such actions are not categorically excluded. Actions that can be characterized by, or may cause any of, the conditions described below are examples of actions that are not categorically excluded:

1. Those with potential to change the existing environment where such change violates directives or other controls that are imposed by any governmental body having jurisdiction, for the purpose of protecting or otherwise affecting that environment;
2. Those with potential or real threat of violation, or continued violation, of an applicable Federal, State, or local law or requirement imposed for protection of the environment or to ensure public health and safety;
3. Those likely to cause controversy with respect to the types or extent of the resulting environmental effects where such controversy is based on pertinent and substantial issues;
4. Those involving the use of technology where the possible effects are highly uncertain or involve unique or unknown risks and where such technology has not been assessed previously for environmental impact;
5. Those which have adverse effects on unique geographic characteristics (e.g., historic, archeological, or cultural resources, park recreation or refuge lands, wilderness areas, wild or scenic rivers, sole or principal drinking water aquifers, prime farmlands, wetlands, floodplains, coastal management zones or ecological or critical areas including those listed on the Department of Interiors National Register of National Landmarks);
6. Those which establish a precedent for future action or represent a decision in principle about future actions with potentially significant environmental effects;
7. Those which have adverse effects on properties listed or eligible for listing on the National Register of Historic Places;
8. Those which have adverse effects on species listed by the Federal Government as endangered or Threatened Species, or which have adverse effects on any designated critical habitat for these species;
9. Those which require assessment in accordance with Executive Order 11988 (Floodplain Management), or Executive

Order 11990 (Protection of Wetlands), or the Fish and Wildlife Coordination Act; and

10. Those which involve the use, transfer, or lease of real property which has been determined, after investigation in accordance with the provisions of CERCLA 120 (h), to have been used as a storage facility for hazardous waste for more than 1 year; and

11. Construction projects which are significantly greater in scope or size than normally experienced for a particular category of action.

Dated: December 29, 1992.

Michel E. Lincoln,

Deputy Director.

[FR Doc. 93-173 Filed 1-5-93; 8:45 am]

BILLING CODE 4160-16-M

National Institutes of Health

John E. Fogarty International Center for Advanced Study in the Health Sciences; Meeting of the Fogarty International Center Advisory Board

Pursuant to Public Law 92-463, notice is hereby given of the twenty-third meeting of the Fogarty International Center (FIC) Advisory Board, February 9, 1993, in the Lawton Chiles International House (Building 16), at the National Institutes of Health.

The meeting will be open to the public from 8:30 a.m. to 2:30 p.m. The morning agenda will include a report by the Director, FIC; a report of the meeting of the NIH Director's Advisory Committee; and a status report on FIC's long-range planning.

The afternoon agenda will be a report on a minority scientists international training initiative and a report on emerging infections.

In accordance with the provisions of sections 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92-463, the meeting will be closed to the public from 2:30 p.m. to adjournment for the review of applications for International Research Fellowships, Senior International Fellowships, Fogarty International Research Collaboration Awards, AIDS International Research Training Program, nominations for Scholars-in-Residence award, and proposals for Scholars Conferences.

Myra Halem, Committee Management Assistant, Fogarty International Center, Building 31, room B2C08, National Institutes of Health, Bethesda, Maryland 20892 (301-496-1491), will provide a summary of the meeting and a roster of the committee members upon request.

Dr. Coralie Farlee, Assistant Director for International Legislation and Advisory Activities, Fogarty International Center (Executive Secretary), Building 31, Room B2C08, telephone 301-496-1491, will provide substantive program information.

Catalog of Federal Domestic Assistance Program No. 93.154, Special International Postdoctoral Research Program in Acquired Immunodeficiency Syndrome and No. 93.989, Senior International Awards program.

Dated: December 23, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93-142 Filed 1-5-93; 8:45 am]

BILLING CODE 4140-01-M

Notice of Meeting of the National Advisory Council for Human Genome Research

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the National Advisory Council for Human Genome Research, National Center for Human Genome Research, January 24 and 25, 1993, in Chevy Chase I & II, Embassy Suites Hotel, Chevy Chase Pavilion, 4300 Military Road, NW., Wisconsin at Western Avenue, Washington, DC.

This meeting will be open to the public on January 25, 1993, from 8:30 a.m. to 10 a.m. to discuss administrative details or other issues relating to committee activities. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92-463, the meeting will be closed to the public on January 24 from 7 p.m. to recess and on January 25, 1993, from 10 a.m. to adjournment, for the review, discussion and evaluation of individual grant applications. The applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Dr. Elke Jordan, Deputy Director, National Center for Human Genome Research, National Institutes of Health, Building 38A, room 605, Bethesda, Maryland 20892, (301) 496-0844, will furnish the meeting agenda, rosters of Committee members and consultants, and substantive program information upon request.

(Catalogue of Federal Domestic Assistance Program No. 93.172, Human Genome Research.)

Dated: December 23, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93-150 Filed 1-5-93; 8:45 am]

BILLING CODE 4140-01-M

National Cancer Institute; Meeting of the Cancer Biology-Immunology Contracts Review Committee (Subcommittees B&D)

Pursuant to Public Law 92-463, notice is hereby given of a meeting of Subcommittees B&D, of the Cancer Biology-Immunology Contracts Review Committee, National Cancer Institute, National Institutes of Health, January 15, 1993, at the Executive Plaza North Building, in Conference Room "G", 6130 Executive Boulevard, Bethesda, Maryland 20892.

This meeting will be open to the public on January 15 from 8:30 a.m. to 9:30 a.m. to discuss administrative details. Attendance by the public will be limited to space available.

In accordance with provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92-463, the meeting will be closed to the public on January 15 from 9:30 a.m. to adjournment for the review, discussion, and evaluation of individual contract proposals. These proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the proposals, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

The Committee Management Officer, National Cancer Institute, Building 31, room 10A06, National Institutes of Health, Bethesda, Maryland 20892, Tel. 301/496-5708, will provide summaries of the meeting and rosters of committee members upon request.

Dr. Lalita D. Palekar, Scientific Review Administrator, Cancer Biology-Immunology Contracts Review Subcommittee C, 5333 Westbard Avenue, room 805, Bethesda, Maryland 20892, Tel. 301/496-7575, will furnish substantive program information.

(Catalog of Federal Domestic Assistance Program Numbers: 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control.)

Dated: December 24, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93-152 Filed 1-5-93; 8:45 am]

BILLING CODE 4140-01-M

National Center for Nursing Research; Meeting: National Advisory Council for Nursing Research and its Subcommittees

Pursuant to Public Law 92-463, notice is hereby given of the meetings of the National Advisory Council for Nursing Research, National Center for Nursing Research; and its Subcommittees, February 1-3, 1993, Building 31C, Conference Room 6, National Institutes of Health, Bethesda, Maryland 20892.

Meetings of the full Council and its Subcommittees will be held at times and places listed below. Attendance by the public will be limited to space available.

The full Council will meet in open session on February 2, from 8:30 a.m. to 4 p.m. and on February 3, from approximately 11 a.m. to adjournment. Agenda items will include the NCNR Director's Report, Molecular Biology Task Force and Interface for the Biological Studies Plan with NIH Strategic Plan, National Nursing Research Agenda Phase II Priorities, and Report on the Division of Extramural Programs.

The Planning Subcommittee will meet in open session February 1, in Building 31B, NCNR Conference Room (5B-03), from 12 noon to 2:30 p.m. to discuss long-term and strategic planning and policy issues.

The Nursing Resources and Health Policy Subcommittee will meet in open session February 1, in Building 31C, Conference Room 6, from 12 noon to 2 p.m. to discuss nursing resources and health policy as they relate to nursing science and the achievement of quality and effective outcomes in patient care.

The Communications Subcommittee will meet in open session February 1, in Building 31C, Conference Room 6, from 2:30 p.m. to 4:30 p.m. to discuss goals and strategies for enhancing communications with specific audiences.

The National Nursing Research Agenda Subcommittee will meet in open session February 1, in Building 31B, NCNR Conference Room (5B-03), from 9 a.m. to 11:30 a.m. to discuss the National Nursing Research Agenda in general and the Priority Expert Panels in particular.

In accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5, U.S. Code and section 10(d)) of Public Law 92-463, the meeting of the Research Subcommittee will be closed to the public on February 1, from 2:30 p.m. to 4:30 p.m., and the meeting of the full Council on February 3, from 8:30 a.m. to approximately 11 a.m. for the review, discussion, and evaluation of individual grant applications. The applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Dr. Ethel Jackson, Executive Secretary, National Advisory Council for Nursing Research, National Institutes of Health, Building 31, room 5B25, Bethesda, Maryland 20892, (301) 496-0472, will provide a summary of the meeting, roster of committee members, and substantive program information upon request.

(Catalog of Federal Domestic Assistance Program No. 93.361, Nursing Research, National Institutes of Health.)

Dated: December 23, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93-141 Filed 1-5-93; 8:45 am]

BILLING CODE 4140-01-M

National Eye Institute; Meeting of the National Advisory Eye Council

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the National Advisory Eye Council (NAEC) on February 4 and 5, 1993, in Building 31C, Conference Room 6, National Institutes of Health, Bethesda, Maryland.

The NAEC meeting will be open to the public from 8:30 a.m. until approximately 11:30 a.m. on Thursday, February 4, 1993. Following opening remarks by the Director, NEI, there will be presentations by the staff of the Institute and discussions concerning Institute programs and policies. Attendance by the public at the open sessions will be limited to space available.

In accordance with provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92-463, the meeting of the NAEC will be closed to the public from approximately 11:30 a.m. on Thursday, February 4 until adjournment on Friday, February 5 for the review, discussion, and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. Lois DeNinno, Committee Management Officer, National Eye Institute, Building 31, room 6A04, National Institutes of Health, Bethesda, Maryland 20892, (301) 496-9110, will provide a summary of the meeting, roster of committee members, and substantive program information upon request.

(Catalog of Federal Domestic Assistance Programs, Nos. 93.867, Retinal and Choroidal Disease Research; 93.868, Anterior Segment Diseases Research; and 93.871, Strabismus, Amblyopia and Visual Processing; National Institutes of Health.)

Dated: December 23, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93-143 Filed 1-5-93; 8:45 am]

BILLING CODE 4140-01-M

National Heart, Lung, and Blood Institute; Heart, Lung, and Blood Special Emphasis Panels Meeting

Pursuant to Public Law 92-463, notice is hereby given of the meetings of the following Heart, Lung, and Blood Special Emphasis Panels.

These meetings will be closed in accordance with the provisions set forth in sec. 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and sec. 10(d) of Public Law 92-463, for the review, discussion and evaluation of individual grant applications, contract proposals, and/or cooperative agreements. These applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Panel: NHLBI SEP on The Framingham Study: Physical Examination, Testing and Surveillance.

Scientific Review Administrator: Dr. C. James Scheirer.

Telephone Number: 301-496-7363.

Dates of Meeting: January 4-5, 1993.

Place of Meeting: Newton Marriott Hotel, Newton, Massachusetts.

Time of Meeting: 7:30 p.m.

Reason for Closure: To review contract proposals.

Name of Panel: NHLBI SEP review for Predictors of Perioperative Cardiac Morbidity (Telephone Conference Call)

Scientific Review Administrator: Dr. David Monsees.

Telephone Number: 301–496–7361.

Dates of Meeting: January 6, 1993.

Place of Meeting: 5333 Westbard Avenue, room 550, Bethesda, MD 20892.

Time of Meeting: 2 p.m. (e.s.t.)

Reason for Closure: To review grant applications.

(Catalog of Federal Domestic Assistance Program Nos. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institutes of Health.)

Dated: December 23, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–145 Filed 1–5–93; 8:45 am]

BILLING CODE 4140–01–M

National Heart, Lung, and Blood Institute; Meeting Heart, Lung, and Blood Special Emphasis Panel

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the following Heart, Lung, and Blood Special Emphasis Panel.

The meeting will be closed in accordance with the provisions set forth in sec. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and sec. 10(d) of Public Law 92–463, for the review, discussion and evaluation of individual grant application, contract proposals, and/or cooperative agreements. These applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Panel: NHLBI SEP on Production Characterization of Adenovirus Vector for Cystic Fibrosis Gene Therapy (Telephone Conference Call)

Dates of Meeting: January 19, 1993.

Time of Meeting: 2 p.m.

Place of Meeting: 5333 Westbard Avenue, room 5A10.

Agenda: To review and evaluate contract proposals.

Contact Person: Dr. Dennis Lang, Scientific Review Administrator, 5333 Westbard Avenue, room 5A10, Bethesda, Maryland 20892, (301) 496–5965.

(Catalog of Federal Domestic Assistance Program Nos. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institutes of Health.)

Dated: December 23, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–146 Filed 1–5–93; 8:45 am]

BILLING CODE 4140–01–M

National Heart, Lung, and Blood Institute; Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the following Heart, Lung, and Blood Special Emphasis Panel.

The meeting will be closed in accordance with the provisions set forth in sec. 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and sec. 10(d) of Public Law 92–463, for the review, discussion and evaluation of individual grant applications, contract proposals, and/or cooperative agreements. These applications and/or proposal and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Panel: NHLBI SEP on the Review of Program Project Grant Applications.

Date of Meeting: January 5, 1993

Time of Meeting: 8 a.m.

Place of Meeting: Holiday Inn Chevy Chase, Chevy Chase, Maryland.

Agenda: To review grant applications.

Contact Person: Dr. Louis M. Ouellette, (301) 496–7915.

(Catalog of Federal Domestic Assistance Program Nos. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institutes of Health.)

Dated: December 22, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–151 Filed 1–5–93; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Environmental Health Services; Notice of Meeting of National Advisory Environmental Health Sciences Council

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the National Advisory Environmental Health Services Council, January 25–26, 1993, at the National Institute of Environmental Health Services, Building 101 Conference Room, South Campus, Research Triangle Park, North Carolina. This meeting will be open to the public on January 25 from 9 a.m. to approximately 2 p.m. and 8:30 a.m. to 10 a.m. on January 26 for the report of the Director, NIEHS, and for discussion of the NIEHS budget, program policies and issues, recent legislation, and other items of interest. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5, U.S.C. section 10(d) of Public Law 92–463, the meeting will be closed to the public on January 25, from approximately 2 p.m. to 5 p.m. and on January 26 from 10 a.m. to adjournment, for the review, discussion and evaluation of individual grant applications.

These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Winona Herrell, Committee Management Officer, NIEHS, Bldg. 31, Rm. B1C02, NIH, Bethesda, Md. 20892 (301) 496–3511, will provide summaries of the meeting and rosters of council members. Dr. Anne Sassaman, Director, Division of Extramural Research and Training, NIEHS, P.O. Box 12233, Research Triangle Park, North Carolina 27709, (919) 541–7723, will furnish substantive program information.

(Catalog of Federal Domestic Assistance Program Nos 93.113, Biological Response to Environmental Agents; 93.114, Applied Toxicological Research and Testing; 93.115, Biometry and Risk Estimation; 93.894, Resource and Manpower Development, National Institutes of Health)

Dated: December 23, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–149 Filed 1–5–93; 8:45 am]

BILLING CODE 4410–01–M

National Institute of General Medical Sciences; Notices of Meeting of the National Advisory General Medical Sciences Council

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the National Advisory General Medical Sciences Council, National Institute of General Medical Sciences, National Institutes of Health, on February 1–2, 1993, Building 1, Wilson Hall, Bethesda, Maryland.

This meeting will be open to the public on February 1, from 8:30 a.m. to 11 a.m. for opening remarks; report of the Director, NIGMS; and other business of the Council. Attendance by the public will be limited to space available.

In accordance with provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92–463, the meeting will be closed to the public on February 1 from 11 a.m. to 6 p.m., and on February 2 from 8:30 a.m. until adjournment, for the review, discussion, and evaluation of individual grant applications. The discussions of these applications could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Mrs. Ann Dieffenbach, Public Information Officer, National Institute of General Medical Sciences, National Institutes of Health, Building 31, room 4A52, Bethesda, Maryland 20892, Telephone: 301–496–7301 will provide a summary of the meeting and a roster of council members. Dr. W. Sue Shafer, Executive Secretary, NAGMS Council, National Institutes of Health, Westwood Building, room 938, Bethesda, Maryland 20892, Telephone: 301–496–7061 will provide substantive program information upon request.

(Catalog of Federal Domestic Assistance Program Nos. 93.821, Biophysics and Physiological Sciences; 93.859, Pharmacological Sciences; 93.862, Genetics Research; 93.863, Cellular and Molecular Basis of Disease Research; 93.880, Minority Access Research Careers [MARC]; and 93.375, Minority Biomedical Research Support [MBRS]).

Dated: December 23, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–148 Filed 1–5–93; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Mental Health; Advisory Committee Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meeting of an advisory committee of the National Institute of Mental Health for January 1993.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and sec. 10(d) of Public Law 92–463, for the review, discussion and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. Joanna L. Kieffer, Committee Management Officer, National Institute of Mental Health, Parklawn Building, room 9–105, 5600 Fishers Lane, Rockville, MD 20857, Area Code (301) 443–4333, will provide a summary of the meeting and a roster of committee members.

Other information pertaining to the meeting may be obtained from the contact indicated.

Committee Name: Neuroscience Subcommittee, Mental Health Special Projects Review Committee.

Meeting Date: January 10–12, 1993.

Place: Hyatt Hotel, 4290 El Camino Real, Palo Alto, CA 94306.

Open: January 10, 8–9 a.m.

Closed: January 10, 9 a.m., to adjournment on January 12.

Contact: Helen D. Craig, room 9C–18, Parklawn Building, Telephone (301) 443–3857.

(Catalog of Federal Domestic Assistance Program Numbers 93.126, Small Business Innovation Research; 93.176, ADAMHA Small Instrumentation Program Grants; 93.242, Mental Health Research Grants; 93.281, Mental Research Scientist Development Award and Research Scientist Development Award for Clinicians; 93.282, Mental Health Research Service Awards for Research Training; and 93.921, ADAMHA Science Education Partnership Award.)

Dated: December 23, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–144 Filed 1–5–93; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Mental Health; Meetings

Pursuant to Public Law 92–463, notice is hereby given of the meetings of the National Advisory Mental Health Council and the review committees of the National Institute of Mental Health for February 1993.

These meetings will be open to the public as indicated below for the discussion of NIMH policy issues and will include current administrative, legislative, and program developments.

All meetings will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92–463, for the review, discussion and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. Joanna L. Kieffer, Committee Management Officer, National Institute of Mental Health, Parklawn Building, room 9–105, 5600 Fisher Lane, Rockville, MD 20857, Area Code 301, 443–4333, will provide a summary of the meeting and a roster of committee members.

Other information pertaining to the meetings may be obtained from the contact person indicated.

Committee Name: Mental Disorders of Aging Review Committee.

Contact: Pyllis L. Zusman, room 9C–02, Parklawn Building, Telephone: 301–443–1340.

Meeting Date: February 3–5, 1993.

Place: Chevy Chase Holiday Inn, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Open: February 3, 1993, 9 a.m.–10 a.m.

Closed: February 3, 1993, 10 a.m.–5 p.m., February 4, 1993, 9 a.m.–5 p.m., February 5, 1993, 9 a.m.–adjournment.

Committee Name: Neuropharmacology and Neurochemistry Review Committee.

Contact: William H. Radcliff, room 9C–18, Parklawn Building, Telephone: 301–443–3857.

Meeting Date: February 4–5, 1993.

Place: Bethesda Holiday Inn, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Open: February 4, 1993, 8:30 a.m.–9:30 a.m.

Closed: February 4, 1993, 9:30 a.m.–5 p.m., February 5, 1993, 8:30 a.m.–adjournment.

Committee Name: Perception and Cognition Review Committee.

Contact: Debra D. Woods, room 9C–23, Parklawn Building, Telephone: 301–443–1177.

Meeting Date: February 4–6, 1993.

Place: Dupont Plaza Hotel, 1500 New Hampshire Avenue, NW., Washington, DC 20036.

Open: February 4, 1993, 9 a.m.–10 a.m.

Closed: February 4, 1993, 10 a.m.–5 p.m., February 5, 1993, 9 a.m.–5 p.m., February 6, 1993, 9 a.m.–adjournment.

Committee Name: National Advisory Mental Health Council.

Contact: Carolyn Strete, Ph.D., room 9–105, Parklawn Building, Telephone: 301, 443–3367.

Meeting Date: February 8–9, 1993.

Place: February 8—Conference Rooms D and E, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

February 9—Wilson Hall, Building 1, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20892.

Open: February 9, 8:30 a.m. to adjournment.

Closed: February 8, 8:30 a.m. to 5 p.m.

Committee Name: Behavioral Neuroscience Review Committee.

Contact: William H. Radcliffe, room 9C–18, Parklawn Building, Telephone: 301, 443–3857.

Meeting Date: February 11–12, 1993.

Place: Chevy Chase Holiday Inn, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.
Open: February 11, 1993, 8:30 a.m.–9:30 a.m.
Closed: February 11, 1993, 9:30 a.m.–5 p.m., February 12, 1993, 8:30 a.m.–adjournment.

Committee Name: Social and Group Processes Review Committee.
Contact: Bernice R. Cherry, room 9C–15, Parklawn Building, Telephone: 301, 443–6470.
Meeting Date: February 11–13, 1993.
Place: Marriott Residence Inn, 7335 Wisconsin Avenue, Bethesda, MD 20814.
Open: February 11, 1993, 9 a.m.–10 a.m.
Closed: February 11, 1993, 10 a.m.–5 p.m., Februrary 12, 1993, 9 a.m.–5 p.m., February 13, 1993, 9 a.m.–adjournment.

Committee Name: Clinical Psychopathology Review Committee.
Contact: Doris Lee-Robb, Room 9C–08, Parklawn Building, Telephone: 301, 443–1340.
Meeting Date: February 17–19, 1993.
Place: Embassy Suites Hotel, 4300 Military Road, NW., Washington, DC 20015.
Open: February 17, 1993, 9 a.m.–10 a.m.
Closed: February 17, 1993, 10 a.m.–5 p.m., February 18, 1993, 9 a.m.–5 p.m., February 19, 1993, 9 a.m.–adjournment.

Committee Name: Health Behavior and Prevention Review Committee.
Contact: Monica F. Woodfork, room 9C–05, Parklawn Building, Telephone: 301, 443–4843.
Meeting Date: February 17–19, 1993.
Place: Chevy Chase Holiday Inn, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.
Open: February 17, 1993, 8:30 a.m.–9:30 a.m.
Closed: February 17, 1993, 9:30 a.m.–5 p.m., February 18, 1993, 8:30 a.m.–5 p.m., February 19, 1993, 8:30 a.m.–adjournment.

Committee Name: Clincial Neuroscience Review Committee.
Contact: Maurine L. Eister, room 9C–18, Parklawn Building., Telephone: 301, 443–3936.
Meeting Date: February 17–19, 1993.
Place: Marriott Residence Inn, 7335 Wisconsin Avenue, Bethesda, MD 20814.
Open: February 17, 1993, 9 a.m.–10 a.m.
Closed: February 17, 1993, 10 a.m.–5 p.m., February 18, 1993, 9 a.m.–5 p.m., February 19, 1993, 9 a.m.–adjournment.

Committee Name: Violence and Traumatic Stress Review Committee.
Contact: Phyllis D. Artis, room 9C–15, Parklawn Building, Telephone: 301, 443–6470.
Meeting Date: February 17–19, 1993.
Place: The River Inn Inn, 924 25th Street, NW., Washington, DC 20037.
Open: February 17, 1993, 8:30 a.m.–9:30 a.m.
Closed: February 17, 1993, 9:30 a.m.–5 p.m., February 18, 1993, 8:30 a.m.–5 p.m., February 19, 1993, 8:30 a.m.–adjournment.

Committee Name: Molecular, Cellular, and Developmental Neurobiology Review Committee.
Contact: Shirley H. Maltz, room 9C–18, Parklawn Building, Telephone: 301, 443–3857.
Meeting Date: February 18–19, 1993.
Place: Crowne Plaza Holiday Inn, 1750 Rockville Pike, Rockville, MD 20852.
Open: February 18, 1993, 8 a.m.–9 a.m.
Closed: February 18, 1993, 9 a.m.–5 p.m., February 19, 1993, 9 a.m.–adjournment.

Committee Name: Cognitive Functional Neuroscience Review Committee.
Contact: Shirley H. Maltz, room 9C–18, Parklawn Building, Telephone: 301, 443–3936.
Meeting Date: February 18–20, 1993.
Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.
Open: February 18, 1993, 9 a.m.–10 a.m.
Closed: February 18, 1993, 10 a.m.–5 p.m., February 19, 1993, 9 a.m.–5 p.m., February 20, 1993, 9 a.m.–adjournment.

Committee Name: Mental Health Small Business Research Review Committee.
Contact: Wm. Gregory Zimmerman, 9C–14, Parklawn Building, Telephone: 301, 443–1367.
Meeting Date: February 22–23, 1993.
Place: Washington Marriott Hotel, 1221 22nd Street, NW., Washington, DC 20037.
Open: February 22, 1993, 9 a.m.–10 a.m.
Closed: February 22, 1993, 10 a.m.–5 p.m., February 23, 1993, 9 a.m.–adjournment.

Committee Name: Child Psychopathology and Treatment Review Committee.
Contact: Tammye M. Cross, room 9C–14, Parklawn Building, Telephone: 301, 443–1367.
Meeting Date: February 24–26, 1993.
Place: Omni Georgetown Hotel, 2121 P Street, NW., Washington, DC 20037.
Open: February 24, 1993, 9 a.m.–10 a.m.
Closed: February 24, 1993, 10 a.m.–5 p.m., February 25, 1993, 9 a.m.–5 p.m., February 26, 1993, 9 a.m.–adjournment.

Committee Name: Services Research Review Committee.
Contact: Wm. Gregory Zimmerman, room 9C–14, Parklawn Building, Telephone: 301, 443–1367.
Meeting Date: February 24–26, 1993.
Place: Washington Marriott, 1221 22nd Street, NW., Washington, DC 20037.
Open: February 24, 1993, 9 a.m.–10 a.m.
Closed: February 24, 1993, 10 a.m.–5 p.m., February 25, 1993, 9 a.m.–5 p.m., February 26, 1993, 9 a.m.–adjournment.

Committee Name: Emotion and Personality Review Committee.
Contact. Sheri L. Schwartzback, room 9C–05, Parklawn Building, Telephone: 301, 443–4843.
Meeting Date: February 25–26, 1993.
Place: Georgetown Holiday Inn, 2101 Wisconsin Avenue, NW., Washington, DC 20007.
Open: February 25, 1993, 8:30 a.m.–9 a.m.
Closed: February 25, 1993, 9 a.m.–5 p.m., February 26, 1993, 8:30 a.m.–adjournment.

Committee Name: Child/Adolescent Risk and Prevention Review Committee.
Contact: Michele D. Campbell, room 9C–23, Parklawn Building, Telephone: 301, 443–1177.
Meeting Date: February 25–27, 1993.
Place: Marriott Residence Inn, 7335 Wisconsin Avenue, Bethesda, MD 20814.
Open: February 25, 1993, 9 a.m.–10 a.m.
Closed: February 25, 1993, 10 a.m.–5 p.m., February 26, 1993, 9 a.m.–5 p.m., February 27, 1993, 9 a.m.–adjournment.

(Catalog of Federal Domestic Assistance Program Numbers 93.126, Small Business Innovation Research; 93.176, ADAMHA Small Instrumentation Program Grants; 93.242, Mental Health Research Grants; 93.281, Mental Research Scientist Development Award and Research Scientist Development Award for Clinicians; 93.282, Mental Health Research Service Awards for Research Training; and 93.921, ADAMHA Science Education Partnership Award.)

Dated; December 23, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–147 Filed 1–5–93; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Neurological Disorders and Stroke; Meeting

Pursuant to Public Law 92–463, notice is hereby given of meetings of committees of the National Institute of Neurological Disorders and Stroke (NINDS). These meetings will be open to the public to discuss program planning, program accomplishments and special reports or other issues relating to committee business as indicated in the notice.

The Council meeting will be open to the public on February 4, 1993, as listed below. The agenda includes a report by the Director, NINDS, and a report by the Director, Division of Intramural Research, NINDS. Attendance by the public will be limited to space available.

These meetings will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and sections 10(d) of Public Law 92–463, for the review, discussion and evaluation of individual grant applications. These applications and discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Summaries of meetings, rosters of committee members, and other information pertaining to the meetings can be obtained from the Executive Secretary or the Scientific Review Administrator indicated.

Name of Committee: The Planning Subcommittee of the National Advisory Neurological Disorders and Stroke Council.
Date: February 3, 1993.
Place: National Institutes of Health, Building 31, Conference Room 8A28, 9000 Rockville Pike, Bethesda, MD 20892.

Open: 1 p.m.–3 p.m.
Closed: 3 p.m.–recess.

Name of Committee: National Advisory Neurological Disorders and Stroke Council.
Dates: February 4–5, 1993.
Place: National Institutes of Health, Shannon Building—Wilson Hall, Bethesda, MD 20892.
Open: February 4, 9 a.m.–1 p.m.
Closed: February 4, 1 p.m.–recess, February 5, 8:30 a.m.–adjournment.
Executive Secretary: Constance W. Atwell, Ph.D. Special Assistant for Extramural Activities, NINDS, National Institutes of Health Bethesda, MD 20892, Telephone: (301) 496–9248.

Name of Committee. Neurological Disorders Program Project Review A Committee.
Dates: February 13–15, 1993.
Place: Pier 66 Resort and Marina, 2301 S.E. 17th Causeway, Fort Lauderdale, FL 33316.
Open: February 13, 7:30 p.m.–8 p.m.
Closed. February 13, 8 p.m.–recess, February 14, 8:30 a.m.–recess, February 15, 8:30 a.m–adjournment.
Scientific Review Administrator: Dr. Katherine Woodbury, Federal Building, room 9C–14, National Institutes of Health, Bethesda, MD 20892, Telephone: (301) 496–9223.

Name of Committee: Training Grant and Career Development Review Committee.
Dates: February 22–23, 1993.
Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.
Open: February 22, 8:30 a.m.–9 a.m.
Closed. February 22, 9 a.m.–recess, February 23, 8 a.m.–adjournment.
Scientific Review Administrator: Dr. Herbert Yellin, Federal Building, room 9C–10, National Institutes of Health, Bethesda, MD 20892, Telephone: (301) 496–9223.

Name of Committee: Neurological Disorders Program Project Review B Committee.
Dates. February 25–27, 1993.
Place: Holiday Inn Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.
Open February 25, 7 p.m.–7:30 p.m.
Closed: February 25, 7:30 p.m.–recess, February 26, 8:30 a.m.–recess, February 27, 8:30 a.m.–adjournment.
Scientific Review Administrator: Dr. Paul Sheehy, Federal Building, room 9C–14, National Institutes of Health, Bethesda, MD 20892, Telephone: (301) 496–9223.

(Catalog of Federal Domestic Assistance Program No. 93.853, Clinical Research Related to Neurological Disorders; No. 93.854, Biological Basis Research in the Neurosciences).

Dated: December 23, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–137 Filed 1–5–93; 8:45 am]

BILLING CODE 4140–01–M

National Institute on Deafness and Other Communication Disorders; Meetings of the National Deafness and Other Communication Disorders Advisory Council and its Research Subcommittee

Pursuant to Public Law 92–463, notice is hereby given of the meetings of the National Deafness and Other Communication Disorders Advisory Council and its Training Subcommittee and Research Subcommittee on January 27–29, 1993, at the National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland. The meeting of the full Council will be held in Conference Room 6, Building 31C, and those of the subcommittees in Conference Room 7, Building 31C.

The meeting of the Training Subcommittee will be open to the public on January 27 from 12:30 pm to adjournment at approximately 2:30 pm. The meeting of the Research Subcommittee will be open to the public on January 27 from 2:30 pm until 3:30 pm for the discussion of policy issues. The meeting of the full Council will be open to the public on January 28 from 8:30 am until recess for a report from the Institute Director and discussion of extramural policies and procedures at the National Institutes of Health and the National Institute on Deafness and Other Communication Disorders and on January 29 from 8:30 am to approximately 9 a.m. for a report on extramural programs of the Division of Communication Sciences and Disorders.

In accordance with the provisions set forth in section 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92–463, the meeting of the Research Subcommittee on January 27 will be closed to the public from 3:30 p.m. to adjournment. The meeting of the full Council will be closed to the public on January 29 from 9 a.m. until adjournment. The closed portions of the meetings will be for the review, discussion, and evaluation of individual grant applications. The applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Further information concerning the Council and Subcommittee meetings may be obtained from Dr. John C. Dalton, Executive Secretary, National Deafness and Other Communication Disorders Advisory Council, National Institute on Deafness and Other Communication Disorders, Executive Plaza South, room 400B, National Institutes of Health, Bethesda, Maryland 20892, 301–496–8693. A summary of the meetings and rosters of the members may also be obtained from his office.

(Catalog of Federal Domestic Assistance Program No. 93.173 Biological Research Related to Deafness and Other Communicative Disorders)

Dated: December 3, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–140 Filed 1–5–93; 8:45 am]

BILLING CODE 4140–01–M

National Library of Medicine; Meetings of the Board of Regents and Subcommittees

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Board of Regents of the National Library of Medicine on February 11–12, 1993, in the Board Room of the National Library of Medicine, 8600 Rockville Pike, Bethesda, Maryland. The Subcommittee will meet on February 10 as follows:

The Extramural Programs Subcommittee, 5th-floor Conference Room, Building 38A, 2 to approximately 3:30 p.m., and the Planning Subcommittee in Conference Room B, Building 38, 4 to approximately 5 p.m. The Extramural Programs Subcommittee will be closed to the public.

The meeting of the Board will be open to the public from 3 to approximately 4 p.m. on February 11 and from 9 a.m. to adjournment on February 12 for administrative reports and program discussions. Attendance will be limited to space available.

In accordance with provisions set forth in sections 552b(c)(4), 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92–463, the entire meeting of the Extramural Programs Subcommittee on February 10 will be closed to the public, and the regular Board meeting on February 11 will be closed from approximately 4 to adjournment for the review, discussion, and evaluation of individual grant applications. These applications and the discussion could reveal confidential trade secrets or commercial property, such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Mr. Robert B. Mehnert, Chief, Office of Inquiries and Publications Management, National Library of

Medicine, 8600 Rockville Pike, Bethesda, Maryland 20894, Telephone Number: 301–496–6308, will furnish a summary of the meeting, rosters of Board members, and other information pertaining to the meeting.

(Catalog of Federal Domestic Assistance Program No. 93.879—Medical Library Assistance, National Institutes of Health.)

Dated: December 23, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–138 Filed 1–5–93; 8:45 am]

BILLING CODE 4140–01–M

Prospective Grant of Exclusive Patent License

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: This is notice in accordance with 15 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i) that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license in a limited field of use to practice the inventions embodies in U.S. Patent Application 07/010,424 (now U.S. Patent Application 07/445,131), entitled "Vector for Recombinant Poxvirus Expressing Rabies Virus Glycoprotein," and U.S. Patent Application 07/198,213 (now U.S. Patent Application 07/829,597), entitled "Raccoon Poxvirus As a Gene Expression and Vaccine Vector for Genes of Rabies and Other Organisms" to Fort Dodge Laboratories Inc. having a place of business at Fort Dodge, Iowa. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license will be for the field of veterinary biologicals. It will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within sixty days from the date of this published Notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

These inventions relate to a novel plasmid containing a recombinant infectious vaccinia poxvirus for use in the production of rabies vaccine and production of rabies virus glycoprotein antigen, antibody, and related reagents. The inventions also relate to a recombinant vector containing raccoon poxvirus as a method for inducing protective immunity against rabies virus and other organisms.

The availability of U.S. Patent Application 07/010,424, for licensing was published in the April 30, 1987 edition of the **Federal Register**. The availability of U.S. Patent Application 07/198,213 for licensing was published in the June 28, 1988 edition of the **Federal Register**. Requests for a copy of the above identified patent applications, inquiries, comments and other materials relating to the contemplated license should be directed to: Mr. Mark Hankins, J.D., Office of Technology Transfer, National Institutes of Health, Box OTT, Bethesda, Maryland 20892 (telephone: (301) 496–7735; FAX: (301) 402–0220). Properly filed competing applications for a license filed in response to this notice will be treated as objections to the grant of the contemplated license. Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer within sixty (60) days of this notice will be considered.

Dated: December 23, 1992.

Reid G. Adler,

Director, Office of Technology Transfer

[FR Doc. 93–153 Filed 1–5–93; 8:45 am]

BILLING CODE 4140–01–M

Public Health Service

Treasury, Postal Service and General Government Appropriations Act of 1992; Delegation of Authority

Notice is hereby given that in furtherance of the delegation of authority of November 19, 1992, by the Secretary of Health and Human Services to the Assistant Secretary for Health, I have delegated to Director, Centers for Disease Control and Prevention, with authority to redelegate, all the authorities vested in the Assistant Secretary for Health under section 633 of the Treasury, Postal Service and General Government Act of 1992, Public Law 102–141, as amended hereafter. This delegation excludes the authority to promulgate regulations and to submit reports to Congress.

This delegation became effective upon date of signature. In addition, I have affirmed and ratified any actions taken by the Director, Centers for Disease Control and Prevention or his subordinates which, in effect, involved the exercise of the authorities delegated herein prior to the effective date of the delegation.

Dated: December 22, 1992.

James O. Mason,

Assistant Secretary for Health.

[FR Doc. 93–93 Filed 1–5–93; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Education Facilities Construction Priority List as of FY 1993

December 31, 1992.

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Indian Affairs (BIA) is publishing an Education Facilities Construction Policy List as of FY 1993. Publication of the Priority List in the **Federal Register** is required by statute. The Priority List includes those projects that were on the New School Construction Priority List for FY 1992 along with additions that have been made to the list. This Priority List is being published "as of FY 1993." Construction funding is not currently available for all of the Education Facilities Construction projects listed on the Priority List. As appropriations become available, Education Facilities Construction projects will be funded for construction in the order in which they are ranked.

FOR FURTHER INFORMATION CONTACT: W. "Buck" Martin, Director, Office of Construction Management, Department of the Interior, Mail Stop 2417 MIB, 1849 C Street, NW., Washington, DC 20240, telephone number (202) 208–3403.

SUPPLEMENTARY INFORMATION: The BIA is publishing the Priority List of Education Facilities Construction projects to satisfy 25 U.S.C. 2005(c) that provides: "At the time any budget request for school construction is presented, the Secretary shall publish in the **Federal Register** and submit with the budget request the current list of all school construction priorities."

The current priority ranking process is in accordance with the "Construction of School Facilities for Indian Children; School Construction Applications and Procedures" that were published in the **Federal Register** on May 22, 1979, at 44 FR 29864. Amended criteria to be used in the priority ranking of new school construction projects were published in the **Federal Register** on April 14, 1988, at 53 FR 12470.

On October 19, 1990, at 55 FR 42497, a notice was published that contained the "New School Construction Priority

List for FY 1992." The notice established a deadline of December 15, 1990, for filing applications to be considered for the FY 1993 priority ranking list.

The Conference Report for the Fiscal Year 1992 Interior and Related Agencies Appropriation Act, House Report No. 256, 102d Cong., 1st Sess., p. 46 (1991) (Conference Report) froze the "New School Construction Priority List for FY 1992." Under the current procedures, the priority list published each year has been a proposed list and subject to the availability of appropriated funds. Not all projects listed received construction funding. Those projects not funded had to file a new or updated application the next year to be considered for priority ranking. Applications were evaluated and a new list was prepared each year.

Congress provided funding for planning and design "for the top ten schools contained on the fiscal year [1992] priority list, to the extent that funds are available." Schools not funded for planning and design in FY 1992 would be funded for planning and design in FY 1993.

"[S]tarting at the top of the fiscal year 1992 list and including Pyramid Lake," construction funding was to be made available after completion of the necessary validations, planning and design. It was recognized by Congress that appropriations for FY 1992 were insufficient to provide construction funding for the ten schools listed on the New School construction Priority List of FY 1992 plus Pyramid Lake. The Conference Report stated that additional funds would be provided to complete these projects in FY 1993 and outyears.

The Conference Report further directed the Department "to review applications and prepare a new school construction priority list for fiscal year 1993, with these schools eligible for planning and design and construction funding, subject to budget constraints in fiscal year 1993 and beyond, in addition to any remaining fiscal year 1992 schools."

The Department published a notice in the **Federal Register** on December 6, 1991, at 56 FR 64185, that new applications and/or additional, supplemental materials in support of existing new school applications on file could be submitted for consideration for priority ranking in FY 1993. The notice established a deadline of January 31, 1992, for filing new or updated applications.

The applications submitted for inclusion on the FY 1993 list have been evaluated and priority ranked. Five (5) schools have been selected for inclusion on the new school priority list for FY 1993. Because Congress has created a continuous multi-year priority ranking list for new school construction, it is misleading to refer to the list as the priority list for FY 1993. Although some planning and design funding is available, construction funding has not been appropriated. Construction funding will not become available until funding has been provided for all the ten (10) schools on the New School Construction Priority List for FY 1992 plus the Congressional add-on, Pyramid Lake.

To prevent any confusion or misunderstanding, the Department is consolidating the FY 1992 and FY 1993 new school construction priority lists into one continuous multi-year list. For reference purposes, the list set out below is entitled: "Education Facilities Construction Priority List as of FY 1993." The list contains: The ten (10) new schools which were included on the "New School Construction Priority List for FY 1992," Nos. 1 through 10; plus Pyramid Lake, which was added by Congress, No. 11; and, the five (5) schools priority ranked for FY 1993, Nos. 12 through 16.

The priority ranking process under current procedures has been subject to criticism, primarily because of the uncertainty of the process, by Indian tribes and Indian organizations, as well as Congress. A decision had been made by the Department, prior to the FY 1992 Interior Appropriations Act, to promulgate regulations to govern the priority ranking process.

The Conference Report acknowledged the actions and directed the Department to continue efforts to revise the priority ranking process for new school construction. The Conference Report stated that emphasis should be given to tribal consultation and to improving the objectivity of the ranking process, to providing continuity to the priority ranking list and to providing procedures for handling emergency needs.

Tribal consultation meetings were held on a draft of a proposed rulemaking document in December 1991 and a proposed rule adding a new Part 294 Education Facilities Construction to title 25 of the Code of Federal Regulations should be published in the **Federal Register** in the near future.

Because of the current efforts to promulgate regulations and the action by Congress to create a continuous multi-year priority list, the Department does not intend to call for the filing of applications for new school construction under the current process, again. However, once the regulations are published as a final rule and are in effect, the Department will provide for the filing of applications.

As the regulations are currently drafted, not only will a notice be published in the **Federal Register**, but also mailed directly to all federally-recognized tribes and BIA-funded schools, whether BIA-operated, contract, or grant. The notice will advise individuals of the relevant procedures to be followed as well as the deadline for filing applications. Publication of a final rule is not anticipated until the end of 1993. Schools listed on the "Education Facilities Construction Priority List of FY 1993" will not have to reapply, but will be retained, in order, on the list. School construction projects priority ranked under the regulations will be added at the end of any schools remaining from the Education Facilities Construction Priority List as of FY 1993.

The "Education Facilities Construction Priority List as of FY 1993" is as follows:

Education Facilities Construction Priority List as of FY 1993

1. Pinon Community School Dorm
2. Eastern Cheyenne River Consolidated School
3. Rock Point Community School
4. Many Farms High School
5. Tucker Day School
6. Shoshone-Bannock/Fort Hall School
7. Standing Pine Day School
8. Chief Leschi School Complex
9. Seba Delkai Boarding School
10. Sac and Fox Settlement School
11. Pyramid Lake
12. Shiprock Alternative School
13. Tuba City Boarding School
14. Fond du Lac Ojibway School
15. Second Mesa Day School
16. Zia Day School

Eddie F. Brown,

Assistant Secretary—Indian Affairs.

[FR Doc. 93-192 Filed 1-5-93; 8:45 am]

BILLING CODE 4310-02-M

National Park Service

Completion of Inventory of Native American Human Remains From Hawaii in the Possession of the Peabody & Essex Museum

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is hereby given in accordance with provisions of the Native American Graves Protection and Repartriation Act, 25 U.S.C. 3003(d), of the completion of the inventory of human remains from Hawaii in the possession of the Peabody & Essex Museum. Representatives of

culturally affiliated Native Hawaiian organizations are advised that these human remains will be retained by the museum until February 5, 1993, after which they may be repatriated to the culturally affiliated group.

The detailed inventory and assessment of these human remains has been made by the Peabody & Essex Museum curatorial staff, specialists in physical anthropology and prehistoric archeology from the Bernice Pauahi Bishop Museum, Honolulu, HI, and representatives of Hui Mālama I Nā Kūpuna 'O Hawai'i Nei, a nonprofit, Native Hawaiian organization incorporated under the laws of the State of Hawaii and recognized under 25 U.S.C. 3001 (6) to provide guidance and expertise in decisions dealing with Native Hawaiian cultural issues, particularly burial issues.

The human remains consist of a cranium collected by Charles Derby in the Sandwich (now Hawaiian) Islands in the 19th Century. The cranium was accessioned by the Essex Institute prior to 1867 and catalogued as Hawaiian. Osteological documentation revealed a "rocker jaw" and upper palate typical of Polynesian individuals. The crania is believed to be of Hawaiian cultural affiliation based on this morphology and collection history.

Based on the above mentioned information, officials of the Peabody & Essex Museum have determined pursuant to 25 U.S.C. 3001 (2) that there is a relationship of shared group identity which can be reasonably traced between these remains and present-day Native Hawaiian organizations.

This notice has been sent to officials of Hui Mālama I Nā Kūpuna 'O Hawai'i Nei and the Office of Hawaiian Affairs. Representatives of any other Native Hawaiian organization which believes itself to be culturally affiliated with these human remains should contact John R. Grimes, Curator of Archeology, Peabody & Essex Museum, East India Square, Salem MA 01970, (508) 745-1876, before February 5, 1993.

Dated: December 31, 1992.

Francis P. McManamon,

Departmental Consulting Archeologist Chief, Archeological Assistance Division.

[FR Doc 93-139 Filed 1-5-93; 8:45 am]

BILLING CODE 4310-70-M

INTERSTATE COMMERCE COMMISSION

[Ex Parte No. 514 (A)]

Privacy Act: Establishment of a System of Records; Office of Inspector General Complaint and Investigative Files

AGENCY: Interstate Commerce Commission.

ACTION: Notice of proposed new system of records and request for comments.

SUMMARY: The Commission (ICC) is establishing a new system of records under the Privacy Act of 1974, as amended (5 U.S.C. 552a), Pub. L. 93-579, to consist of the complaint and investigatory file of the ICC's Office of Inspector General (OIG). The new system of records facilitates the OIG's ability to collect, maintain, use and disclose information pertaining to individuals, thus helping to ensure that the OIG may efficiently and effectively perform its investigations and other authorized duties and activities.

DATES: Comments are due February 5, 1993.

ADDRESSES: An original and two copies of comments referring to Ex Parte No. 514 (A) should be submitted to: Office of the Secretary, Case Control Branch, room 1324, Interstate Commerce Commission, Washington, DC 20423.

FOR FURTHER INFORMATION CONTACT: S. Arnold Smith, Freedom of Information/Privacy Officer (202) 927-6317. [TDD for hearing impaired: (202) 927-5721.

SUPPLEMENTARY INFORMATION: As required by 5 U.S.C. 552a(e)(4), the ICC is notifying the public of the establishment of a new system of records in its OIG (32-20-0015). This system is being established as part of the formal creation of an OIG within the ICC under the authority of the 1988 amendments to the Inspector General Act of 1978. See Pub. L. No. 100-504, 102 Stat.251 (amending 5 U.S.C. App. 3 1978)). Among the OIG's statutory duties are the prevention and detection of fraud, waste, and abuse relating to the ICC's programs and operations through the conduct of audits and investigations and the preparation of reports to the ICC's Chairman and to Congress.

The system of records being established consists of complaint and investigatory files compiled and maintained by the OIG. Due to the law enforcement nature of these records, the proposed system may be exempted by the ICC from certain provisions of the Privacy Act including disclosure to individuals who are the subject of a record in the system. See 5 U.S.C. 552a(j)(2) and (k)(2). The exemption of the system is the subject of a companion notice of proposed rulemaking to amend ICC Rule 49 CFR 1007.12. That notice is published in the proposed rule section of today's **Federal Register.** Pursuant to 5 U.S.C. 552a(o) and OMB Circular No. A-130, the ICC has submitted its report on the proposed establishment of this system of records to both Houses of Congress and to OMB.

Unless changes are made in response to comments received from the public, this action will become effective 30 days after final publication of the proposed amendment to ICC Rule 49 CFR 1007.12. The effective date may be extended if the Director of the Office of Management and Budget (OMB) declines, in whole or in part, the ICC's request to waive the 60 day period prescribed by OMB for advance notice to it and Congress. See OMB Circular No. A-130, App.1 at section 4b.(c)(4).

Accordingly, the ICC proposes to establish the following system of records.

32-20-0015

SYSTEM NAME:

OIG Complaint and Investigative Files.

SYSTEM LOCATION:

OIG, ICC. Room 2121, Washington, DC 20423.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals involved in complaints reported to and investigations conducted by the OIG relating to the programs and operations of the ICC.

CATEGORIES OF RECORDS IN THE SYSTEM:

Files containing information relevant to complaints and investigations. Files include all relevant correspondence, internal staff memoranda, copies of all subpoenas issued, affidavits, witness statements, transcripts of testimony and accompanying exhibits, working papers of the staff, and any other reports, documents, and records. These records are used as a basis for the issuance of subpoenas, suitability determinations, and civil, criminal, and administrative actions.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The authority for maintenance of the system is found under the Inspector General Act Amendments of 1988, Public Law 100-504, 102 Stat. 251 (amending 5 U.S.C. App. 3 (1978)).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures generally permitted under 5 U.S.C. 552a(b), these records or information in these records may specifically be disclosed pursuant to 5 U.S.C. 552a(b)(3) as follows, provided that no routine use specified herein shall be construed to limit or waive any other routine use specified herein:

(1) To other agencies, offices, establishments, and authorities, whether federal, state, local, foreign, or self-regulatory (including, but not limited to, organizations such as professional associations or licensing boards), authorized or with the responsibility to investigate, litigate, prosecute, enforce, or implement a statute, rule, regulation, or order, where the record or information, by itself or in connection with other records or information:

(a) Indicates a violation or potential violation of law, whether criminal, civil, administrative, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule, or order issued pursuant thereto, or

(b) Indicates a violation or potential violation of a professional, licensing, or similar regulation, rule or order, or otherwise reflects on the qualifications or fitness of an individual who is licensed or seeking to be licensed;

(2) To any source, private or governmental, to the extent necessary to secure from such source information relevant to and sought in furtherance of a legitimate investigation or audit;

(3) To agencies, offices, or establishments of the executive, legislative, or judicial branches of the federal or state government:

(a) Where such agency, office, or establishment has an interest in the individual for employment purposes, including a security clearance or determination as to access to classified information, and needs to evaluate the individual's qualifications, suitability, or loyalty to the United States Government, or

(b) Where an agency, office, or establishment conducts an investigation of the individual for purposes of granting a security clearance, or making a determination of qualifications, suitability, or loyalty to the United States Government or access to classified information or restricted areas, or

(c) Where the records or information in those records are relevant and necessary to a decision with regard to the hiring or retention of an employee or disciplinary or other administrative action concerning the employee, or

(d) Where disclosure is requested in connection with the award of a contract or other determination relating to a government procurement, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the record is relevant and necessary to the requesting agency's decision on the matter, including but not limited to, disclosure to any Federal agency responsible for considering suspension or debarment action where such record would be germane to a determination of the propriety or necessity of such action, or disclosure to the United States General Accounting Office, the General Services Administration Board of Contract Appeals, or any other Federal contract board of appeals in cases relating to an agency procurement;

(4) To the Office of Personnel Management, the Office of Government Ethics, the Merit Systems Protection Board, the Office of Special Counsel, the Equal Employment Opportunity Commission, or the Federal Labor Relations Authority or its General Counsel, of records or portions thereof relevant and necessary to carry out their authorized functions, such as, but not limited to, rendering advice requested by the OIG, investigations of alleged or prohibited personnel practices (including unfair labor or discriminatory practices), appeals before official agencies, offices, panels or boards, and authorized studies or reviews of civil service or merit systems or affirmative action programs;

(5) To independent auditors or other private firms with which the OIG has contracted to carry out an independent audit or investigation, or to analyze, collate, aggregate or otherwise refine data collected in the system of records, subject to the requirement that such contractors shall maintain Privacy Act safeguards with respect to such records;

(6) To any authorized component of the ICC, the Department of Justice, or other law enforcement authority, and for disclosure by such parties:

(a) To the extent relevant and necessary in connection with litigation in proceedings before a court or other adjudicative body, where (i) the United States is a party to or has an interest in the litigation, including where the ICC, or an ICC component, or an ICC official or employee in his or her official capacity, or an individual ICC official or employee whom the Department of Justice has agreed to represent, is or may likely become a party, and (ii) the ligation is likely to affect the agency or any component thereof, or

(b) For purposes of obtaining advice, including advice concerning the accessibility of a record or information under the Privacy Act or the Freedom of Information Act;

(7) To the National Archives and Record Administration for records management inspections conducted under authority of 44 U.S.C. 2904 and 2096;

(8) To a Congressional office from the record of a subject individual in response to an inquiry from the Congressional office made at the request of the individual, but only to the extent that the record would be legally accessible to that individual;

(9) To any direct recipient of federal funds, such as a contractor, where such record reflects serious inadequacies with a recipient's personnel and disclosure of the record is for purpose of permitting a recipient to take corrective action beneficial to the Government;

(10) To debt collection contractors for the purposes of collecting debts owed to the Government, as authorized under the Debt Collection Act of 1982, 31 U.S.C. 3718, and subject to applicable Privacy Act safeguards;

(11) To a grand jury pursuant either to a federal or state grand jury subpoena, or to a prosecution request that such record be released for the purposes of its introduction to a grand jury where subpoena or request has been specifically approved by a court;

(12) To OMB for the purposes of obtaining advice regarding ICC obligations under the Privacy Act; or

(13) To the Secretary of the ICC for purpose of placing any ex parte communication, which has not already been reported to the Secretary pursuant to 49 CFR 1102.2(e), in the correspondence section of the appropriate public docket.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

The OIG files consist of paper records maintained in binders or folders, and on automated data storage devices. Files are secured at all times.

RETRIEVABILITY:

Indexed on disk by case number. Paper records are filed numerically by case number. At this time, records are not cross-indexed by name and/or by subject but are expected to be retrieved in this fashion in the near future.

ACCESS CONTROL:

Access to the records is limited to authorized staff in OIG and to other

authorized officials or employees of ICC on a need-to-know basis as determined by the OIG. All records are kept in limited access areas during duty hours and in locked files at all other times.

RETENTION AND DISPOSAL:

To be retained for an unlimited period of time.

SYSTEM MANAGER AND ADDRESS:

Inspector General, OIG, ICC, room 2121, Washington, DC 20423.

NOTIFICATION PROCEDURE:

See 49 CFR Part 1007.

RECORD ACCESS PROCEDURE:

Same as above.

CONTESTING RECORD PROCEDURE:

Same as above.

RECORD SOURCE CATEGORIES:

Information in these records is obtained from all individuals and entities who may assist OIG in evaluating complaints and conducting investigations authorized by Pub. L. 100–504.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

This system is exempted from 5 U.S.C. 552a, except subsections (b), (c)(1) and (2), (e)(4)(A) through (F), (e)(6), (7), (9), (10), and (11) and (i), under 552a(j)(2) to the extent the system of records pertains to the enforcement of criminal laws; and is exempted from 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H), (I), and (f) under 5 U.S.C. 552a(k)(2), to the extent the system of records consists of investigatory materials compiled for law enforcement purposes, other than that material within the scope of the exemption at 5 U.S.C. 552a(j)(2).

5 U.S.C. App. 3 (1978) prohibits disclosure by the OIG of the identity of any employee, without the consent of the employee, who submits a complaint or provides information concerning the possible existence of an activity constituting a violation of law, rules or regulations, or mismanagement, gross waste of funds, abuse of authority, or a substantial and specific danger to the public health or safety.

Decided: December 21, 1992.

By the Commission, S. Arnold Smith, Freedom of Information/Privacy Officer.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–251 Filed 1–5–93; 8:45 am]

BILLING CODE 7035–01–M

[Finance Docket No. 32189]

The Broe Cos., Inc.; Continuance in Control Exemption; Central Kansas Railway, Inc.

AGENCY: Interstate Commerce Commission.

ACTION: Notice of exemption.

SUMMARY: The Commission, under 49 U.S.C. 10505, exempts The Broe Companies, Inc. from the regulatory requirements of 49 U.S.C. 11343, *et seq.*, for its continuance in control of Central Kansas Railway, Inc. (CKR) once CKR becomes a rail carrier.[1]

DATES: This exemption is effective on December 31, 1992. Petitions to reopen must be filed by January 26, 1993.

ADDRESSES: Send pleadings referring to Finance Docket No. 32189 to: (1) Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

(2) Petitioners' representatives: Louis E. Gitomer, Suite 210, 919 18th Street, NW., Washington, DC 20006.

FOR FURTHER INFORMATION CONTACT: Richard B. Felder, (202) 927–5610.

[TDD for hearing impaired: (202) 927–5721].

SUPPLEMENTARY INFORMATION: Additional information is contained in the Commission's decision. To purchase a copy of the full decision, write to, call, or pick up in person from: Dynamic Concepts, Inc., room 2229, Interstate Commerce Commission Building, Washington, DC 20423. Telephone: (202) 289–4357/4359. [Assistance for the hearing impaired is available through TDD services (202) 927–5721].

Decided: December 23, 1992.

By the Commission, Chairman Philbin, Vice Chairman McDonald, Commissioners Simmons and Phillips.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–179 Filed 1–5–93; 8:45 am]

BILLING CODE 7035–01–M

[Docket No. AB–3 (Sub-No. 104X]

Missouri Pacific Railroad Co., Abandonment Exemption; in Muskogee, McIntosh and Haskell Counties, OK

AGENCY: Interstate Commerce Commission.

ACTION: Notice of exemption.

SUMMARY: The Commission exempts from the prior approval requirements of 49 U.S.C. 10903–10904 the Abandonment by Missouri Pacific Railroad Company of 43.0 miles of its Midland Valley Branch between Shopton and Kerr McGee, OK, subject to standard labor protective conditions, environmental and historic preservation conditions, and a public use condition. In addition, interim trail use has been approved.

DATES: Provided no formal expression of intent to file an offer of financial assistance has been received, this exemption will be effective on February 5, 1993. Formal expressions of intent to file an offer[1] of financial assistance under 49 CFR 1152.27(c)(2) must be filed by January 16, 1993; petitions to stay must be filed by January 19, 1993; and petitions to reopen must be filed by February 1, 1993.

ADDRESSES: Send pleadings referring to Docket No. AB–3 (Sub-No. 104X) to:

(1) Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423, and

(2) Petitioner's representatives: Joseph D. Anthofer, Jeanna L. Regier, 1416 Dodge Street, #830, Omaha, NE 68179.

FOR FURTHER INFORMATION CONTACT: Richard B. Felder (202) 927–5610, [TDD for hearing impaired: (202) 927–5721].

SUPPLEMENTARY INFORMATION: Additional information is contained in the Commission's decision. To purchase a copy of the full decision, write to, call, or pick up in person from: Dynamic Concepts, Inc., Room 2229, Interstate Commerce Commission Building, Washington, DC 20423. Telephone: (202) 289–4357/4359. [Assistance for the hearing impaired is available through TDD services (202) 927–5271.]

Decided: December 29, 1992.

By the Commission, Chairman Philbin, Vice Chairman McDonald, Commissioners Simmons and Phillips.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–277 Filed 1–5–93; 8:45 am]

BILLING CODE 7035–01–M

[Docket No. AB–12 (Sub-No. 148X]

Southern Pacific Transportation Company—Abandonment Exemption—in Tyler, Jasper, and Angelina Counties, TX

Southern Pacific Transportation Company (SP) has filed a notice of exemption under 49 CFR part 1152

[1] CKR is acquiring approximately 890 miles of railroad from The Atchison, Topeka and Santa Fe Railway Company. See Finance Docket No. 32190, Central Kansas Railway, Inc.—Acquisition and Operation Exemption—Certain Lines of The Atchison, Topeka and Santa Fe Railway Company (notice of exemption filed December 10, 1992).

[1] *See Exempt. of Rail Abandonment—Offers of Finan. Assist.*, 4 I.C.C.2d 164 (1987).

Subpart F—Exempt Abandonments to abandon a 32.05-mile portion of its Rockland Branch rail line in Tyler, Jasper, and Angelina Counties, TX, between milepost 76.85, at or near the Hillister rail station, and milepost 108.90, at or near the Dolan rail station.

SP has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) any overhead traffic has been rerouted over other lines; and (3) no formal complaint filed by a user of rail service on the line (or a State or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Commission or any U.S. District Court or has been decided in favor of a complainant within the 2-year period. SP also has been certified that it has complied with the requirements at 49 CFR 1152.50(d)(1) (notice to government agencies), 49 CFR 1105.12 (newspaper publication), 49 CFR 1105.7, and 49 CFR 1105.8.

As a condition to this exemption, any employee affected by the abandonment shall be protected under Oregon Short Line R. Co.—Abandonment—Goshen, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10505(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on February 6, 1993, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[1] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[2] and trail use/rail banking statements under 49 CFR 1152.29 must be filed by January 19, 1993.[3] Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by January 27, 1993 with: Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

A copy of any petition filed with the Commission should be sent to applicant's representative: Gary A. Laakso, Southern Pacific Building, One Market Plaza, room 846, San Francisco, CA 94105.

If the notice of exemption contains false or misleading information, use of the exemption is void *ab initio*.

Applicant has filed an environmental report which addresses the abandonment's effects, if any, on the environmental or historic resources.

The Section of Energy and Environment (SEE) will issue an environmental assessment (EA) by January 12, 1993. Interested persons may obtain a copy of the EA from SEE by writing to it (Room 3219, Interstate Commerce Commission Building, Washington, DC 20423) or by calling Elaine Kaiser, Chief, SEE, at (202) 927-6248. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Decided: December 28, 1992.

By the Commission, Julia M. Farr, Acting Director, Office of Proceedings.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93-178 Filed 1-5-93; 8:45 am]

BILLING CODE 7035-01-M

[1] A stay will be routinely issued by the Commission in these proceedings where an informed decision on environmental issues (whether raised by a party or by the Section of Energy and Environment in its independent investigation) cannot be made prior to the effective date of the notice of exemption. See Exemption of Out-of-Service Rail Lines, 5 I.C.C.2d 377 (1989). Any entity seeking a stay involving environmental concerns is encouraged to file its request as soon as possible to permit this Commission to review and act on the request before the effective date of this exemption.

[2] See Exempt. of Rail Abandonment—Offers of Finan. Assist., 4 I.C.C.2d 164 (1987).

[3] The Commission will accept late-filed trail use statements so long as it retains jurisdiction to do so.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Registration

By Notice dated November 16, 1992, and published in the **Federal Register** on November 23, 1992, (57 FR 55000), North Pacific Trading Company, 1505 SE Gideon Street, Portland, Oregon 97202, made application to the Drug Enforcement Administration to be registered as an importer of Marihuana (7370), a basic class of controlled substance listed in Schedule I.

No comments or objections have been received. Therefore, pursuant to section 1008(a) of the Controlled Substances Import and Export Act and in accordance with title 21 Code of Federal Regulations § 1311.42, the above firm is granted registration as a importer of the basic class of controlled substance listed above.

Dated: December 29, 1992.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 93-236 Filed 1-5-93; 8:45 am]

BILLING CODE 4410-09-M

Importation of Controlled Substances; Application

Pursuant to section 1008 of the Controlled Substances Import and Export Act (21 U.S.C. 958(i)), the Attorney General shall, prior to issuing a registration under this section to a bulk manufacturer of a controlled substance in Schedule I or II and prior to issuing a regulation under section 1002(a) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with 1311.42 of title 21, Code of Federal Regulations (CFR), notice is hereby given that on December 3, 1992, Research Biochemicals Inc., One Strathmore Road, Natick, Massachusetts 01760, made a written request to the Drug Enforcement Administration to be registered as an importer of Morphine (9300) a basic class of controlled substance in Schedule II. The firm plans to import 2 grams of morphine-6 glucuronide for research purposes.

Any manufacturer holding, or applying for, registration as a bulk manufacturer of this basic class of controlled substance may file written comments on or objections to the application described above and may, at the same time, file a written request for a hearing on such application in accordance with 21 CFR 1301.54 in such form as prescribed by 21 CFR 1316.47.

Any such comments, objections, or requests for a hearing may be addressed to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: DEA Federal Register Representative (CCR), and must be filed no later than February 5, 1993.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1311.42(b), (c), (d), (e), and (f). As noted in a previous notice at 40 FR 43745-46 (September 23, 1975), all applicants for registration to import a basic class of any controlled substance in Schedule I or II are and will continue to be required to demonstrate to the Deputy Assistant

Administrator of the Drug Enforcement Administration that the requirements for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 21 CFR 1311.42(a), (b), (c), (d), (e), and (f) are satisfied.

Dated: December 28, 1992.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 93-235 Filed 1-5-93; 8:45 am]

BILLING CODE 4410-09-M

Manufacturer of Controlled Substances; Registration

By notice dated November 16, 1992, and published in the **Federal Register** on November 23, 1992, (57 FR 55002), Toxi-Lab, Inc., 2 Goodyear, Irvine, California 92718, made application to the Drug Enforcement Administration to be registered as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Phencyclidine (7471)	II
1-Piperidinocyclohexanecarbonitrile (8603).	II
Benzoylecgonine (9180)	II

No comments or objections have been received. Therefore, pursuant to section 303 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and title 21, Code of Federal Regulations § 1301.54(e), the Deputy Assistant Administrator hereby orders that the application for registration submitted by the above firm for registration as a bulk manufacturer of the basic classes of controlled substances listed above is granted.

Dated: December 29, 1992.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 93-238 Filed 1-5-93; 8:45 am]

BILLING CODE 4410-09-M

Manufacturer of Controlled Substances; Registration

By Notice dated November 16, 1992, and published in the **Federal Register** on November 23, 1992, (57 FR 52002), Upjohn Company, 7171 Portage Road, Kalamazoo, Michigan 49001, made application to the Drug Enforcement Administration to be registered as a bulk manufacturer of 2,5-Dimethoxyamphetamine (7396), a basic class of controlled substance listed in Schedule I.

No comments or objections have been received. Therefore, pursuant to section 303 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and title 21, Code of Federal Regulations § 1301.54(e), the Deputy Assistant Administrator hereby orders that the application for registration submitted by the above firm for registration as a bulk manufacturer of the basic class of controlled substance listed above is granted.

Dated: December 29, 1992.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 93-237 Filed 1-5-93; 8:45 am]

BILLING CODE 4410-09-M

Office of Justice Programs

Office for Victims of Crime; FY 1993 Assistance to Victims of Federal Crime in Indian Country Discretionary Grant Program Application Kit

AGENCY: Office of Justice Programs, Office for Victims of Crime, DOJ.

ACTION: Public announcement of the availability of the FY 1993 Assistance to Victims of Federal Crime in Indian Country Discretionary Grant Program Application Kit for first-time applicants.

SUMMARY: The Office for Victims of Crime (OVC) is publishing this Notice of availability of the FY 1993 Discretionary Grant Application Kit for the State agencies appointed by the Governors in Alabama, Colorado, Iowa, Louisiana, Mississippi, Nebraska, North Carolina, and Texas.

DATES: Applications must be submitted to the Office for Victims of Crime by the due date indicated in the Application Kit.

ADDRESSES: Applications should be addressed to the Office for Victims of Crime, Federal Crime Victims Division, room 1386, 633 Indiana Avenue, NW., Washington, DC 20531. To obtain a copy of the Application Kit, call (202) 616-3579.

FOR FURTHER INFORMATION CONTACT: Toni Thomas, Program Specialist, at the above address. Telephone: (202) 514-6444.

SUPPLEMENTARY INFORMATION:

Authority

The action is authorized under Sec. 1404(c)(1)(B) of the Victims of Crime Act of 1984 (VOCA), as amended, 42 U.S.C. 10603(c)(1)(B).

Background

In 1988 OVC initiated a program of making grants to State victim assistance programs for the purpose of awarding subgrants to Indian tribes or tribal organizations. This has resulted in the expansion of victim assistance programs in tribal communities in 15 different States. These States are working with Indian tribes to enhance the network of services developed by using a combination of Federal, State and tribal funds. OVC now plans to extend this successful program so that other tribes in areas of Federal jurisdiction can work with State victim assistance programs to establish victim assistance services in their communities.

On November 4, 1992, the Office for Victims of Crime, published a Notice in the **Federal Register**, 57 FR 52639, announcing the FY 1993 Comprehensive Discretionary Program Plan. That publication announced the availability of $250,000 to eligible States for Assistance to Victims of Federal Crime in Indian Country. The Assistance to Victims of Federal Crime in Indian Country Discretionary Grant Application Kit, announced herein, expands upon information provided in the program plan and defines specific application requirements and deadlines.

Brenda G. Meister,

Acting Director, Office for Victims of Crime.

[FR Doc. 93-91 Filed 1-5-93; 8:45 am]

BILLING CODE 4410-18-M

DEPARTMENT OF LABOR

Office of the Secretary

Glass Ceiling Commission; Open Meeting

SUMMARY: Pursuant to title II of the Civil Rights Act of 1991 (Pub. L. 102-166) and section 9 of the Federal Advisory Committee Act (FACA) (Pub. L. 92-462, 5 U.S.C. app. II) a Notice of Establishment of the Glass Ceiling Commission was published in the **Federal Register** on March 30, 1992 (57 FR 10776). Pursuant to section 10(a) of FACA, this is to announce a meeting of the Commission which is to take place on Monday, January 25, 1993.

The purpose of the Commission is to, among other things, focus greater attention on the importance of eliminating artificial barriers to the advancement of minorities and women to management and decision making positions in business. The Commission has the practical task of:

(a) Conducting basic research into the practices, policies and manner in which

management and decision making positions in business are filled;

(b) Conducting comparative research of businesses and industries in which minorities and women are promoted to management and decision making positions, and businesses and industries in which minorities and women are not promoted to such positions; and

(c) Recommending measures designed to enhance opportunities for and the elimination of artificial barriers to the advancement of minorities and women to management and decision making positions.

TIME AND PLACE: The meeting will be held on Monday, January 25, 1993 from 10 a.m. to 5 p.m. at the U.S. Department of Labor, 200 Constitution Avenue, NW., room C-2313, Washington, DC.

AGENDA: The agenda for the meeting is as follows:

(a) Introduction of Commission Members;

(b) Discussion of procedures to be followed in conducting Commission business;

(c) Discussion of Commission objectives including, to the extent practicable, a delineation of specific tasks and projected time frames for achieving such objectives; and

(d) Ancillary considerations attendant to ongoing Commission activities.

PUBLIC PARTICIPATION: The meeting will be open to the public. Seating will be available to the public on a first-come, first-served basis. Seats will be reserved for the media. Handicapped individuals should contact the Commission if special accommodations are needed. Individuals or organizations wishing to submit written statements should send thirty (30) copies to Mrs. Elizabeth Leonard, Executive Director, Glass Ceiling Commission, U.S. Department of Labor, 200 Constitution Avenue, NW., room S-2018, Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Mrs. Elizabeth Leonard, Executive Director, Glass Ceiling Commission, U.S. Department of Labor, 200 Constitution Avenue, NW., room S-2018, Washington, DC 20210, (202) 219-8271.

Signed at Washington, DC this 30th day of December, 1992.

Lynn Martin,

Secretary of Labor.

[FR Doc. 93-160 Filed 1-5-93; 8:45 am]

BILLING CODE 4510-23-M

Employment and Training Administration

[TA-W-27,816, TA-W-27,817, TA-W-27,818]

Lally Manufacturing Corp.; Adams, New York, New York Mill, NY and Port Leyden, NY; Dismissal of Application for Reconsideration

Pursuant to 29 CFR 90.18 an application for administrative reconsideration was filed with the Director of the Office of Trade Adjustment Assistance for workers at Lally Manufacturing Corporation, Adams, New York, New York Mill, New York and Port Leyden, New York. The review indicated that the application contained no new substantial information which would bear importantly on the Department's determination. Therefore, dismissal of the application was issued.

TA-W-27,816, TA-W-27,817, TA-W-27,818; Lally Manufacturing Corporation, Adams, New York, New York Mill, New York and Port Leyden, New York (December 30, 1992)

Signed at Washington, DC this 30th day of December, 1992.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[FR Doc. 93-159 Filed 1-5-93; 8:45 am]

BILLING CODE 4510-30-M

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to section 211(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under title II, chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than January 18, 1993.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than January 18, 1993.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, DC this 21st day of December, 1992.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

APPENDIX

Petitioner (union/workers/firm)	Location	Date received	Date of petition	Petition number	Artices produced
Philips Consumer (workers)	Jefferson City, TN	12/21/92	12/08/92	28,109	TV cabinets.
Superior Technology, Inc (IBEW)	Paris, TX	12/21/92	12/03/92	28,110	Meter boxes.
West Tech, Inc./Van Dale, Inc. (workers)	Long Lake, MN	12/21/92	12/11/92	28,111	Farm machinery.
General Atronics Corp., cathode ray (workers)	Philadelphia, PA	12/21/92	12/15/92	28,112	Cathode ray tubes.
Air City Models and Tools (IAMAW)	Dayton, OH	12/21/92	12/12/92	28,113	Dashboard foam for GM autos.
General Motors-Inland Fisher Guide (workers)	Syracuse, NY	12/21/92	12/09/92	28,114	Plastic auto trim.
The Bargman Company (GMP)	Coldwater, MI	12/21/92	12/10/92	28,115	RV accessories.
Hitachi Zosen Clearing, Inc. (workers)	Chicago, IL	12/21/92	12/07/92	28,116	Metal stamping presses, etc.
Oil Dynamics, Inc. (workers)	Tulsa, OK	12/21/92	12/10/92	28,117	Submersible pumping systems.
Struthers-Dunn (IUE)	Pitman, NJ	12/21/92	12/04/92	28,118	Electrical mechanical relays.
Hercules, Inc. (OCAW)	Burlington, NJ	12/21/92	11/30/92	28,119	Modified resins and plasticizers.
Accessories Unlimited of Maine (workers)	Cornish, ME	12/21/92	12/07/92	28,120	Luggage and handbags.
Moline Corp. (GMPPA)	Belvidere, IL	12/21/92	12/09/92	28,121	Cast, malleable iron products.
Moline Corp. (GMPPA)	St. Charles, IL	12/21/92	12/09/92	28,122	Cast, malleable iron products.
Klasic Div. of KLA (workers)	San Jose, CA	12/21/92	12/04/92	28,123	Servicing equipment.
Valeo Climate Control Corp. (UAW)	Fort Worth, TX	12/21/92	12/04/92	28,124	Auto air conditioners & component parts.

APPENDIX—Continued

Petitioner (union/workers/firm)	Location	Date received	Date of petition	Petition number	Artices produced
Florsheim Shoe Co. (UFCW)	Anna, IL	12/21/92	11/17/92	28,125	Men's dress shoes.
General Electric Co., OH Lamp Plant (workers)	Warren, OH	12/21/92	11/09/92	28,126	Decorative lamps.
E.G. & G Vactec Optoelectronics (UAW)	St. Louis, MO	12/21/92	12/11/92	28,127	Optoelectronic devices.
Mona Lisa Coat (ILGWU)	Hoboken, NJ	12/21/92	12/09/92	28,128	Coats and suits.
Felters Company (workers)	Millbury, MA	12/21/92	12/08/92	28,129	Wet processing goods.
Wells Oilfield Specialties, Inc. (workers)	Coalinga, CA	12/21/92	11/30/92	28,130	Oil and gas.
Wells Oilfield Specialties, Inc. (workers)	Bakersfield, CA	12/21/92	11/30/92	28,131	Downhold oilfield pumps.
Teledyne Vasco (USWA)	Latrobe, PA	12/21/92	12/07/92	28,132	Specialty steel.
Distel Tool & Machine Co. (UAW)	Warren, MI	12/21/92	12/08/92	28,133	Large stamping dies.
AT & T Technologies (workers)	Oklahoma City, OK	12/21/92	12/07/92	28,134	Cables.
Allied Tube & Conduit (Co.)	Liberty, TX	12/21/92	10/29/92	28,135	Steel pipe & tubing.
Goodyear Tire & Rubber Co. (URW)	Logan, OH	12/21/92	12/09/92	28,136	Instrument panels for autos.
Coca-Cola Bottling Co. of NY (IBT)	Paterson, NJ	12/21/92	12/08/92	28,137	Carbonated beverages.
JIK Ltd. (workers)	Allentown, PA	12/21/92	11/27/92	28,138	Women's sportswear.
GTE (workers)	Potosi, MO	12/21/92	12/01/92	28,139	Public telephone services.
Paterson Canning Co. (IBT)	Paterson, NJ	12/21/92	12/08/92	28,140	Carbonated beverages.
Cleaver Brooks (LIU)	Lebanon, PA	12/21/92	12/08/92	28,141	Steam and hot water generated boilers.
HOMCO International, Inc. (workers)	Bakersfield, CA	12/21/92	11/01/92	28,142	Oil.

Job Training Partnership Act; Announcement of Proposed Noncompetitive Grant Awards

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice of intent to award a noncompetitive grant.

SUMMARY: The Employment and Training Administration (ETA) announces its intent to award a noncompetitive grant to The Association for Manufacturing Technology, McLean, Virginia, for the provision of specialized services under the authority of the Job Training Partnership Act (JTPA).

DATES: It is anticipated that this grant award will be executed by January 29, 1993, and will be funded for twelve months. Submit comments by 4:45 p.m. (Eastern Time), on January 21, 1993.

ADDRESSES: Submit comments regarding this proposed assistance award to: U.S. Department of Labor, Employment and Training Administration, room C–4305, 200 Constitution Avenue, NW., Washington, DC 20210, Attention: Reda Harrison: Reference FR–DAA–008–92.

SUPPLEMENTARY INFORMATION: The Employment and Training Administration (ETA) announces its intent to award a noncompetitive grant to The Association for Manufacturing Technology (AMT) of McLean, Virginia, in accordance with the Department of Labor Manual Series (DLMS), Volume No. 2, section 836(g)(5). AMT will produce a series of national satellite teleconferencing programs on state of the art manufacturing technology designed to accelerate the implementation of advanced manufacturing technology methods for U.S. machine tool manufacturers. In line with DOL's Technical & Education Assistance for Mid- and Small-sized firms (TEAMS) initiative, AMT will test teleconferencing as a methodology for building small firm networks to train workers for high performance. The majority of member companies which will participate in the downlink broadcasts employs less than 70 persons. AMT's ultimate goal through the BETA series broadcast is to establish highly replicable outcomes for the U.S. machine tool and other industries in need of increasing the skills of their workforce.

Funds for this activity are authorized by the Job Training Partnership Act, as amended, Title IV—Federally Administered Programs. The proposed funding is approximately $100,000 for twelve months.

Signed at Washington, DC on December 17, 1992.

Robert D. Parker,

ETA Grant Officer.

[FR Doc. 93–157 Filed 1–5–93; 8:45 am]

BILLING CODE 4510–30–M

Job Training Partnership Act; Announcement of Proposed Noncompetitive Grant Award

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice of intent to award a noncompetitive grant.

SUMMARY: The Employment and Training Administration (ETA) announces its intent to award a noncompetitive grant to the Bay State Center for Applied Technology of Boston, Massachusetts to participate in the development and operation of a comprehensive network of small machine shops in Western Massachusetts.

DATES: It is anticipated that this grant award will be executed by January 29, 1993, and will be funded for twenty-four months. Submit comments by 4:45 p.m. (Eastern Time), on January 21, 1993.

ADDRESSES: Submit comments regarding this proposed assistance award to: U.S. Department of Labor, Employment and Training Administration, room C–4305, 200 Constitution Avenue, NW., Washington, DC 20210, Attention: Laura Cesario; Reference FR–DAA–010–92.

SUPPLEMENTAL INFORMATION: The Employment and Training Administration (ETA) announces its intent to award a noncompetitive grant to the Bay State Center for Applied Technology, in accordance with the Department of Labor Manual Series (DLMS), Volume No. 2, section 836(g)(4). The Bay State Center for Applied Technology will be part of a partnership to develop a comprehensive skills upgrading program that will be combined with industrial modernization strategies for small and mid-sized firms. The partnership will consist of the State of Massachusetts, the Western Massachusetts National Tooling and Machining Association, and the Western Massachusetts Precision Institute. This project will support the Department of Labor Technical and Education Assistance for Mid- and Small-sized firms (TEAMS) goal to support the provision of a broad range of services in the areas of technical training and work restructuring. The partnership with the Bay State Center for Applied Technology supports the goals of TEAMS in its development and operation of a comprehensive network of small machine shops in Western Massachusetts.

Funds for this activity are authorized by the Job Training Partnership Act, as amended, Title IV—Federally Administered Programs. The proposed funding is approximately $200,000 for twenty-four months.

Signed at Washington, DC on December 17, 1992.

Robert D. Parker,

ETA Grant Officer.

[FR Doc. 93-155 Filed 1-5-93; 8:45 am]

BILLING CODE 4510-30-M

Job Training Partnership Act; Announcement of Proposed Noncompetitive Grant Award

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice of intent to award a noncompetitive grant.

SUMMARY: The Employment and Training Administration (ETA) announces its intent to award a noncompetitive grant to the United Auto Workers Labor Employment and Training Company of New York, New York to develop a model approach for training and human resource development for small and mid-size firms in the international trade and financial sectors.

DATES: It is anticipated that this grant award will be executed by January 29, 1993, and will be funded for six months. Submit comments by 4:45 p.m. (Eastern Time), on January 21, 1993.

ADDRESSES: Submit comments regarding this proposed assistance award to: U.S. Department of Labor, Employment and Training Administration, room C-4305, 200 Constitution Avenue, NW., Washington, DC 20210, Attention: Laura Cesario; Reference FR-DAA-011-92.

SUPPLEMENTARY INFORMATION: The Employment and Training Administration (ETA) announces its intent to award a noncompetitive grant to the United Auto Workers Labor and Employment Company (UAW-LETC), in accordance with the Department of Labor Manual Series (DLMS), Volume No. 2, section 836(g)(4). In cooperation with the Port Authority of New York and the UAW-LETC, a model approach for training and human resource development for small and mid-size firms in the international trade and financial sectors would be developed. The partnership will assist World Trade Center companies in meeting their human resource needs by offering placement, training and other human resource services, specifically tailored to the needs of those companies. This project will support the Department of Labor Technical and Education Assistance for Mid- and Small-sized firms (TEAMS) goal to support the provision of a broad range of services in the areas of technical training and work restructuring. The partnership with the UAW-LETC presents a unique opportunity to develop worker skill assessment tools for use on a national basis in the service sector of the economy, an area of significant importance to the TEAMS outreach program, and one in which TEAMS needs to develop technical assistance tools.

Funds for this activity are authorized by the Job Training Partnership Act, as amended, Title IV—Federally Administered Programs. The proposed funding is approximately $75,000 for six months.

Signed at Washington, DC on December 17, 1992.

Robert D. Parker,

ETA Grant Officer.

[FR Doc. 93-156 Filed 1-5-93; 8:45 am]

BILLING CODE 4510-30-M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 92-79]

Landsat Advisory Process

AGENCY: National Aeronautics and Space Administration.

ACTION: Request for public advice and comments.

SUMMARY: This request for public advice and comments is issued pursuant to Public Law 102-555, the Land Remote Sensing Policy Act of 1992, dated October 1992. Section 101(e) of this Law requires the Landsat Program Management to seek impartial advice and comments regarding the status, effectiveness, and diversity of the program plans from individuals who represent a broad range of public and private sector perspectives and a full spectrum of interest in the Landsat program and other data and services it provides. Those wishing to provide such advice and comments, via a survey which will be used as input for a report to Congress, can obtain further information on the Landsat advisory process by contacting Stanley R. Schneider, Landsat Advisory Process Coordinator, National Aeronautics and Space Administration, Code SED, 300 E Street, SW., Washington, DC 20546. Fax: (202) 358-3098.

DATES: Comments must be received on or before February 1, 1993.

FOR FURTHER INFORMATION CONTACT: Stanley R. Schneider at the address above.

Dated: December 30, 1992.

L.A. Fisk,

Associate Administrator for Space Science and Applications.

[FR Doc. 93-191 Filed 1-5-93; 8:45 am]

BILLING CODE 7510-01-M

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50-269, 50-270, and 50-287]

Duke Power Co.; Oconee Nuclear Station, Unit Nos. 1, 2, and 3; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of amendments to Facility Operating License Nos. DPR-38, DPR-47, and DPR-55 issued to the Duke Power Company (the licensee), for operation of the Oconee Nuclear Station, Units 1, 2, 3, located in Oconee County, South Carolina.

Environmental Assessment

Identification of Proposed Action

The proposed action would revise the limitations on concentrations of radioactive material released in liquid effluents and the limitations on the dose rate resulting from radioactive material released in gaseous effluents, and reflect the relocation of the prior 10 CFR 20.106 requirements to the new 10 CFR 20.1302. These changes are in response to the new 10 CFR part 20. The review of an additional item, to revise the BASES for the liquid holdup tank TS, was not completed and consequently is not included in the amendment. It will be addressed by separate correspondence.

The Need for the Proposed Action

The proposed action is needed in order to retain operational flexibility consistent with 10 CFR part 50, Appendix I, concurrent with the implementation of the revised 10 CFR part 20.

Environmental Impacts of the Proposed Action

The proposed revision does not change the actual release rates as referenced in the TS as a dose rate to the maximally exposed member of the public. Therefore, there will be no increase in the types or amounts of effluents that may be released offsite, nor an increase in individual or cumulative occupational radiation exposures. Therefore, the Commission

concludes that there are no significant radiological environmental impacts associated with the proposed changes.

With regard to potential nonradiological impacts, the proposed changes do not affect nonradiological effluent and have no other environmental impact. Therefore, the Commission concludes that there are no significant non-radiological impacts associated with the proposed changes.

Alternative to the Proposed Action

Since the Commission's staff has concluded that there is no significant environmental impact associated with the proposed changes to the TS, any alternative to the amendments will have either no significantly different environmental impact or greater environmental impact. The principal alternative would be to deny the requested amendments. This would not reduce environmental impacts as a result of plant operation.

Alternative Use of Resources

This action does not involve the use of resources not previously considered in connection with the Final Environmental Statement related to the operation of the Oconee Nuclear Station, Units 1, 2, and 3, dated March 1972.

Agencies and Persons Consulted

The Commission's staff did not consult other agencies or persons.

Finding of No Significant Impact

The Commission has determined not to prepare an environmental impact statement for the proposed license amendments.

Based on the above environmental assessment, the Commission concludes that the proposed action will not have a significant effect on the quality of the human environment.

For further information with respect to this action, see the application dated November 5, 1992, as supplemented December 9 and 18, 1992, which is available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, DC and at the Oconee County Library, 501 West South Broad Street, Walhalla, South Carolina.

Dated at Rockville, Maryland, this 30th day of December 1992.

For the Nuclear Regulatory Commission.

Timothy A. Reed,

Acting Director, Project Directorate II-3, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 93-170 Filed 1-5-93; 8:45 am]

BILLING CODE 7590-01-M

[Docket Nos. 50-369 and 50-370]

Duke Power Co., McGuire Nuclear Station, Unit Nos. 1 and 2; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of amendments to Facility Operating License Nos. NPF-9 and NPF-17 issued to the Duke Power Company (the licensee), for operation of the McGuire Nuclear Station, Units 1 and 2, located in Mecklenburg County, North Carolina.

Environmental Assessment

Identification of Proposed Action

The proposed action would revise the limitations on concentrations of radioactive material released in liquid effluents and the limitations on the dose rate resulting from radioactive material released in gaseous effluents, and reflect the relocation of the prior 10 CFR 20.106 requirements to the new 10 CFR 20.1302. These changes are in response to the new 10 CFR part 20. The review of an additional item, to revise the BASES for the liquid holdup tank TS, was not completed and consequently is not included in the amendment. It will be addressed by separate correspondence.

The Need for the Proposed Action

The proposed action is needed in order to retain operational flexibility consistent with 10 CFR part 50, appendix I, concurrent with the implementation of the revised 10 CFR part 20.

Environmental Impacts of the Proposed Action

The proposed revision does not change the actual release rates as referenced in the TS as a dose rate to the maximally exposed member of the public. Therefore, there will be no increase in the types or amounts of effluents that may be released offsite, nor an increase in individual or cumulative occupational radiation exposures. Therefore, the Commission concludes that there are no significant radiological environmental impacts associated with the proposed changes.

With regard to potential nonradiological impacts, the proposed changes do not affect nonradiological effluent and have no other environmental impact. Therefore, the Commission concludes that there are no significant nonradiological impacts associated with the proposed changes.

Alternative to the Proposed Action

Since the Commission's staff has concluded that there is no significant environmental impact associated with the proposed changes to the TS, any alternative to the amendments will have either no significantly different environmental impact or greater environmental impact. The principal alternative would be to deny the requested amendments. This would not reduce environmental impacts as a result of plant operation.

Alternative Use of Resources

This action does not involve the use of resources not previously considered in connection with the Final Environmental Statement related to the operation of William B. McGuire Nuclear Station, Units 1 and 2 dated April 1976, and its addendum dated January 1981.

Agencies and Persons Consulted

The Commission's staff did not consult other agencies or persons.

Finding of No Significant Impact

The Commission has determined not to prepare an environmental impact statement for the proposed license amendments.

Based on the above environmental assessment, the Commission concludes that the proposed action will not have a significant effect on the quality of the human environment.

For further information with respect to this action, see the application dated November 5, 1992, as supplemented December 9 and 18, 1992, which is available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, DC and at the Atkins Library, University of North Carolina (UNCC Station), North Carolina 28223.

Dated at Rockville, Maryland, this 30th day of December, 1992.

For the Nuclear Regulatory Commission.

Timothy A. Reed,

Acting Director, Project Directorate II-3, Division of Reactor Projects—I/II Office of the Nuclear Reactor Regulation.

[FR Doc. 93-169 Filed 1-5-93; 8:45 am]

BILLING CODE 7590-01-M

[Docket Nos. 50-413 and 50-414]

Duke Power Co., et al., Catawba Nuclear Station, Unit Nos. 1 and 2; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of amendments to Facility

Operating License Nos. NPF-35 and NPF-52 issued to the Duke Power Company (the licensee), for operation of the Catawba Nuclear Station, Units 1 and 2, located in York County, South Carolina.

Environmental Assessment

Identification of Proposed Action

The proposed action would revise the limitations on concentrations of radioactive material released in liquid effluents and the limitations on the dose rate resulting from radioactive material released in gaseous effluents, and reflect the relocation of the prior 10 CFR 20.106 requirements to the new 10 CFR 20.1302. These change are in response to the new 10 CFR part 20. The review of an additional item, to revise the BASES for the liquid holdup tank TS, was not completed and consequently is not included in the amendment. It will be addressed by separate correspondence.

The Need for the Proposed Action

The proposed action is needed in order to retain operational flexibility consistent with 10 CFR part 50, appendix I, concurrent with the implementation of the revised 10 CFR part 20.

Environmental Impacts of the Proposed Action

The proposed revision does not change the actual release rates as referenced in the TS as a dose rate to the maximally exposed member of the public. Therefore, there will be no increase in the types or amounts of effluents that may be released offsite, nor an increase in individual or cumulative occupational radiation exposures. Therefore, the Commission concludes that there are no significant radiological environmental impacts associated with the proposed changes.

With regard to potential nonradiological impacts, the proposed changes do not affect nonradiological effluent and have no other environmental impact. Therefore, the Commission concludes that there are no significant nonradiological impacts associated with the proposed changes.

Alternative to the Proposed Action

Since the Commission's staff has concluded that there is no significant environmental impact associated with the proposed changes to the TS, any alternative to the amendments will have either no significantly different environmental impact or greater environmental impact. The principal alternative would be to deny the requested amendments. This would not reduce environmental impacts as a result of plant operation.

Alternative Use of Resources

This action does not involve the use of resources not previously considered in connection with the Final Environmental Statement related to the operation of the Catawba Nuclear Station, Units 1 and 2, dated January 1983.

Agencies and Persons Consulted

The Commission's staff did not consult other agencies or persons.

Finding of No Significant Impact

The Commission has determined not to prepare an environmental impact statement for the proposed license amendments.

Based on the above environmental assessment, the Commission concludes that the proposed action will not have a significant effect on the quality of the human environment.

For further information with respect to this action, see the application dated November 5, 1992, as supplemented December 9 and 18, 1992, which is available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, DC and at the York County Library, 138 East Black Street, Rock Hill, South Carolina.

Dated at Rockville, Maryland, this 30th day of December, 1992.

For the Nuclear Regulatory Commission.

Timothy A. Reed,

Acting Director, Project Directorate II-3, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 93-168 Filed 1-5-93; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-245]

Northeast Nuclear Energy Co., Millstone Nuclear Power Station, Unit 1; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of a one-time exemption from 10 CFR 50, appendix J, paragraph III.A.6(b) to the Northeast Nuclear Energy Company (NNECO or the licensee) for Millstone Nuclear Power Station, Unit 1, located in New London County, Connecticut.

Environmental Assessment

Identification of the Proposed Action

The proposed action would grant a one-time exemption to provide relief from the accelerated Type A containment integrated leak rate test frequency required by appendix J to 10 CFR part 50 when two consecutive Type A tests have failed to meet their acceptance criteria.

The Need for the Proposed Action

One of the conditions of all operating licenses for water-cooled power reactors, as specified in 10 CFR 50.54(o), is that primary reactor containments shall meet the containment leakage test requirements set forth in 10 CFR part 50, appendix J.

Appendix J to 10 CFR part 50, paragraph III.A.6(b), requires, in part, that if two consecutive periodic Type A tests fail to meet the applicable acceptance criteria in III.A.5(b), a Type A test shall be performed at each plant shutdown for refueling or approximately 18 months, whichever occurs first, until two consecutive Type A tests meet the acceptance criteria in III.A.5(b), after which time the normal retest schedule specified in III.D (three tests in 10 years) may be resumed.

NRC Information Notice (IN) No. 85-71 states that licensees may submit a Corrective Action Plan (CAP) with an alternate leakage test program proposal as an exemption request for NRC staff review if it is determined that Type B and C leakage rates constitute the identified contributor to the failure of the two Type A tests. If the CAP and alternate leakage rate test program is approved, the licensee is allowed to implement the corrective action and alternate leakage rate test program in lieu of the required increase in Type A test frequency.

Millstone Unit 1 experienced failures of the "As-Found" Type A tests in 1987 and 1991, therefore, a test is required to be performed during the present operating cycle in late December 1992 or January 1993. In order to perform this required Type A test, Millstone Unit 1 would have to undergo a forced shutdown. Such a shutdown would result in an increase in occupational radiation exposure and an additional transient on the plant.

Because the licensee determined that Type C local leakage rates were the reason for the "As-Found" Type A test failures, NNECO submitted a CAP with an alternate leakage test program proposal in lieu of the required accelerated testing and a request for exemption from 10 CFR 50, Appendix J, Paragraph III.A.6(b).

Environmental Impacts of the Proposed Action

The proposed action would provide a one-time exemption from the accelerated Type A containment integrated leak rate test frequency

required by appendix J to 10 CFR part 50 when two consecutive Type A tests have failed to meet their acceptance criteria. The NRC staff has reviewed the proposed exemption and concluded that the licensee's CAP and alternate leakage rate test program are acceptable. The NRC staff finds that the CAP and alternate leakage rate test program are an acceptable alternative to the increased Type A test frequency (every 18 months) and that there is reasonable assurance that the containment leakage-limiting function will be maintained. Therefore, the subject exemption is acceptable and the licensee will return to the normal test schedule of three tests in 10 years. With the normal test schedule, Type A tests would be scheduled to be performed at the next two plant shutdowns for refueling (currently expected to be in 1994 and 1996).

Thus, radiological releases will not differ from those determined previously and the proposed exemption does not otherwise affect facility radiological effluent or occupational exposures. With regard to potential nonradiological impacts, the proposed exemption does not affect plant nonradiological effluents and have no other environmental impact. Therefore, the Commission concludes there are no measurable radiological or nonradiological environmental impacts associated with the proposed exemption.

Alternatives to the Proposed Action

Since the Commission has concluded there is no measurable environmental impact associated with the proposed exemptions, any alternatives with equal or greater environmental impact need not be evaluated. The principal alternative to the exemptions would be to deny the exemptions requested. Such action would not enhance the protection of the environment.

Alternative Use of Resources

This action does not involve the use of resources not considered previously in the Final Environmental Statement for Millstone Nuclear Power Station, Unit 1.

Agencies and Persons Consulted

The NRC staff reviewed the licensee's request and did not consult other agencies or persons.

Finding of No Significant Impact

Based on the foregoing environmental assessment, the Commission concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the Commission has determined not to prepare an environmental impact statement for the proposed exemptions.

For further details with respect to this proposed action, see the licensee's letter dated November 4, 1992, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, and at the local public document room located at the Learning Resources Center, Thames Valley State Technical College, 574 New London Turnpike, Norwich, Connecticut 06360.

Dated at Rockville, Maryland this 30th day of December, 1992.

For the Nuclear Regulatory Commission.

John F. Stolz,

Director, Project Directorate I-4, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 93-172 Filed 1-5-93; 8:45 am]

BILLING CODE 7590-01-M

Biweekly Notice

Applications and Amendments to Operating Licenses Involving No Significant Hazards Considerations

I. Background

Pursuant to Public Law (P.L.) 97-415, the Nuclear Regulatory Commission (the Commission or NRC staff) is publishing this regular biweekly notice. P.L. 97-415 revised section 189 of the Atomic Energy Act of 1954, as amended (the Act), to require the Commission to publish notice of any amendments issued, or proposed to be issued, under a new provision of section 189 of the Act. This provision grants the Commission the authority to issue and make immediately effective any amendment to an operating license upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued from December 12, 1992, through December 23, 1992. The last biweekly notice was published on December 23, 1992 (57 FR 61105).

Notice Of Consideration Of Issuance Of Amendment To Facility Operating License, Proposed No Significant Hazards Consideration Determination, And Opportunity For a Hearing

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendments would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination. The Commission will not normally make a final determination unless it receives a request for a hearing.

Written comments may be submitted by mail to the Rules and Directives Review Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room P-223, Phillips Building, 7920 Norfolk Avenue, Bethesda, Maryland from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555. The filing of requests for hearing and petitions for leave to intervene is discussed below.

By February 5, 1993, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555 and at the local public document room for the particular facility involved. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the

Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) the nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received before action is taken. Should the Commission take this action, it will publish in the **Federal Register** a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington DC 20555, by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1-(800) 325-6000 (in Missouri 1-(800) 342-6700). The Western Union operator should be given Datagram Identification Number N1023 and the following message addressed to **(Project Director):** petitioner's name and telephone number, date petition was mailed, plant name, and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to the attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of factors specified in 10 CFR 2.714(a)(1)(i)-(v) and 2.714(d).

For further details with respect to this action, see the application for amendment which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, and at the local public document room for the particular facility involved.

Arizona Public Service Company, et al., Docket Nos. STN 50-528, STN 50-529, and STN 50-530, Palo Verde Nuclear Generating Station, Unit Nos. 1, 2, and 3, Maricopa County, Arizona

Date of amendment requests: November 20, 1992

Description of amendment requests: The amendment requests propose to increase the allowable out-of-service time for the Core Operating Limit Supervisory System (COLSS) from one hour to four hours before the more restrictive limits based on the Core Protection Calculators (CPCs) must be applied.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensees have provided their analysis about the issue of no significant hazards consideration, which is presented below:

Standard 1 -- Involve a significant increase in the probability or consequences of an accident previously evaluated.

This proposed amendment distinguishes between the ACTION requirements applicable when COLSS is either in service or out of service. If COLSS is in service the ACTIONs and time requirements remain unchanged. When COLSS is out of service the requirement for initiating corrective action within 15 minutes is replaced with the requirement to restore linear heat rate (LHR)

and departure from nucleate boiling ratio (DNBR) within 4 hours. The purpose of the proposed amendment is to provide a reasonable opportunity for appropriate corrective actions when the COLSS becomes inoperable.

The technical specification (TS) Limiting Conditions for Operation (LCOs) for DNBR margin and LHR are more restrictive when operating without the COLSS due to the uncertainties associated with the CPCs. Consequently, when the COLSS becomes inoperable, the existing LHR and DNBR limits based on CPC information can only be satisfied by either a power reduction or by restoring the COLSS to service. By itself, a loss of the COLSS or returning the COLSS to service does not affect plant operation and does not affect the actual DNBR or the LHR. In addition, a loss of the COLSS does not constitute a change in actual core power distribution. Therefore, during normal operation within the COLSS power operating limits (POLs), if there are no indications that the actual DNBR margin or LHR has degraded, a power reduction will not significantly improve the level of confidence that the existing margin is below the required margin discussed in Chapter 15 of the Updated Final Safety Analysis Report (UFSAR).

When either TS 3.2.1 or TS 3.2.4 is not satisfied, compensatory actions will provide additional assurance that the actual DNBR margin and LHR do not exceed the safety limits stated in the UFSAR. Compensatory actions will be provided in a revision to the surveillance test procedure for monitoring LHR and DNBR while in the 4-hour ACTION for COLSS out of service. The revised procedure will allow continued full power operation after COLSS becomes unavailable, consistent with the revised TS ACTIONs. In addition, the revised procedure will require LHR and DNBR to be monitored at least every 15 minutes for the 4-hour ACTION period when COLSS is out of service and the more restrictive CPC limits are not met as required by the LHR and DNBR TS LCOs.

The primary consideration in extending the COLSS out-of-service time limit is the remote possibility of a slow, undetectable transient that degrades the DNBR margin or LHR within the 4-hour ACTION time which is then followed by an anticipated operational occurrence or accident. The plant parameters monitored by COLSS which could affect DNBR margin and LHR include RCS flow rate, axial and radial power distribution, cold leg temperature, reactor core power, RCS pressure, and azimuthal tilt. Cold leg temperature, core power, and RCS pressure are monitored by operators using redundant, safety grade control room indications. Operating experience indicates that changes in RCS flow rate are rare and involve only large obvious step changes. Therefore, any change in RCS flow rate will be quickly identified by operators using other redundant, safety-grade instrumentation.

Azimuthal tilt variations occur either slowly over the entire cycle due to burnup variations or due to asymmetric events such as an inadvertent drop or misalignment of a Control Element Assembly (CEA). The probability of dropping or misaligning a CEA is remote, and it is very unlikely that a CEA would drop within a given 4-hour period. In the unlikely event this were to occur, the safety related Control Element Assembly Calculators (CEACs) would alert operators that corrective action was required. A large temperature difference (i.e. an asymmetric steam generator transient) could also produce a core tilt variation but the CPCs have been specifically designed to detect this type of event and ultimately provide the appropriate protection system response. Thus, during the proposed 4-hour ACTION statement any degradation of azimuthal tilt is very unlikely when the plant is operating at steady state conditions and would be quickly and positively identified. Additionally, an adverse change in azimuthal tilt would result in a degradation in the CPC monitored LHR and DNBR margin.

Axial xenon oscillations are a normal consequence of the Palo Verde core designs, particularly near the end of a fuel cycle. The resultant axial core power fluctuations are strictly controlled to ensure efficient and even fuel burnup. As a result, axial power shape is strictly maintained by existing procedures well within the limits assumed in the safety analysis. Typically, one full xenon oscillation will take approximately 26 hours. It is unlikely that a change in axial shape index (ASI) during the 4-hour ACTION period of steady state plant operation would either be undetected or lead to a condition outside the range of initial conditions assumed in the safety analysis since a change would have to be initiated by either a power transient or CEA movement. In the event of an inadvertent power transient or CEA movement, the CPCs would provide the appropriate protection system response. Additionally, any adverse change in ASI would result in a degradation in the CPC monitored LHR and DNBR margin.

The proposed amendment does not modify either the LHR or DNBR LCOs. The core power distribution during all phases of normal operation and anticipated operational occurrences will remain bounded by the initial conditions assumed in Chapter 15 of the UFSAR. The COLSS calculated POLs and the CPC-based LHR and DNBR operating limits will remain unchanged. Increasing the time to 4 hours for restoration of LHR and DNBR to within limits would reduce the number and rate of power reductions. While decreasing the potential for RPS actuation, the proposed change would not significantly increase the probability of exceeding the core power operating limits based on LHR and DNBR. Therefore, this proposed change will not significantly increase the probability or consequences of an accident previously evaluated.

Standard 2 -- Create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed amendment is limited to changing administrative limits and does not involve any physical change to plant systems or to the COLSS and CPC software. These changes will not affect any safety-related equipment used in the mitigation of anticipated operational occurrences or design basis accidents. The only change resulting from this amendment will be to the procedure for operating when COLSS is out of service. The procedural changes will be reviewed and implemented in accordance with 10 CFR 50.59 and TS Administrative Controls. The DNBR and LHR LCOs are not affected by these changes. Therefore, this change will not create the possibility of a new or different kind of accident from any accident previously evaluated.

Standard 3 -- Involve a significant reduction in a margin of safety.

TS LCOs 3.2.1 and 3.2.4 ensure that operation of the reactor is within the range of conditions assumed in the Safety Analysis. Therefore, maintaining LHR and DNBR within the existing LCOs will ensure that no anticipated operational occurrence or postulated accident will result in core conditions exceeding Specified Acceptable Fuel Design Limits or the maximum peak cladding temperature of 2200°F specified by 10 CFR 50.46. The UFSAR Chapter 15 analysis remains bounding because there has been no change to the LHR and DNBR limits. Administrative limits will be in place to provide additional assurance that potential reductions in core thermal margin, while in the extended 4-hour ACTION, will be quickly detected, and should it prove necessary, result in a decrease in reactor power and subsequent compliance with the LCOs. Therefore, this change will not result in a significant reduction in a margin of safety.

The NRC staff has reviewed the licensees' analysis and, based on that review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment requests involve no significant hazards consideration.

Local Public Document Room location: Phoenix Public Library, 12 East McDowell Road, Phoenix, Arizona 85004

Attorney for licensees: Nancy C. Loftin, Esq., Corporate Secretary and Counsel, Arizona Public Service Company, P.O. Box 53999, Mail Station 9068, Phoenix, Arizona 85072-3999

NRC Project Director: Theodore R. Quay

Carolina Power & Light Company, Docket No. 50-261, H. B. Robinson Steam Electric Plant, Unit No. 2, Darlington County, South Carolina

Date of amendment request: November 20, 1992

Description of amendment request: The proposed amendment would revise the Technical Specifications to add a requirement for a refueling interval calibration of the Auxiliary Feedwater (AFW) flow instrumentation and delete the separate requirement for a refueling interval functional test. A change in the type of instrumentation used to monitor AFW flow resulted in a change in the method of operability verification required. The new instrumentation, installed by a plant modification, can be

calibrated; whereas, the old instrumentation could only be functionally tested.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated because the proposed amendment only provides a means of calibration for this equipment. Since the AFW flow indication system provides the operator sufficient information to allow for the recognition and isolation of faulted AFW supply piping to the steam generators, the increase in accuracy and reliability of this indication resulting from its calibration would not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. The proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

Since the AFW flow indication system does not interface with any system involved in an accident initiation sequence, the possibility of a new or different kind of accident cannot be created by introduction of a new required calibration of that system. Therefore, the proposed changes do not create the possibility of a new or difference kind of accident from any accident previously evaluated.

3. The proposed amendment does not involve a significant reduction in the margin of safety.

The subject instrumentation calibration has no impact on accident sequences. The improved reliability and accuracy of the subject instrumentation, as a result of its calibration, serve to improve the operator's ability to respond to AFW flow failure events. This potentially improved response to events does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Hartsville Memorial Library, Home and Fifth Avenues, Hartsville, South Carolina 29550

Attorney for licensee: R. E. Jones, General Counsel, Carolina Power & Light Company, P. O. Box 1551, Raleigh, North Carolina 27602

NRC Project Director: Elinor G. Adensam

Georgia Power Company, Oglethorpe Power Corporation, Municipal Electric Authority of Georgia, City of Dalton, Georgia, Docket Nos. 50-424 and 50-425, Vogtle Electric Generating Plant, Units 1 and 2, Burke County, Georgia

Date of amendment request: May 27, 1992, as supplemented December 7, 1992

Description of amendment request: The proposed amendments would revise Sections 3.0 and 4.0 of the Vogtle Electric Generating Plant Units 1 and 2 Technical Specifications (TS) to incorporate the changes recommended in NRC's Generic Letter 87-09, "Sections 3.0 and 4.0 of the Standard Technical Specifications (STS) on the Applicability of Limiting Conditions for Operation and Surveillance Requirements." In this letter the NRC has concluded that certain recommended modifications to TSs 3.0.4, 4.0.3, and 4.0.4 would clarify the intent of these TSs and would resolve three problems associated with the existing requirements, as follows: (1) TS 3.0.4 would be revised to remove any unnecessary restrictions on operational mode changes in those cases where conformance with Action Statement requirements provides an acceptable level of safety for continued operation for an unlimited period of time; (2) TS 4.0.3 would be revised to provide a 24-hour delay before implementing TS Action Statement requirements due to a missed surveillance, in those cases where the allowed time to perform the missed surveillance is less than 24 hours; and (3) TS 4.0.4 would be revised to assure that its Surveillance Requirements do not prevent the plant's passage through or to Operational Modes as required to comply with TS Action Statement requirements.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Revision to Specification 3.0.4 and associated bases

a. The proposed change will not significantly increase the probability or consequences of an accident previously evaluated because the change simply recognizes those cases where conformance to the action requirements associated with an LCO establishes an acceptable level of safety for continued operation of the facility for an unlimited period of time. Generally, individual specifications that have action requirements which allow continued operation note that Specification 3.0.4 does not apply. However, exceptions to Specification 3.0.4 have not been consistently applied. Rather than applying individual exceptions to Specification 3.0.4 (except in those cases where an exception to Specification 3.0.4 exists and the specification does not satisfy the provisions under which mode changes are permitted by the revision to Specification 3.0.4) the revision to Specification 3.0.4 defines the conditions under which the requirements do apply. Furthermore, Georgia Power Company concurs with the NRC staff position that good practice dictates that plant startup should normally be initiated only when all required equipment is operable, and that startup with inoperable equipment must be the exception rather than the rule. Therefore, since the proposed change will ensure consistent application of Specification 3.0.4 while continuing to ensure an acceptable level of safety for continued operation of the facility, the probability or consequences of an accident previously evaluated will not be significantly increased.

b. This change does not create the possibility of a new or different kind of accident from any accident previously evaluated. If an LCO has action requirements that permit continued operation for an unlimited period of time, it follows that an acceptable level of safety is provided by conformance to those action requirements. Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

c. The proposed change will not involve a significant reduction in a margin of safety. As previously stated, the proposed revision to Specification 3.0.4 defines the conditions under which Specification 3.0.4 applies. The fact that the action requirements allow for continued operation of the facility for an unlimited period of time implies that an acceptable level of safety is provided for and maintained by conformance to the action requirements. Therefore, it follows that the proposed change does not involve a significant reduction in a margin of safety.

2. Deletion...of individual exceptions to Specification 3.0.4. Where individual specifications satisfy the provisions of revised Specification 3.0.4 under which mode changes would be allowed, the individual exemption statements have been deleted or added, as necessary. The following specifications and tables are affected by this change:

Specification

3.1.3.2, 3.2.4, 3.3.3.1, 3.3.3.2, 3.3.3.3, 3.3.3.4, 3.3.3.9, 3.3.3.10, 3.3.3.11, 3.4.10, 3.7.1.5, 3.7.9, 3.7.10, 3.8.4.1, 3.9.7, 3.9.9, 3.9.11, 3.9.12, 3.11.1.1, 3.11.1.2, 3.11.1.3, 3.11.1.4, 3.11.2.1, 3.11.2.2, 3.11.2.3, 3.11.2.4, 3.11.2.5, 3.11.2.6, 3.11.3, 3.11.4, 3.12.1, 3.12.2, 3.12.3

Table

3.3-1, 3.3-2, 3.3-8

a. The proposed change will not significantly increase the probability or consequences of an accident previously evaluated. Each specification listed above...presently contains an exception to the provisions of Specification 3.0.4. Georgia Power Company has determined that all...or part of these specifications listed above satisfy the provisions of revised Specification 3.0.4 under which mode changes would be

allowed. In other words, each specification has action requirements which provide an acceptable level of safety for continued operation of the facility for an unlimited period of time. Therefore, in accordance with Generic Letter 87-09 the individual exceptions to Specifications 3.0.4 are no longer required and should be deleted in order to avoid confusion about the applicability of Specification 3.0.4. The net effect is that there is no change in the requirements. The individual exceptions to Specification 3.0.4 will be replaced by revised Specification 3.0.4. The exception to 3.0.4 is being added to Specification 3.7.1.2 to clarify that mode changes are not allowed with three auxiliary feedwater pumps inoperable. Since there is no net change in the requirements, it follows that the proposed change will not significantly increase the probability or consequences of an accident previously evaluated.

b. This change does not create the possibility of a new or different kind of accident from any accident previously evaluated. Since there is no net change in the requirements, it follows that there is no possibility of a new or different kind of accident as a result of this change.

c. The proposed change will not involve a significant reduction in the margin of safety because there is no net change in the requirements.

3. Revision to Specification 4.0.3 and associated bases

a. The proposed change will not significantly increase the probability or consequences of an accident previously evaluated. The existing...Technical Specifications state that the allowable outage time limits apply upon discovery that a required surveillance has been inadvertently omitted. Therefore, the only change in requirements associated with adopting the wording of Generic Letter 87-09 for Specification 4.0.3 and its associated bases involves the addition of a 24-hour interval for performing a missed surveillance if the allowable outage time is less than 24 hours.

Generic Letter 87-09 states that it is overly conservative to assume that systems or components are inoperable when a surveillance requirement has not been performed. The letter further states that the majority of surveillances demonstrate that systems or components in fact are operable, and when a surveillance is missed it is primarily a question of verification of operability by the performance of the required surveillance. In some cases, the condition of a missed surveillance could force a plant shutdown which would be unnecessary if in fact the system or component in question was operable. If a plant shutdown is required before a missed surveillance is completed, it is likely that it would be conducted while the plant is being shut down because completion of a missed surveillance could terminate the shutdown requirement. This is undesirable since it increases the risks to the plant and public safety for two reasons. First, the plant would be in a transient state involving changing plant conditions that offer the potential for an upset that could lead to a demand for the system or component being tested. Secondly, a shutdown would increase the pressure on the plant staff to expeditiously complete the required surveillance so that the plant could be returned to power operation. This would further increase the potential for a plant upset when both the shutdown and surveillance activities place a demand on the plant operations. The NRC staff has concluded that, based on consideration of plant conditions, adequate planning, availability of personnel, time required to perform the missed surveillance, and the safety significance of the delay in completion of the surveillance, 24 hours would be an acceptable time limit for completing a missed surveillance when the allowable outage time limit is less than 24 hours or when shutdown action requirements apply. Furthermore, the NRC staff concludes that the 24-hour time limit would balance the risks associated with an allowance for completing the surveillance within this period against the risks associated with the potential for a plant upset and challenge to safety systems when the alternative is a shutdown to comply with action requirements before the surveillance can be completed. Finally, the deletion of the statement that exceptions to Specification 4.0.3 are noted in individual specifications is an administrative change since the implied exceptions do not exist. Specification 4.0.3 always applies.

Georgia Power Company agrees with the evaluation of the NRC staff as presented in Generic Letter 87-09 and therefore concludes that this aspect of the revision to Specification 4.0.3 will not involve a significant increase in the probability or consequences of an accident previously evaluated.

b. This change does not create the possibility of a new or different kind of accident from any accident previously evaluated. As stated in item 3a above, the proposed revision should minimize the potential for a plant upset due to efforts to comply with an LCO in the event of a missed surveillance. The deletion of the statement regarding noted exceptions to Specification 4.0.3 is an administrative change since the noted exceptions do not exist. Therefore, this change does not create the possibility of a new or different kind of accident.

c. The proposed change does not involve a significant reduction in the margin of safety. Equipment operability will continue to be verified as required by the Technical Specifications. The proposed revision should minimize the potential for plant upset due to efforts to meet an LCO in the event of a missed surveillance. The deletion of the statement regarding noted exceptions to Specification 4.0.3 is administrative since the noted exceptions do not exist. Therefore, this change does not involve a significant reduction in the margin of safety.

4. Revision to Specification 4.0.4 and associated bases

a. The proposed change will not significantly increase the probability or consequences of an accident previously evaluated. As discussed in item 3a, the potential for a plant upset and challenge to safety systems is heightened if surveillances are performed during the transition to shutdown to comply with action requirements, and it should not apply when mode changes are imposed by action requirements. Since the proposed change should reduce the potential for plant upset and challenge to safety systems, there is no significant increase in the probability or consequences of an accident previously evaluated.

b. The proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated. As stated in item 4a, this change should reduce the potential for plant upset and challenge to safety systems. This change is a clarification which will facilitate conformance to action requirements when mode changes are required. Therefore, the change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

c. The proposed change does not involve a significant reduction in the margin of safety. The proposed change is a clarification which will facilitate compliance with action requirements when mode changes are required. The result should be an enhancement to plant safety in the event that inoperable equipment or an out of limit condition requires a plant shutdown. Therefore, there is not significant reduction in the margin of safety.

5. Revision of the bases for Specifications 3.0.1, 3.0.2, 3.0.3, 3.0.4, 4.0.1, 4.0.2, 4.0.3, 4.0.4, and 4.0.5

a. The proposed change will not significantly increase the probability or consequences of an accident previously evaluated because the Technical Specification requirements have not changed (i.e., Specifications 3.0.1, 3.0.2, 3.0.3, 3.0.4, 4.0.1, 4.0.2, 4.0.3, 4.0.4, and 4.0.5). The bases associated with these requirements have simply been rewritten for clarity. Therefore, there will be no significant increase in the probability or consequences of an accident previously evaluated.

b. The proposed change will not create the possibility of a new or different kind of accident from any accident previously evaluated. As stated in item 5a, there are no changes to the requirements proposed. The proposed change will result in improved bases for the subject specifications. Therefore, there is no possibility of a new or different kind of accident from any previously evaluated.

c. The proposed change will not involve a significant reduction in the margin of safety because the requirements have not changed.

The staff has reviewed the licensee's no significant hazards analysis given above. Based on this review and the consistency of the proposed changes with those recommended in Generic Letter 87-09, the staff proposes to determine that the proposed amendments meet the three 10 CFR 50.92(c) standards and do not involve a significant hazards consideration.

Local Public Document Room location: Burke County Public Library, 412 Fourth Street, Waynesboro, Georgia 30830.

Attorney for licensee: Mr. Arthur H. Domby, Troutman, Sanders,

NationsBank Plaza, Suite 5200, 600 Peachtree Street, NE., Atlanta, Georgia 30308-2210.

NRC Project Director: David B. Matthews

Georgia Power Company, Oglethorpe Power Corporation, Municipal Electric Authority of Georgia, City of Dalton, Georgia, Docket Nos. 50-424 and 50-425, Vogtle Electric Generating Plant, Units 1 and 2, Burke County, Georgia

Date of amendment request: December 7, 1992

Description of amendment request: The proposed amendments would revise the Technical Specifications (TS) to change the frequency of reporting the quantity of each of the principal radionuclides released from the plant site to unrestricted areas in liquid and in gaseous effluents from semiannual to annual. These changes would be implemented by further modifying certain related changes (TS Sections 1.19, 6.8.1, and 6.13.2) proposed by the licensee with respect to NRC Generic Letter (GL) 89-19 on March 4, 1992, that were noticed in the **Federal Register** on August 19, 1992 (57 FR 37565). Specifically, the title "Annual Radioactive Effluent Release Report" would be used instead of "Semiannual Radioactive Effluent Release Report." This title appears in TSs 1.19, 6.8.1, 6.13.2, and TS Index page XXIII.

The proposed change for TS 6.8.1 would also require that the Annual Radioactive Effluent Release Report covering the operation of the unit during the previous calendar year be submitted before May 1 of each year, and that the quantity of solid waste releases be reported on an annual, rather than a semiannual, basis.

Basis for proposed no significant hazards consideration determination: As noticed in the **Federal Register** on August 31, 1992 (57 FR 39353), the NRC has amended 10 CFR 50.36a to reduce the required frequency of reporting the quantity of each principal radionuclide released to unrestricted areas in liquid and gaseous effluents from semiannual to annual. The proposed amendments would revise the TS to be consistent with the revised regulation. The reporting requirement for solid wastes is not addressed by the revised 10 CFR 50.36a. However, to be consistent with the proposed changes for liquid and gaseous effluents, the licensee proposes that the quantity of solid waste releases also be reported on an annual basis.

As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated. The proposed changes are administrative in nature and do not involve any change to the configuration or method of operation of any plant equipment that is used to mitigate the consequences of an accident. Also, the proposed changes do not alter the conditions or assumptions in any of the Final Safety Analysis Report (FSAR) accident analyses. Since the FSAR accident analyses remain bounding, the radiological consequences previously evaluated are not adversely affected by the proposed changes. Therefore, it can be concluded that the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. The proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated. The proposed changes are administrative in nature and do not involve any change to the configuration or method of operation of any plant equipment that is used to mitigate the consequences of an accident. Accordingly, no new failure modes have been defined for any plant system or component important to safety nor has any new limiting failure been identified as a result of the proposed changes. Also, there will be no change in the types or increase in the amount of effluents released offsite. Therefore, it can be concluded that the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. The proposed changes do not involve a significant reduction in a margin of safety. The proposed changes are administrative in nature and do not adversely impact the plant's ability to meet applicable regulatory requirements related to liquid and gaseous effluents, and solid waste releases. The proposed change[s] would also eliminate an unnecessary burden of governmental regulation without reducing protection for public health and safety. Therefore, it can be concluded that the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Burke County Public Library, 412 Fourth Street, Waynesboro, Georgia 30830.

Attorney for licensee: Mr. Arthur H. Domby, Esquire, Troutman, Sanders, NationsBank Plaza, Suite 5200, 600 Peachtree Street, NE., Atlanta, Georgia 30308-2210.

NRC Project Director: David B. Matthews

Houston Lighting & Power Company, City Public Service Board of San Antonio,Central Power and Light Company, City of Austin, Texas, Docket Nos. 50-498and 50-499, South Texas Project, Units 1 and 2, Matagorda County, Texas

Date of amendment request: September 28, 1992, as supplemented on November 12, 1992.

Description of amendment request: Two proposed changes to the Technical Specification (TSs) were included in the submittal. The first change is to replace the variable shutdown margin requirements for Modes 1 and 2 with a constant value for all values of boron concentration. The second change is intended to clarify when an overall reactivity balance is to be performed to confirm core design predictions, and hence validate shutdown margin.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration. The NRC staff has reviewed the licensee's analysis against the standards of 10 CFR 50.92(c). The NRC staff's review is presented below.

1. The proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

Figure 3.1-1 of the TSs presently requires that shutdown margin be maintained as a function of boron concentration for Modes 1, 2, 3, and 4. The shutdown margin is a constant value of 1.75 percent $\Delta k/k$ up to a boron concentration of 900 ppm and then increases linearly with boron concentration. The presence of the variable shutdown requirement for Modes 1 and 2 may place the plant in a condition that is more restrictive than required in order to meet its safety analysis. The use of longer fuel cycles will cause the reactor core to be more reactive at beginning of life (BOL). This, in turn causes the "all rods in" critical boron concentration to increase at BOL. Use of the current Figure 3.1-1 of TS 3.1.1.1 requires additional shutdown margin over the 1.75 percent $\Delta k/k$ for the higher boron concentrations. For Modes 1 and 2, the safety analyses were performed using a constant value of 1.75 percent $\Delta k/k$, so any shutdown margin above that is more than is required to meet the safety analysis.

The licensee is also requesting that the surveillance requirement as stated in TS 4.1.1.1.2 be exempt from the requirements of TS 4.0.4. TS 4.1.1.1.2 requires that "the overall core reactivity balance shall be compared to predicted

values to demonstrate agreement within +1 percent $\Delta k/k$ at least once per 31 Effective Full Power Days." The TS is applicable in Modes 1, 2, 3, and 4. There is no exemption from TS 4.0.4. TS 4.0.4 prevents a mode change unless all surveillance requirements are met. Therefore, as written, TS 4.1.1.1.2 would have to be satisfied before entry into Mode 4 and each succeeding mode. However, performing a reactivity balance prior to criticality is not possible. As part of a normal reactor startup process, an estimated critical condition (ECC) is performed. If the ECC is in error by a specified amount, plant procedures are followed to ascertain the source of the error and to take appropriate action.

For the above stated reasons, the proposed TS changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. The proposed changes do not create the possibility of a new or different kind of accident from any previously stated.

The design basis for the shutdown margin in Modes 1 and 2 is unchanged.

The proposed change in the applicability of surveillance requirement (TS 4.1.1.1.2) does not affect the accuracy of the parameters used in the shutdown margin calculation performed for compliance with TS 3.1.1.1.

For the above reasons, the proposed changes do not create the possibility of a new or different accident from any previously stated.

3. The proposed changes do not involve a significant reduction in a margin of safety.

The design basis for the shutdown margin in Modes 1 and 2 remains unchanged.

The proposed change in the surveillance requirement does not affect the accuracy of the parameters used in the shutdown margin calculation performed for compliance with TS 3.1.1.1.

For the above reasons, the proposed changes do not involve a significant reduction in the margin of safety.

Based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the request for amendments involves no significant hazards consideration.

Local Public Document Room location: Wharton County Junior College, J. M. Hodges Learning Center, 911 Boling Highway, Wharton, Texas 77488.

Attorney for licensee: Jack R. Newman, Esq., Newman & Holtzinger, P.C., 1615 L Street, N.W., Washington, D.C. 20036

NRC Project Director: Suzanne C. Black

Indiana Michigan Power Company, Docket Nos. 50-315 and 50-316, Donald C. Cook Nuclear Plant, Unit Nos. 1 and 2, Berrien County, Michigan

Date of amendment request: February 12, 1992

Description of amendment request: The proposed amendments would change Technical Specifications to reflect the addition of clean water tanks and associated pumps, piping, and valves to the fire suppression water system in Units 1 and 2.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated.

[The proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.] The newly installed fire water storage tanks and their three associated pumps will supply enough water and pumping capability to be able to put out the largest single fire hazard even if one of the three pumps fail, which is in accordance with Branch Technical Position APSCB 9.5-1. Maintaining two of the existing pumps that take suction off of Lake Michigan is an added conservatism that results in Cook Nuclear Plant having two completely separate and independent sources of fire suppression water. Consequently, the proposed changes to the Cook Nuclear Plant design and Technical Specifications will not involve a significant increase in the probability or consequences of an accident previously evaluated.

(2) Create the possibility of a new or different kind of accident from any previously analyzed.

[The proposed amendment does not create the possibility of a new or different kind of accident from any previously analyzed.] The proposed system is designed in accordance with 10CFR50 Appendix A General Design Criterion 3. As such, no new potential fire hazards will be located in the vicinity of any structures, systems, or components important to safety. In addition, the effects of the fire water storage tanks rupturing have been analyzed to ensure that the safety capability of structures, systems, or components important to safety is not impaired.

In addition, by having the two pumps that take suction from Lake Michigan, we will still have a readily available source of fire suppression water in the event that the tanks fail. Consequently, the proposed changes will not create the possibility of a new or different kind of accident from any previously analyzed.

(3) Involve a significant reduction in a margin of safety.

[The proposed amendment does not involve a significant reduction in the margin of safety.] The margin of safety was carefully considered in the design of the proposed system. It was realized early in the design process that if we did not maintain the capability to obtain water from [the] Lake Michigan then the overall margin of safety would be reduced for two reasons.

First, Lake Michigan is essentially an infinite source of water and the tanks are not. Second, if both tanks catastrophically failed, no fire suppression water would exist until an alternate source was established.

The number of pumps is also important to the margin of safety. Although only three pumps are needed to meet the requirements of Branch Technical Position APSCB 9.5-1, a reduction in the number of pumps from four in the existing system to three in the new system would also reduce the margin of safety.

However, zebra mussel infestation of the existing system also poses the potential to reduce the margin of safety. Therefore, it was decided to install a new system with clean water stored in tanks and to also maintain two of the existing diesel-engine-driven lake pumps in the new system design. In this manner we address the zebra mussel problem and maintain the capability of obtaining water from Lake Michigan. We also increase the number of pumps from four in the existing system to five in the new system. By keeping the lake pumps isolated we eliminate any concern that the new portion of the system will become infested with zebra mussels. Periodically starting the lake pumps and flushing their discharge piping per the proposed T/Ss requirements, and chemically treating the pumps and discharge piping will help to ensure that they will be kept operational and free of zebra mussels. By increasing the number of pumps, having diversity in our available water sources, and addressing the zebra mussel problem, we have not only addressed the design issues that may have potentially reduced the margin of safety, but have actually increased the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Maude Preston Palenske Memorial Library, 500 Market Street, St. Joseph, Michigan 49085.

Attorney for licensee: Gerald Charnoff, Esq., Shaw, Pittman, Potts and Trowbridge, 2300 N Street, NW, Washington, DC 20037.

NRC Project Director: L. B. Marsh.

Niagara Mohawk Power Corporation, Docket No. 50-410, Nine Mile Point Nuclear Station, Unit 2, Oswego County, New York

Date of amendment request: November 24, 1992

Description of amendment request: The proposed amendment would revise Section 6.0, "Administrative Controls," of the Technical Specifications (TS). TS 6.5.1 would be revised to reflect changes in the size and composition of the Station Operations Review Committee (SORC) that are intended to improve the efficiency of the station review function. TS 6.5.3.6 would be revised to change the quorum requirements for the Safety Review and Audit Board (SRAB) to ensure membership continuity during scheduled meetings. TS 6.3 and 6.4 would be revised to delete several references and thereby improve consistency with 10 CFR Part 55.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

The operation of NMP2 [Nine Mile Point Nuclear Station, Unit 2], in accordance with the proposed amendment, will not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed changes to Technical Specification 6.5.1 are consistent with STS [Standard Technical Specifications] guidelines regarding number of members associated with a "Unit Review Group", designated at NMP2 as the "Station Operations Review Committee (SORC)". Proposed changes to the SORC quorum requirements incorporate BWR [boiling-water reactor] STS guidelines combined with later operating BWR plant provisions regarding establishment of a SORC Vice-Chairman position. The SORC Vice-Chairman position, with duties, responsibilities and qualifications similar to those of the SORC Chairman, is adopted from later operating BWR plant provisions found acceptable to the NRC. In addition, the authority presently granted to the SORC Chairman to appoint alternate SORC members and to convene SORC, is extended to the Vice-Chairman.

These changes provide a flexibility in the implementation of the SORC review process which should enhance the timeliness of response to routine activities as well as to emerging circumstances requiring SORC review. During SORC Chairman absence, the Vice-Chairman position assures the continuity required for effective implementation of the day-to-day SORC functions. Continued technical adequacy of the process is assured by retention of existing procedural controls requiring verification that SORC members or alternates present have appropriate technical background necessary for an adequate safety review of agenda items, as well as the requirements to designate other personnel, as necessary, for attendance at meetings where additional information or expertise is needed.

The SORC function of advising the Plant Manager on all matters related to nuclear safety, as stated in TS 6.5.1.1, remains unchanged. Similarly, the specific SORC responsibilities detailed in TS 6.5.1.6 are not affected by the proposed changes. The number of alternates permitted by TS 6.5.1.3 remains unchanged thereby maintaining the present condition that there always be at least a majority at each SORC meeting who are permanent SORC members.

The proposed change to the SRAB quorum meets the requirements of ANSI [American National Standards Institute] N18.7-1976 Sections 4.3.2.1 and 4.3.2.3. These require that the committee consist of no less than five (5) persons and that the quorum consist of not less than a majority of the principles or duly appointed alternates. This will ensure membership continuity during scheduled meetings. The proposed changes are consistent with STS guidelines, ANSI N18.7-1976 and the SRAB charter.

The proposed changes to TS 6.3 and 6.4 are administrative in nature and since no changes will be made to the Operator and Senior Operator license training programs, there is no impact on nuclear safety.

The proposed changes do not affect any accident precursors and do not alter or modify existing limitations on the function, use of alternates, and responsibilities of the SORC. Addition of STS and later operating BWR plant provisions applicable to NMP2 assures retention of an adequate level and quality of review of matters related to nuclear safety, and therefore does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The operation of NMP2, in accordance with the proposed amendment, will not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed changes for NMP2 Technical Specification Section 6.0 are based on STS guidelines and on later operating BWR plant provisions found acceptable to the NRC. These proposed changes have been reviewed for acceptability at NMP2 considering similarity of NMP2 nuclear safety review processes versus the STS and later operating BWRs. No new conditions of operation are introduced by the proposed changes. The proposed changes do not modify existing setpoints or design assumptions for system operation.

Since the proposed changes do not alter the functions and responsibilities of SORC and SRAB to review matters related to nuclear safety, do not modify the present level of plant system operability, and do not affect the Operator and Senior Operator license training programs, the proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The operation of NMP2, in accordance with the proposed amendment, will not involve a significant reduction in a margin of safety.

The proposed changes to Technical Specification Section 6.0 represent a combination of present requirements, STS guidelines and provisions that have been found acceptable for use on other operating BWRs with review processes similar to those at NMP2. The proposed SORC changes are intended to provide the flexibility required for continued timely SORC review of routine activities as well as review of emergent conditions, without compromising the technical adequacy of the process. The proposed SRAB quorum requirements will ensure membership continuity during scheduled SRAB meetings.

Existing procedural administrative controls requiring verification that SORC members or alternates present have appropriate technical background necessary for an adequate safety review of agenda items, as well as the requirements to designate other personnel, as necessary, for attendance at meetings where additional information or expertise is needed, remain in effect.

Since the proposed changes are based on STS guidelines and NRC accepted provisions at other operating plants that are applicable at NMP2, and since procedural administrative controls remain in place to assure presence of adequate technical expertise during the SORC review process, the proposed changes do not involve a significant reduction in a margin of safety.

Therefore, based on the above evaluation, Niagara Mohawk has concluded that these changes do not involve significant hazards consideration.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126.

Attorney for licensee: Mark J. Wetterhahn, Esquire, Winston & Strawn, 1400 L Street, NW., Washington, DC 20005-3502.

NRC Project Director: Robert A. Capra

Northern States Power Company, Docket Nos. 50-282 and 50-306, Prairie Island Nuclear Generating Plant, Unit Nos. 1 and 2, Goodhue County, Minnesota

Date of amendments request: January 21, 1992

Description of amendments request: The amendments revise surveillance tests intervals for engineered safety feature systems pump and valves to be consistent with the standard technical specifications.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the

licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed amendment will not involve a significant increase in the probability or consequences of an accident previously evaluated.

The decrease in the number of equipment operational transients will increase reliability more than the delay in problem identification. The net effect of this change will have a positive effect on equipment availability. These changes are consistent with Standard Technical Specifications. Therefore, these changes will not effect the probability or consequences of previously analyzed accidents.

2. The proposed amendment will not create the possibility of a new or different kind of accident from any accident previously analyzed.

These changes only affect the equipment testing frequency, and therefore will not create the possibility of a new kind of accident or different kind of accident.

3. The proposed amendment will not involve a significant reduction in the margin of safety.

These changes will improve the performance of equipment and are intended to reduce the potential for equipment failures due to unnecessary testing. No safety margins will be affected.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Jay Silberg, Esq., Shaw, Pittman, Potts, and Trowbridge, 2300 N Street, NW, Washington, DC 20037.

NRC Project Director: L. B. Marsh

Pacific Gas and Electric Company, Docket Nos. 50-275 and 50-323, Diablo Canyon Nuclear Power Plant, Unit Nos. 1 and 2, San Luis Obispo County, California

Date of amendment requests: October 27, 1992 (Reference LAR 92-06)

Description of amendment requests: The proposed amendment would revise the combined Technical Specifications (TS) for the Diablo Canyon Power Plant (DCPP) Units 1 and 2 to relocate Table 3.8-1, "Motor-Operated Valves (MOVs) Thermal Overload Protection and Bypass Devices," to Diablo Canyon Power Plant procedures. The relocation is proposed in accordance with the guidance provided in Generic Letter (GL) 91-08, "Removal of Component Lists from Technical Specifications," dated May 6, 1991. TS 3/4.8.4 would be revised by removing reference to TS Table 3.8-1 and rewording in accordance with GL 91-08. The associated Bases would also be appropriately revised.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the change involve a significant increase in the probability or consequences of an accident previously evaluated?

The proposed changes simplify the TS, meet the regulatory requirements for control of MOV thermal overload and bypass devices, and are consistent with the recommendations of NUREG 1024 and GL 91-08. The procedural details of the MOV thermal overload protection and bypass devices table have not been changed, only relocated to a different controlling document. The proposed change is administrative in nature, should result in improved administrative practices, and does not affect plant operations.

Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the change create the possibility of a new or different kind of accident from any accident previously evaluated?

The proposed changes are administrative in nature, do not result in physical alterations or changes to the operation of the plant, and cause no change in the method by which any safety-related system performs its function.

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the change involve a significant reduction in a margin of safety?

The administrative change to relocate TS Table 3.8-1 to DCPP plant procedures does not alter basic regulatory requirements and does not affect any safety analyses. Adequate control of the content of the table is assured by existing administrative procedures.

The proposed relocation of TS Table 3.8-1 does not alter the requirements for MOV thermal overload protection and bypass devices operability currently in the TS. The LCO and surveillance requirements would be retained in the revised TS. Therefore, the proposed change would not affect the meaning, application, and function of the TS requirements.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment requests involve no significant hazards consideration.

Local Public Document Room location: California Polytechnic State University, Robert E. Kennedy Library, Government Documents and Maps Department, San Luis Obispo, California 93407

Attorney for licensee: Christopher J. Warner, Esq., Pacific Gas and Electric Company, P.O. Box 7442, San Francisco, California 94120

NRC Project Director: Theodore R. Quay

The Cleveland Electric Illuminating Company, Centerior Service Company, Duquesne Light Company, Ohio Edison Company, Pennsylvania Power Company, Toledo Edison Company, Docket No. 50-440, Perry Nuclear Power Plant, Unit No. 1, Lake County, Ohio

Date of amendment request: September 28, 1992

Description of amendment request: The proposed amendment would revise the Technical Specifications by removing the Reactor Protection System (RPS) trip and the Main Steam Line (MSL) Isolation Actuation signal requirements from the Main Steam Line Radiation Monitors (MSLRMs). This Technical Specification (TS) change requires revisions to TS 2.2.1 "Reactor Protection System Instrumentation Setpoints," TS 3.3.1 "Reactor Protection System Instrumentation," and TS 3.3.2 "Isolation Actuation Instrumentation."

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. These changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed change does not involve any increase in the probability of a previously evaluated accident. The RPS trips and Main Steam Line isolations being deleted were in place only to react to a previously evaluated accident, the Control Rod Drop Accident (CRDA). The elimination of the trips/isolations will not change the probability of occurrence of the CRDA, and thus has no affect [sic] on the probability of occurrence of previously evaluated accidents.

The consequences of previously evaluated accidents are also not increased as result of the proposed changes. No credit was ever taken for the RPS trip from the Main Steam Line radiation monitors (MSLRMs) in the Control Rod Drop Accident (CRDA) accident sequence description or in the associated radiological assessment (the scram signal assumed in the CRDA is the APRM Upscale signal). At PNPP, the CRDA accident sequence description also does not depend upon the Main Steam Line isolation signals from the MSLRMs. The plant will continue to be operated in compliance with the Banked Position Withdrawal Sequence (BPWS) analysis criteria, which are unchanged by this proposed amendment.

These criteria are enforced by the Rod Pattern Controller portion of the Rod Pattern Control System (RPCS), whose design and Technical Specification controls are also unchanged by this amendment, and conformance to the BPWS criteria ensure that an individual control rod's worth is such that if it is dropped during rod withdrawals, the enthalpy rise will continue to be less than the acceptance criteria for such scenarios. A CRDA event would not result in any significant radiological release, and the magnitude of any such release would continue to be less than any level which would have caused an isolation signal from the MSLRMs. As noted in the Bases for Specification 3.1.4.2, during power reductions below the LPSP [Low Power Setpoint], the Rod Pattern Controller portion of RPCS provides automatic supervision to assure that out-of-sequence rods will not be withdrawn or inserted. If this condition is not correctable in a manner consistent with the BPWS analysis, controls are in place to scram the plant. If the Rod Pattern Controller portion of RPCS is inoperable when thermal power is below the Low Power Setpoint, Technical Specification 3.1.4.2, Rod Pattern Control System, requires that no control rod be moved except by scram. Therefore, enforcement of the BPWS/RPCS requirements assures that the CRDA is of no significance at PNPP, and that the Main Steam Line isolation signal from the MSLRMs is not required.

Even though the BPWS/RPCS is designed to minimize the consequences of the CRDA, a hypothetical radiological assessment of a CRDA was performed which assumed that the BPWS/RPCS and their corresponding requirements do not exist in order to evaluate the radiological consequences without subsequent main steam line isolation, as compared to previous design basis assessments. This assessment was performed consistent with the BWR Owners Group Topical Report NEDO-31400 "Safety Evaluation for Eliminating the Boiling Water Reactor Main Steam Line Isolation Valve Closure Function and Scram Function of the Main Steam Line Radiation Monitor," which has been reviewed and generically accepted by the NRC staff in a Safety Evaluation Report (SER) dated May 15, 1991.

The NEDO-31400 submittal and the NRC's SER analyzed the proposed changes and both concluded that as long as the individual utilities met certain conditions the changes would not significantly affect the consequences of a previously evaluated accident. This amendment request documents how PNPP meets the conditions imposed by the NRC's SER, and that the PNPP design is in fact bounded by the NEDO-31400 radiological analysis. Thus this assessment also shows that there is no significant increase in the consequences of any previously evaluated accident.

2 The proposed changes do not create the possibility of a new or different kind of accident from any previously evaluated.

The proposed changes request the removal of the Technical Specification requirements for the RPS trips and main steam line isolation signals generated by the MSLRMs. The original reason for the signals was to respond to a CRDA as discussed above. The elimination of these signals, which served only in a mitigative function, do not create the possibility of a new or different kind of accident from those previously evaluated. Also, radiation monitors with alarm functions will remain installed in the plant to warn the operators of a high radiation condition in the main steam lines, or in the offgas system. In addition, the trip signal from the MSLRMs to the mechanical vacuum pump line isolation valves will remain installed in the plant, and will be addressed in the Technical Specifications. As such, the condenser release path through the mechanical vacuum pump line will still be isolated on a high Main Steam Line Radiation condition. Thus no new or different accident can be postulated by the proposed changes.

3. The proposed changes do not involve a significant reduction in the margin of safety.

A reliability assessment of the elimination of the MSLRM scram function on reactivity control failure frequency and core damage frequency was performed as part of the NEDO analysis. The results of the analysis indicated a negligible increase in reactivity control failure frequency with deletion of the MSLRM scram function. However, this increase is offset by the reduction in the transient initiating events (inadvertent scrams). This reduction in transient initiating events represents a reduction in core damage frequency. The final result was determined to be a net improvement to safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Perry Public Library, 3753 Main Street, Perry, Ohio 44081

Attorney for licensee: Jay Silberg, Esq., Shaw, Pittman, Potts & Trowbridge, 2300 N Street, NW., Washington, DC 20037

NRC Project Director: John N. Hannon

Toledo Edison Company, Centerior Service Company, and The Cleveland Electric Illuminating Company, Docket No. 50-346, Davis-Besse Nuclear Power Station, Unit No. 1, Ottawa County, Ohio

Date of amendment request: July 28, 1992

Description of amendment request: The proposed amendment wouldddelete Technical Specification (TS) 3/4.9.9, "Refueling Operations - Containment Purge and Exhaust Isolation System," and its bases, because of its redundancy to other TS that address the operability requirements of the containment purge and exhaust isolation system. Also, the proposed amendment would revise TS 3/4.3.2, "Safety System Instrumentation - Safety Features Actuation System Instrumentation," and TS 3/4.9.4, "Refueling Operations - Containment Penetrations," and its bases. The effect of this proposed change would be to allow the bypass of the safety features actuation system in Mode 6, "Refueling," by the use of the containment purge and exhaust system noble gas monitor in conjunction with manual closure of the containment purge and exhaust isolation valves instead of automatic closure.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

Toledo Edison had reviewed the proposed changes and determined that a significant hazards consideration does not exist because operation of the DBNPS in accordance with the changes would:

1a. Not involve a significant increase in the probability of an accident previously evaluated because the initiators regarding the fuel handling accident (USAR Section 15.4.7.3) are not affected by the deletion of TS 3/4.9.9 or the use of the containment purge and exhaust system noble gas monitor (RE5052C) to automatically contain any release in progress.

1b. Not involve a significant increase in the consequences of an accident previously evaluated because the assumptions discussed in the fuel handling accident (USAR Section 15.4.7.3) are not affected by the deletion of TS 3/4.9.9 or allowing the use of the containment purge and exhaust system noble gas monitor (RE5052C) to automatically contain a release in progress. Furthermore, manual operator action can be taken to isolate containment in lieu of the SFAS area radiation monitors' automatic containment isolation function. No credit is taken in the assumptions for the containment isolation. Thus, the deletion of TS 3/4.9.9 and the use of the containment purge and exhaust system noble gas monitor (RE5052C) and manual operator action does not involve a significant increase in the consequences of an accident previously evaluated. There is no significant change in the ability of DBNPS to contain a release of radioactivity.

2b. Not create the possibility of a different kind of accident from any accident previously evaluated because the operability requirements of the containment purge and exhaust isolation system contained in the TS 3/4.9.9 are adequately addressed by SR 4.3.2, SR 4.6.3, and TS 3/4.9.4. Thus, deletion of TS 3/4.9.9 does not affect the operability of the containment purge and exhaust isolation system and, therefore, does not create the possibility of a different kind of accident from any accident previously evaluated.

Allowing the use of the containment purge and exhaust system noble gas monitor (RE5052C) to automatically contain a release in progress in lieu of the SFAS area radiation monitors' automatic containment isolation function does not introduce any different accident initiators. Furthermore, manual

operator action can be taken to isolate containment. Thus, it does not create the possibility of a different kind of accident from any accident previously evaluated.

3. Not involve a significant reduction in a margin of safety because neither the purpose nor the function of the containment purge and exhaust isolation system is being changed by the deletion of TS 3/4.9.9. The operability requirements of TS 3/4.9.9 are adequately addressed in SR 4.3.2, SR 4.6.3, and TS 3/4.9.4.

Allowing the use of the containment purge and exhaust system noble gas monitor (RE5052C) to automatically contain a release in progress in lieu of the SFAS area radiation monitors automatic isolation function is acceptable based on the accident analysis assuming no isolation or filtration for the fuel handling accident in containment. Furthermore, manual operator action can be taken to isolate containment. Thus, it does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: University of Toledo Library, Documents Department, 2801 Bancroft Avenue, Toledo, Ohio 43606

Attorney for licensee: Jay E. Silberg, Esquire, Shaw, Pittman, Potts and Trowbridge, 2300 N Street, N.W., Washington, DC 20037

NRC Project Director: John N. Hannon

Toledo Edison Company, Centerior Service Company, and The Cleveland Electric Illuminating Company, Docket No. 50-346, Davis-Besse Nuclear Power Station, Unit No. 1, Ottawa County, Ohio

Date of amendment request: September 11, 1992

Description of amendment request: The proposed amendment would delete Technical Specification (TS) Figures 5.1-1, 5.1-2, 5.1-3, and 5.1-4 regarding the Davis-Besse Nuclear Power Station exclusion area, low population zone, unrestricted area boundary for liquid effluents, and unrestricted area boundary for gaseous effluents, respectively. Also, TS 5.1, "Site," would be revised to reference 10 CFR Part 100, "Reactor Site Criteria," and TS Section 1.0, "Definitions," instead of the four figures.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

Toledo Edison has reviewed the proposed changes and determined that a significant hazards consideration does not exist because operation of the Davis-Besse Nuclear Power Station, Unit Number 1, in accordance with the proposed changes would:

1a. Not involve a significant increase in the probability of an accident previously evaluated because this is strictly an administrative change to delete from the Davis-Besse Nuclear Power Station (DBNPS) Technical Specifications (TS) information that is already maintained in the DBNPS Updated Safety Analysis Report (USAR). There are no accident initiators or assumptions affected by the proposed changes.'

1b. Not involve a significant increase in the consequences of an accident previously evaluated because this is strictly an administrative change to delete from the DBNPS TS information that is already maintained in the DBNPS USAR. There is no effect on the source term or containment isolation, and no increase in radiological effluents.

2a. Not create the possibility of a new kind of accident from any accident previously evaluated because this is strictly an administrative change to delete from the DBNPS TS information that is already maintained in the DBNPS USAR.

2b. Not create the possibility of a different kind of accident from any accident previously evaluated because this is strictly an administrative change to delete from the DBNPS TS information that is already maintained in the DBNPS USAR.

3. Not involve a significant reduction in a margin of safety because this is strictly an administrative change to delete from the DBNPS TS information that is already maintained in the DBNPS USAR.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: University of Toledo Library, Documents Department, 2801 Bancroft Avenue, Toledo, Ohio 43606

Attorney for licensee: Jay E. Silberg, Esquire, Shaw, Pittman, Potts and Trowbridge, 2300 N Street, N.W., Washington, DC 20037

NRC Project Director: John N. Hannon

Union Electric Company, Docket No. 50-483, Callaway Plant, Unit 1, Callaway County, Missouri

Date of amendment request: November 3, 1992 and December 1, 1992

Description of amendment request: This proposed amendment would revise Technical Specification (TS) 3.3.2 "Engineered Safety Features Actuation System (ESFAS) Instrumentation," TS 3.8.1 "Alternating Current (AC) Sources," and their associated surveillances. These TS revisions would require the Load Shedder Emergency Load Sequencer (LSELS) and the supplying 4KV Bus undervoltage devices to be operable during plant modes 5 and 6.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

The proposed change does not involve a significant hazards consideration because operation of Callaway Plant with this change would not:

1. Involve a significant increase in the probability or consequences of an accident previously evaluated. The Callaway Safety Analysis Report has been reviewed and been found to be unaffected by this proposed change. This change will not increase the probability or consequences of any accident or malfunction of equipment because the LSELS will be required to be operable in modes 5 and 6 which enhances plant operabilily

2. Create the possibility of a new or different kind of accident from any previously evaluated. This change increases the operability requirement for the LSELS. There is no new type of accident or malfunction created and the method and manner of plant operation will only change by adding OPERABILITY requirements for LSELS in MODES 5 & 6, which enhances plant safety in shutdown modes.

3. Involve a significant reduction in a margin of safety. The margin of safety remains unaffected since no design change is made and plant operation remains the same.

As discussed above, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated or create the possibility of a new or different kind of accident from any previously evaluated. This change does not result in a significant reduction in a margin of safety. Therefore, it has been determined that the proposed change does not involve a significant hazards consideration.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Callaway County Public Library, 710 Court Street, Fulton, Missouri 65251.

Attorney for licensee: Gerald Charnoff, Esq., Shaw, Pittman, Potts & Trowbridge, 2300 N Street, N.W., Washington, DC 20037

NRC Project Director: John N. Hannon

Union Electric Company, Docket No. 50-483, Callaway Plant, Unit 1, Callaway County, Missouri

Date of amendment request: November 3, 1992 and December 4, 1992

Description of amendment request: This proposed amendment would revise Table 4.3-1 "Reactor Trip System Instrumentation Surveillance Requirements," Note 5, to reflect that integral bias curves, rather than detector plateau curves, are used to calibrate the source range instrumentation. The low-noise preamplifiers, provided for the Callaway Nuclear Instrumentation System, do not accommodate the use of the traditional detector plateau curves to calibrate the source range.

The integral bias curve is considered to be a more inclusive calibration than the detector plateau curves. The intermediate range and power range channels will continue to be calibrated by using the detector plateau curves.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

The proposed change to Technical Specification Table [4.3-1] does not involve a significant hazard consideration because operation of the Callaway Plant with this change would not:

1. Involve a significant increase in the probability or consequences of an accident previously evaluated.

Plant equipment is not modified by calibrating the NIS [Nuclear Instrumentation System] source range instrumentation using the integral bias curve. Using the integral bias curve is a more inclusive calibration than the plateau curve and provides the same information, i.e., the high voltage operating point. The change does not affect accident initiators or assumptions. The consequences due to accidents previously evaluated are not being changed.

2. Create the possibility of a new or different kind of accident from any previously evaluated.

No new accidents are created by the changes being made. No new equipment is being added. No new modes of operation or means of control are being made. The probability of a malfunction of equipment important to safety is unchanged since the calibration of the NIS source range instrumentation using the integral bias curve, rather than the plateau curve, provides the same information. The consequences of malfunctions of equipment important to safety are not changed. No new malfunctions are being created. No new controlling modes or equipment operations are being created.

3. Involve a significant reduction in a margin of safety.

Using the integral bias curve is a more inclusive calibration than the plateau curve and provides the same information, i.e., the high voltage operating point. As discussed above, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated, create the possibility of a new or different kind of accident from any previously evaluated, or result in a significant reduction in a margin of safety. Therefore, it has been determined that the proposed change does not involve a significant hazards consideration.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Callaway County Public Library, 710 Court Street, Fulton, Missouri 65251.

Attorney for licensee: Gerald Charnoff, Esq., Shaw, Pittman, Potts & Trowbridge, 2300 N Street, N.W., Washington, DC 20037

NRC Project Director: John N. Hannon

Washington Public Power Supply System, Docket No. 50-397, Nuclear Project No. 2, Benton County, Washington

Date of amendment request: November 25, 1992

Description of amendment request: The amendment proposes to change Section 6 (Administrative Controls) of the Technical Specifications (TS) to: (1) modify the title of the Nuclear Safety Assurance Group (NSAG) to the Nuclear Safety Assurance Division (NSAD), and Director of Licensing and Assurance to Director of Quality Assurance, (2) modify the titles of the members on the Plant Operations Committee (POC), (3) delete the position of Assistant Plant Manager as Vice Chairman of the POC, and allow the Plant Manager to designate a Vice Chairman from the POC membership, and record the designation in the POC meeting minutes, and (4) add the Engineering Services Division Manager as a POC member. One title change involves splitting the current combined responsibilities for Chemistry/Radiation Protection into two different management positions responsible for their respective activities. The Radiation Protection Manager will remain as a member of the POC.

The proposed changes are needed to implement a reorganization of plant management to make the various divisions of station operation more responsive to plant issues and events.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration. The NRC staff has reviewed the licensee's analysis against the standards of 10 CFR 50.92(c). The NRC staff's review is presented below.

The changes are administrative in nature and involve no physical alteration of the plant, or changes to setpoints, operating conditions, or operating parameters. The response of the plant to previously evaluated accidents thus is not affected. Therefore, the proposed change will not involve a significant increase in the probability or consequences of an accident previously evaluated.

The administrative nature of the proposed changes do not affect the design, operation, maintenance, or testing of the plant. Thus no new modes of failure are created. Therefore, these changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed changes reflect a planned organizational change that do not change the qualification requirements or competence of the members of the POC. The same technical level of Plant Management Staff is still required to constitute a quorum. The addition of the Engineering Services Division Manager to POC membership expands the capability to more completely cover appropriate aspects of station operation. Thus, the capability of POC to meet its responsibilities is not diminished. Therefore, these changes do not involve a significant reduction in a margin to safety.

Based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Richland Public Library, 955 Northgate Street, Richland, Washington 99352

Attorney for licensee: Nicholas S. Reynolds, Esq., Winston & Strawn, 1400 L Street, N.W., Washington, D.C. 20005-3502

NRC Project Director: Theodore R. Quay

Wolf Creek Nuclear Operating Corporation, Docket No. 50-482, Wolf CreekGenerating Station, Coffey County, Kansas

Date of amendment request: October 28, 1992

Description of amendment request: The proposed technical specification revisions are being made to various parameter values, limiting conditions

for operation, and surveillance requirements as a result of analyses performed to support Cycle 7 operation, including the introduction of the VANTAGE 5H fuel design. Although the analyses were also performed assuming an increased power level, the proposed Cycle 7 changes do not include an increase in the rated thermal power defined by the facility operating license. Specific changes proposed include the incorporation of a Core Operating Limits Report in accordance with Generic Letter 88-16, increases in allowable peaking factors, changes to power distribution monitoring to reflect a change to the licensee's nuclear design methodology, increase in the most positive moderator temperature coefficient, changes to several reactor protection system setpoints, decrease in the reactor coolant system thermal design flow, increase in the allowable tolerance on the main steam safety valve setpoints, and an increase in the required shutdown margin in Mode 5, Cold Shutdown.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration. The NRC staff has reviewed the licensee's analysis against the standards of 10 CFR 50.92(c). The NRC staff's review is presented below.

1. Do the proposed changes involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed changes do not significantly change the actual operation of plant systems, structures or components. The changes in fuel assembly design, power distribution monitoring, and reactivity parameter values have been evaluated and determined to be acceptable. These changes have been analyzed in accordance with methodologies which have been approved by or are currently under review by the NRC staff. Since the changes do not significantly revise plant hardware or operating practices, no increase in the probability of an accident has been introduced. The changes, including those involving changes in setpoints, setpoint tolerances, or other analysis assumptions have been analyzed and determined to have minimal impact on the consequences of any previously evaluated accident.

2. Do the proposed changes create the possibility of a new or different kind of accident from any previously evaluated.

The proposed changes do not introduce any significant changes to the performance requirements for or mode of operation of any systems or components and therefore, do not introduce any new failure modes. Changes to specific parameter values or tolerances have been analyzed utilizing methodologies either approved by or currently under review by the NRC and the plant has been determined to remain within established operating limits. Therefore, there is no possibility of the creation of a new or different kind of accident from those previously evaluated.

3. Do the proposed changes involve a significant reduction in the margin of safety.

The analyses performed to justify Cycle 7 operation, including all of the proposed changes, demonstrated that applicable design and safety limits continue to be satisfied. The proposed changes to various parameter values, limiting conditions for operation, and surveillance requirements reflect changes in the core design methodology and selected analysis assumptions. However, the analyses methodologies utilized have either been approved or are currently under review by the NRC. These reviews and the specific analysis results associated with the proposed changes have demonstrated that the margin of safety is not significantly reduced.

Local Public Document Room Locations: Emporia State University, William Allen White Library, 1200 Commercial Street, Emporia, Kansas 66801 and Washburn University School of Law Library, Topeka, Kansas 66621

Attorney for licensee: Jay Silberg, Esq., Shaw, Pittman, Potts and Trowbridge, 2300 N Street, N.W., Washington, D. C. 20037

NRC Project Director: Suzanne C. Black, Director

Previously Published Notices Of Consideration Of Issuance Of Amendments To Operating Licenses, Proposed No Significant Hazards Consideration Determination, And Opportunity For A Hearing

The following notices were previously published as separate individual notices. The notice content was the same as above. They were published as individual notices either because time did not allow the Commission to wait for this biweekly notice or because the action involved exigent circumstances. They are repeated here because the biweekly notice lists all amendments issued or proposed to be issued involving no significant hazards consideration.

For details, see the individual notice in the **Federal Register** on the day and page cited. This notice does not extend the notice period of the original notice.

Pennsylvania Power and Light Company, Docket No. 50-387 Susquehanna Steam Electric Station, Unit 1, Luzerne County, Pennsylvania

Date of amendment request: November 30, 1992

Brief description of amendment request: The amendment would revise the Technical Specifications to authorize operation of the Reactor Water Cleanup (RWCU) system in the current fuel cycle (Cycle 6) with the RWCU system non-regenerative heat exchanger discharge high temperature channel substituting for the inoperable 'B' RWCU high flow isolation trip channel.Date of publication of individual notice in **Federal Register:** December 15, 1992, (57 FR 59363)

Expiration date of individual notice: January 14, 1993

Local Public Document Room location: Osterhout Free Library, Reference Department, 71 South Franklin Street, Wilkes-Barre, Pennsylvania 18701.Notice Of Issuance Of Amendment To Facility Operating License

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for Hearing in connection with these actions was published in the **Federal Register** as indicated. No request for a hearing or petition for leave to intervene was filed following this notice.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has

made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendments, (2) the amendments, and (3) the Commission's related letters, Safety Evaluations and/or Environmental Assessments as indicated. All of these items are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, D.C., and at the local public document rooms for the particular facilities involved. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Director, Division of Reactor Projects.

Baltimore Gas and Electric Company, Docket Nos. 50-317 and 50-318, Cliffs Nuclear Power Plant, Unit Nos. 1 and 2, Calvert County, Maryland

Date of application for amendments: September 1, 1992, as supplemented on November 11, 1992.

Brief description of amendments: The amendments revise the Unit Nos. 1 and 2 spent fuel pool enrichment limit. The enrichment limit is decreased from 5.0 weight percent (w/o) U-235 to a value of 4.52 w/o U-235.

Date of issuance: December 22, 1992

Effective date: December 22, 1992

Amendment Nos.: 176 and 153

Facility Operating License Nos. DPR-53 and DPR-69: Amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** September 30, 1992 (57 FR 45075)The Commission's related evaluation of these amendments is contained in a Safety Evaluation dated December 22, 1992. No significant hazards consideration comments received: No

Local Public Document Room location: Calvert County Library, Prince Frederick, Maryland 20678.

Boston Edison Company, Docket No. 50-293, Pilgrim Nuclear Power Station,Plymouth County, Massachusetts

Date of application for amendment: October 8, 1992

Brief description of amendment: This amendment revises Technical Specifications to incorporate an asterisk referencing a footnote granting relief to allow only one train of SGTS and CRHEAF system operable prior to and during refueling activities during RFO No. 9.

Date of issuance. December 16, 1992

Effective date: December 16, 1992

Amendment No.: 144

Facility Operating License No. DPR-35: Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** October 28, 1992 (57 FR 48813) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 16, 1992. No significant hazards consideration comments received: No

Local Public Document Room location: Plymouth Public Library, 11 North Street, Plymouth, Massachusetts 02360.

Carolina Power & Light Company, Docket No. 50-261, H. B. Robinson SteamElectric Plant, Unit No. 2, Darlington County, South Carolina

Date of application for amendment: June 5, 1992

Brief description of amendment: The amendment clarifies Item 44 of Technical Specification Table 4.1-1, which specifies the minimum frequencies for checks, calibrations and tests of the containment vessel high-range monitors (R-32A and B) by revising the footnote so that the calibration method is clearly identified as an acceptable alternative to the NRC-preferred calibration technique described in NUREG-0737, but which does not preclude the use of the NUREG-0737 methodology.

Date of issuance: December 10, 1992

Effective date: December 10, 1992

Amendment No. 143

Facility Operating License No. DPR-23. Amendment revises the Technical Specifications.

Date of initial notice in **Federal Register:** June 24, 1992 (57 FR 28196) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 10, 1992. No significant hazards consideration comments received: No

Local Public Document Room location: Hartsville Memorial Library, Home and Fifth Avenues, Hartsville, South Carolina 29550

Consumers Power Company, Docket No. 50-255, Palisades Plant, Van Buren County, Michigan

Date of application for amendment: October 13, 1989 and August 27, 1992.

Brief description of amendment: This amendment would modify the Palisades Plant Technical Specification (TS) Section to incorporate the guidance provided in NRC Generic Letter (GL) 89-01 for implementation of programmatic controls for Radiological Effluent Technical Specifications (RETS) in the Administrative Controls Section of the TS and the relocation of procedural details of RETS to the Offsite Dose Calculation Manual (ODCM) or to the Process Control Program (PCP). This amendment also changes the reporting requirement for major modifications to radioactive liquid, gaseous, and solid waste treatment systems from a special report to a 10 CFR 50.59 report.

Date of issuance: December 18, 1992

Effective date: December 18, 1992

Amendment No.: 154

Facility Operating License No. DPR-20. Amendment revises the Technical Specifications.

Date of initial notice in **Federal Register:** February 7, 1990 (55 FR 4262)The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 18, 1992. No significant hazards consideration comments received: No.

Local Public Document Room location: Van Wylen Library, Hope College, Holland, Michigan 49423.

Entergy Operations, Inc., Docket No. 50-368, Arkansas Nuclear One,Unit No. 2, Pope County, Arkansas

Date of application for amendment: October 15, 1991

Brief description of amendment: The amendment deleted two inboard containment purge isolation valves from Technical Specification Table 3.6-1.

Date of issuance: December 14, 1992

Effective date: December 14, 1992

Amendment No.: 140

Facility Operating License No. NPF-6. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** September 2, 1992 (57 FR 40211)The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 14, 1992. No significant hazards consideration comments received: No.

Local Public Document Room location: Tomlinson Library, Arkansas Tech University, Russellville, Arkansas 72801

Entergy Operations, Inc., Docket No. 50-368, Arkansas Nuclear One,Unit No. 2, Pope County, Arkansas

Date of application for amendment: October 9, 1990, as supplemented by letters dated May 12, and September 28, 1992

Brief description of amendment: The amendment revised TS 3/4.8.1, "A.C. Sources," to achieve consistency with Generic Letter 84-15, "Proposed Staff Actions to Improve and Maintain Diesel Generator Reliability." The changes were intended to reduce testing of the emergency diesel generators and

improve their reliability. Editorial changes were also made.

Date of issuance: December 15, 1992

Effective date: 30 days from the date of issuance

Amendment No.: 141

Facility Operating License No. NPF-6. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** November 28, 1990 (55 FR 494500). The additional information contained in the supplemental letters dated May 12, and September 28, 1992, was clarifying in nature and, thus, within the scope of the initial notice and did not affect the staff's proposed no significant hazards consideration determination.The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 15, 1992. No significant hazards consideration comments received: No.

Local Public Document Room location: Tomlinson Library, Arkansas Tech University, Russellville, Arkansas 72801

Houston Lighting & Power Company, City Public Service Board of San Antonio, Central Power and Light Company, City of Austin, Texas, Docket Nos. 50-498 and 50-499, South Texas Project, Units 1 and 2, Matagorda County, Texas

Date of amendment request: June 26, 1991, as supplemented by letters dated January 24, 1992 and June 24, 1992.

Brief description of amendments: The amendments make changes to the Technical Specifications in accordance with the guidance provided in Generic Letter 89-01. The changes consist of relocating the procedural details of Radiological Effluent Technical Specifications (RETS) into the Offsite Dose Calculation Manual (ODCM) or the Process Control Program (PCP) in a manner that ensures these details are incorporated into plant operating procedures. In addition, programmatic controls would be added to the Administrative Controls section of Technical Specifications to satisfy the regulatory requirements and control changes to the procedural details of ODCM or PCP.

Date of issuance: December 21, 1992

Effective date: December 21, 1992, to be implemented within 15 days of issuance.

Amendment Nos.: Amendment Nos. 47 and 36

Facility Operating License Nos. NPF-76 and NPF-80: Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** September 18, 1991 and September 30, 1992 (56 FR 47238 and 57 FR 45085). The Commission'srelated evaluation of the amendments is contained in a Safety Evaluation dated December 21, 1992. No significant hazards consideration comments received: No.

Local Public Document Room location: Wharton County Junior College, J. M. Hodges Learning Center, 911 Boling Highway, Wharton, Texas 77488

Indiana Michigan Power Company, Docket Nos. 50-315 and 50-316, Donald C. Cook Nuclear Plant, Unit Nos. 1 and 2, Berrien County, Michigan

Date of application for amendments: February 15, 1991 as supplemented September 13, 1991.

Brief description of amendments: The amendments make administrative changes to the TS for both units. Four items in the proposed change were not purely administrative in nature. The changes dealt with operability of the automatic trip logic, engineered safety featured system instrumentation, containment air lock, and the physical stops on the Auxiliary Building Crane. These changes will be evaluated under a separate cover.

Date of issuance: November 13, 1992

Effective date: November 13, 1992

Amendments Nos.: 168 and 151Facility Operating Licenses Nos. DPR-58 and DPR-74. Amendments revised theTechnical Specifications.

Date of initial notice in **Federal Register:** July 10, 1991 (56 FR 31435) and November 13, 1991 (56 FR 57697).The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated November 13, 1992. No significant hazards consideration comments received: No.

Local Public Document Room location: Maude Preston Palenske Memorial Library, 500 Market Street, St. Joseph, Michigan 49085.

Nebraska Public Power District, Docket No. 50-298, Cooper Nuclear Station, Nemaha County, Nebraska

Date of amendment request: November 15, 1991

Brief description of amendment: The amendment modified the technical specifications to remove the Rod Sequence Control System, and reduce the Rod Worth Minimizer Low Power Setpoint from 20 percent to 10 percent.

Date of issuance: December 22, 1992

Effective date: December 22, 1992

Amendment No.: 156

Facility Operating License No. DPR-46 Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** July 8, 1992 (57 FR 30251)The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 22, 1992. No significant hazards consideration comments received: No.

Local Public Document Room location: Auburn Public Library, 118 15th Street, Auburn, Nebraska 68305.

Niagara Mohawk Power Corporation, Docket No. 50-220, Nine Mile Point Nuclear Station Unit No. 1, Oswego County, New York

Date of application for amendment: October 16, 1992

Brief description of amendment: The amendment revises Technical Specification Surveillance Requirement 4.1.4.b. to extend the current quarterly pump surveillance test interval for Core Spray System 11 from January 10, 1993, until February 20, 1993.

Date of issuance: December 17, 1992

Effective date: December 17, 1992

Amendment No.: 135

Facility Operating License No. DPR-63: Amendment revises the Technical Specifications.

Date of initial notice in **Federal Register:** November 12, 1992 (57 FR 53787)The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 17, 1992. No significant hazards consideration comments received: No

Local Public Document Room location: Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126.

Niagara Mohawk Power Corporation, Docket No. 50-220, Nine Mile Point Nuclear Station Unit No. 1, Oswego County, New York

Date of application for amendment: September 17, 1992

Brief description of amendment: The amendment revises Technical Specification 3.6.12/4.6.12, "Reactor Protection System Motor Generator Set Monitoring," and associated Bases to reflect the replacement of Motor Generator Sets 162 and 172 with Static Uninterruptible Power Supplies. The amendment also makes conforming changes to the Table of Contents and a minor editorial change to Technical Specification 4.6.12.

Date of issuance: December 17, 1992

Effective date: December 17, 1992

Amendment No.: 136

Facility Operating License No. DPR-63: Amendment revises the Technical Specifications.

Date of initial notice in **Federal Register:** October 14, 1992 (57 FR

47140)The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 17, 1992. No significant hazards consideration comments received: No

Local Public Document Room location: Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126.

Northeast Nuclear Energy Company, et al., Docket No. 50-336, Millstone Nuclear Power Station, Unit No. 2, New London County, Connecticut

Date of application for amendment: August 5, 1992, as supplemented October 20, 1992

Brief description of amendment: The amendment incorporates into the Technical Specifications the addition of two containment isolation valves to the auxiliary feedwater system and changes to Technical Specification Table 3.6-2, "Containment Isolation Valves."

Date of issuance: December 14, 1992

Effective date: December 14, 1992

Amendment No.: 166

Facility Operating License No. DPR-65. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** September 2, 1992 (57 FR 40216) The October 20, 1992, submittal provided additional clarifying information that did not change the initial no significant hazards consideration determination. The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 14, 1992. No significant hazards consideration comments received: No.

Local Public Document Room location: Learning Resources Center, Thames Valley State Technical College, 574 New London Turnpike, Norwich, Connecticut 06360.

Northern States Power Company, Docket Nos. 50-282 and 50-306, Prairie Island Nuclear Generating Plant, Unit Nos. 1 and 2, Goodhue County, Minnesota

Date of application for amendments: March 20, 1992 as revised July 23 and November 6, 1992. The July 23 and November 6, 1992 letters contained clarifying information to the amendment application. This information did not change the scope of the amendment request or the proposed determination of no significant hazards consideration.

Brief description of amendments: The amendments add and revise limiting conditions for operation and surveillance requirements to reflect the facility station blackout project modifications that will be complete upon startup of the Prairie Island units from the Fall 1992 outages.

Date of issuance: December 17, 1992

Effective date: December 17, 1992

Amendment Nos.: 103 and 96

Facility Operating License Nos. DPR-42 and DPR-60. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** April 15, 1992 (57 FR 13135) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 17, 1992. No significant hazards consideration comments received: No.

Local Public Document Room location: Minneapolis Public Library, Technology and Science Department, 300 Nicollet Mall, Minneapolis, Minnesota 55401.

Power Authority of the State of New York, Docket No. 50-333, James A. FitzPatrick Nuclear Power Plant, Oswego County, New York

Date of application for amendment: November 20, 1992

Brief description of amendment: The amendment revises Technical Specification (TS) 3.0.D and its associated Bases to incorporate recommendations of NRC Generic Letter (GL) 87-09, "Sections 3 0 And 4.0 Of The Standard Technical Specifications (STS) On The Applicability Of Limiting Conditions For Operation And Surveillance Requirements." Specifically, GL 87-09 provides guidance to address unnecessary restrictions on mode changes by TS 3.0.4 (FitzPatrick TS 3.0.D) and inconsistent application of exceptions.

Date of issuance: December 17, 1992

Effective date: December 17, 1992

Amendment No.: 184

Facility Operating License No. DPR-59: Amendment revised the Technical Specifications.Public comments requested as to proposed no significant hazards consideration: Yes (57 FR 56430, dated November 27, 1992). That notice provided an opportunity to submit comments on the Commission's proposed no significant hazards consideration determination. No comments have been received. The notice published November 27, 1992, also provided for an opportunity to request a hearing by December 28, 1992, but indicated that if the Commission makes a final no significant hazards consideration determination any such hearing would take place after issuance of the amendment.

The Commission's related evaluation of the amendment, finding of exigent circumstances, and final no significant hazards consideration determination are contained in a Safety Evaluation dated December 17, 1992.

Local Public Document Room location: Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126.

Public Service Electric & Gas Company, Docket No. 50-354, Hope Creek Generating Station, Salem County, New Jersey

Date of application for amendment: June 4, 1992 and July 8, 1992, as supplemented by letters dated September 1, 1992, October 6, 1992, and November 16, 1992.

Brief description of amendment: This amendment changes Technical Specification 6.3 to delete the Operations Manager as a position requiring a Senior Reactor Operator (SRO) license and delineate the requirements for the Operations Manager position, and changes TS 6.3.1 and 6.4.1 to delete existing licensed operator qualification and training requirements that are superseded based on 1) INPO accreditation of Hope Creek's licensed operator training programs, and 2) promulgation of the revised 10 CFR Part 55.

Date of issuance: December 21, 1992

Effective date: December 21, 1992

Amendment No.: 56

Facility Operating License No. NPF-57: This amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** July 22, 1992 (57 FR 32576) and August 19, 1992 (57 FR 37571)The Commission's related evaluation of the amendment is contained in aSafety Evaluation dated December 21, 1992. No significant hazards consideration comments received: No

Local Public Document Room location: Pennsville Public Library, 190 S. Broadway, Pennsville, New Jersey 08070

South Carolina Electric & Gas Company, South Carolina Public Service Authority, Docket No. 50-395, Virgil C. Summer Nuclear Station, Unit No. 1, Fairfield County, South Carolina

Date of application for amendment: April 15, 1992

Brief description of amendment: The amendment changes the Technical Specifications to revise Engineered Safety Features response times to account for sequential stroking of the outlet isolation valves on the refueling water storage tank and volume control tank.

Date of issuance: December 15, 1992

Effective date: December 15, 1992

Amendment No.: 108

Facility Operating License No. NPF-12. Amendment revises the Technical Specifications.

Date of initial notice in **Federal Register:** June 10, 1992 (57 FR 24679)The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 15, 1992. No significant hazards consideration comments received: No

Local Public Document Room location: Fairfield County Library, Garden and Washington Streets, Winnsboro, South Carolina 29180.

Union Electric Company, Docket No. 50-483, Callaway Plant, Unit 1, - Callaway County, Missouri

Date of application for amendment: December 20, 1991 and October 30, 1992

Brief description of amendment: The amendment revised Technical Specification Table 3 3-4, "Engineered Safety Features Actuation System Instrumentation Trip Setpoint," Functional Unit 8.b, to change the trip setpoint, the allowable value, total allowance, sensor error, and "Z" value for the "4 KV Undervoltage-Grid Degraded Voltage" protection function to agree with the required design values.

Date of issuance: December 16, 1992

Effective date: December 16, 1992

Amendment No.: 74

Facility Operating License No. NPF-30. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** April 29, 1992 (57 FR 18179)The October 30, 1992, letter provided clarifying information only and did not affect the staff's proposed no significant hazards consideration determination. The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 16, 1992. No significant hazards consideration comments received: No.Sholly

Local Public Document Room location: Callaway County Public Library, 710 Court Street, Fulton, Missouri 65251.

Union Electric Company, Docket No. 50-483, Callaway Plant, Unit 1, Callaway County, Missouri

Date of application for amendment: March 15, 1991, December 13, 1991, September 16, 1992 and October 30, 1992.

Brief description of amendment: The amendment revised Technical Specification (TS) ACTION statement 3.6.1.2, and the surveillance criteria in TS 4.6.1.2.b to establish two conditions for determining the acceptability of the periodic Type A tests conducted pursuant to Appendix J to 10 CFR Part 50. These conditions are the "as found" and the "as left" conditions; each has separate acceptance criteria.

Date of issuance: December 16, 1992

Effective date: December 16, 1992

Amendment No.: 75

Facility Operating License No. NPF-30. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** September 4, 1991 (56 FR 43816)The December 13, 1991, September 16, 1992 and October 30, 1992 submittals provided additional clarifying information that did not change the initial proposed significant hazards consideration determination. The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 16, 12992. No significant hazards consideration comments received: No.

Local Public Document Room location: Callaway County Public Library, 710 Court Street, Fulton, Missouri 65251.

Virginia Electric and Power Company, et al., Docket Nos. 50-338 and 50-339, North Anna Power Station, Units No. 1 and No. 2, Louisa County, Virginia

Date of application for amendments: September 4, 1992

Brief description of amendments: The amendments revise the current NA-1&2 TS pertaining to the monitoring program for secondary waiver chemistry. The revised TS are consistent with the Steam Generator Owners' Group and Electric Power Research Institute guidelines and NUREG-0452, Revision 4, "Standard Technical Specifications for Westinghouse Pressurized Water Reactors."

Date of issuance: December 9, 1992

Effective date: December 9, 1992

Amendment Nos.: 169, 148

Facility Operating License Nos. NPF-4 and NPF-7. Amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** October 14, 1992 (57 FR 47141)The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated December 9, 1992. No significant hazards consideration comments received: No.

Local Public Document Room location: The Alderman Library, Special Collections Department, University of Virginia, Charlottesville, Virginia 22903-2498.

Virginia Electric and Power Company, Docket Nos. 50-280 and 50-281, Surry Power Station, Unit Nos. 1 and 2, Surry County, Virginia.

Date of application for amendments. July 28, 1992

Brief description of amendments: These amendments delete the operability and surveillance requirements for the hydrogen monitor from the explosive gas monitoring instrumentation requirements for the waste gas holdup system. In addition, a requirement is added to submit a special report to the NRC if the oxygen concentration in a waste gas decay tank exceeds the TS limit and is not returned to below that limit in a specified time. Finally, administrative changes were made to achieve consistency with the Standard Technical Specifications.

Date of issuance: December 14, 1992

Effective date: December 14, 1992

Amendment Nos. 171, 170

Facility Operating License Nos. DPR-32 and DPR-37: Amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** September 2, 1992 (57 FR 40223) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 14, 1992. No significant hazards consideration comments received: No

Local Public Document Room location: Swem Library, College of William and Mary, Williamsburg, Virginia 23185

Dated at Rockville, Maryland, this 29th day of December 1992.

For the Nuclear Regulatory Commission

Martin J. Virgilio,

Acting Director, Division of Reactor Projects III/IV/V, Office of Nuclear Reactor Regulation

[Doc. 93–44 Filed 1–5–93; 8:45 am]

BILLING CODE 7590–01–F

[Docket No. 50–373]

Commonwealth Edison Co.; Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. NPF–11, issued to Commonwealth Edison Company (CECo, the licensee), for operation of the LaSalle County Station, Unit 1, located in LaSalle County, Illinois.

The proposed amendment requests changes to Technical Specification 5.0.

"Design Features" to address the planned rerack of the spent fuel pool at the LaSalle County Station. The proposed rerack would increase the spent fuel pool storage capacity from 1080 to 3986 storage cells. The added capacity would extend the projected loss of the full core discharge capability date from 2002 to 2013.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

(1) Would operation of the facility in accordance with the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

In the course of the analysis, CECo has considered the following potential accident scenarios:

1. A fuel assembly drop in the spent fuel pool.
2. Tool drops from the elevated worktable.
3. Loss of spent fuel pool cooling system flow.
4. A seismic event.
5. Rack (heavy load) drop during [rack installation].

It has been concluded that the proposed modification to the spent fuel pool does not increase the probability of accident scenarios 1–4 since the increase in storage capacity is not assumed to be an initiator of events involving the loss of spent fuel pool cooling, a dropped spent fuel assembly in the spent fuel pool, or a seismic event. A tool drop from the elevated worktable, although not a previously analyzed accident, is bounded by the consequences of the fuel drop accident.

CECo has also considered the probability of an accident resulting from a postulated rack (heavy load) drop during the [installation] process. LaSalle Technical Specification 3.9.7.b. restricts movement of loads heavier than the weight of a single spent fuel assembly from being carried over fuel stored in the spent fuel pool. All work in the spent fuel pool area will be controlled and performed in strict accordance with specific written procedures and administrative controls to prevent the movement of a rack directly over any fuel, all of which will be stored in the Unit 2 Spent Fuel Storage Pool. Therefore the probability of an accident resulting from the drop of a rack module on spent fuel is [very low].

* * * * *

Accordingly, the proposed Technical Specification and the associated modification does not involve an increase in the probability of an accident previously evaluated, or an accident of a different type.

CECo has evaluated the consequences of a fuel assembly drop in the spent fuel pool and determined that the criticality acceptance criterion, $k_{eff} \leq 0.95$, is not violated. In addition, CECo determined that the radiological consequences of a fuel assembly drop are bounded by the [Updated Final Safety Analysis Report] UFSAR analyses. Analyses demonstrate that the calculated doses are well within 10 CFR part 100 guidelines. The results of an analysis show that a dropped fuel assembly on the racks will not distort the racks such that stored fuel assemblies would be impacted. Thus, the consequences of this type of accident are not significantly changed from the previously evaluated spent fuel assembly drops.

The spent fuel pool system is a passive system with the exception of the Fuel Pool Cooling and Cleanup system and HVAC equipment. The redundancies in the cooling system and the HVAC hardware are not reduced by the planned storage densification. The extent of active hardware in these systems is only marginally changed. Therefore, the probability of occurrence or malfunction of safety equipment leading to loss of spent fuel pool cooling flow is not increased.

The consequences of a loss of spent fuel pool cooling system flow have been evaluated and it was determined that sufficient time remains available to provide an alternate means for cooling in the event of a complete failure of the cooling system. Thus, the consequences of this type of accident are not increased from previously evaluated loss of cooling system flow accidents.

The consequences of a seismic event have been evaluated. The new racks are designed and will be fabricated to meet the requirements of applicable portions of the NRC Regulatory Guides and published standards. The new free-standing racks are designed so that the integrity of both the racks and the pool structure is maintained during and after a seismic event with no resultant damage to stored fuel. Thus, the consequences of a seismic event are not increased from previously evaluated events.

The probability and consequences of a spent fuel cask drop will not be affected by the replacement of the racks. LaSalle Technical Specification 3.9.7. restricts movement of spent fuel casks from traveling over any region of the spent fuel pool. During the reracking of the Unit 1 Spent Fuel Storage Pool, all spent fuel will be stored in the Unit 2 Spent Fuel Storage Pool.

The consequences of a rack (heavy load) drop during [installation] have been considered. There is no equipment which is essential to the safe shutdown of the reactor or employed to mitigate the consequences of an accident which is beneath, adjacent to or otherwise within the area of influence of any loads that will be handled during the expansion modification. An analysis was also performed to determine the effect on the integrity of the spent fuel pool structure following the free fall of the heaviest rack module. The analysis concluded that the maximum load due to the rack drop event is well below the cumulative impact load produced during the seismic event, and as such is bounded by the seismic analysis. Therefore, the consequences of a rack (heavy load) drop during construction are not increased from previously evaluated events.

In summary, it is concluded that the proposed amendment to replace the spent fuel racks in the Unit 1 spent fuel pool does not involve an increase in the probability or consequences of an accident previously evaluated.

(2) Would operation of the facility in accordance with the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

CECo has evaluated the proposed modification in accordance with the guidance of the NRC Position Paper, "OT Position for Review and Acceptance of Spent Fuel Storage and Handling Applications," appropriate NRC Regulatory Guides, appropriate NRC Standard Review Plans, and appropriate Industry codes and standards. In addition, CECo has reviewed several previous NRC Safety Evaluation Reports for rerack applications similar to this proposed modification.

No unproven technology will be utilized either in the construction process or in the analytical techniques necessary to justify the planned fuel storage expansion. The basic reracking technology in this instance has been developed and demonstrated in other applications for fuel pool capacity increases previously approved by the NRC.

Based upon the foregoing, CECo concludes that the proposed Technical Specification and associated reracking modification does not create the possibility of a new or different kind of accident from any accident previously evaluated.

(3) Would operation of the facility in accordance with the proposed amendment involved a significant reduction in the margin of safety?

* * * * *

The established acceptance criterion for criticality is that the neutron multiplication factor in spent fuel pools shall be less than or equal to 0.95, including all uncertainties, under all conditions. This margin of safety has been adhered to in the criticality analysis methods for the new rack design.

The methods used in the criticality analysis conform to the applicable portions of the appropriate NRC guidance and industry codes, standards, and specifications. In meeting the acceptance criteria for criticality in the spent fuel pool, the analyses showed that k_{eff} is always less than 0.95, including uncertainties at a 95% confidence and 95% probability. Therefore, the proposed amendment does not involve a reduction in the margin of safety for nuclear criticality, as defined in the UFSAR.

The K-infinity criticality approach for allowing storage of advanced fuel designs in the new Unit 1 fuel racks includes the same type of conservatisms that were used in the original analysis performed for the new spent fuel storage racks. Therefore, the use of the K-infinity analysis does not involve a reduction in the margin of safety for nuclear criticality.

Conservative methods were used to calculate the maximum fuel cladding temperature and the increase in temperature of the water in the spent fuel pool. The thermal-hydraulic evaluation used the methods previously employed for evaluations of previously licensed high density spent fuel racks to demonstrate that adequate temperature margin is maintained. The proposed modification will increase the heat load in the spent fuel pool. However, the evaluation shows that the existing spent fuel cooling system will maintain the bulk pool water temperature at or below 140 degrees Fahrenheit with both cooling trains in operation. Thus, it is demonstrated that the peak value of the pool bulk temperature is lower than the temperature guidelines for both normal and abnormal conditions specified in the Standard Review Plan, section 9.1.3. The evaluation also shows that maximum local water temperatures along the hottest fuel assembly are below the nucleate boiling condition value. Thus, there is no reduction in the margin of safety for thermal hydraulic or spent fuel cooling concerns as defined in the UFSAR.

The main safety function of the spent fuel pool and the racks is to maintain the spent fuel assemblies in a safe configuration through all normal or abnormal loadings. Abnormal loadings which have been considered are the effect of an earthquake and the impact due to the drop of a spent fuel assembly. The mechanical, material, and structural design of the new spent fuel racks is in accordance with applicable portions of "NRC OT Position for Review and Acceptance of Spent Fuel Storage and Handling Applications," dated April 14, 1978, as modified January 18, 1979 and other applicable NRC guidance and industry codes. The rack materials used are comparable with the spent fuel pool and spent fuel assemblies. The structural considerations of the new racks address margins of safety against tilting and deflection or movement, such that the racks, if they do impact each other during the postulated seismic events, will only come in contact with each other at locations designed for that purpose. In addition the spent fuel assemblies remain intact and no criticality concerns exist. Thus the margins of safety as defined in the UFSAR are not reduced by the proposed rerack.

The Finite Element Method was used to evaluate the margins of the spent fuel pool concrete structure. The evaluation demonstrates that the strength margin of safety of the fuel pool structure is maintained.

From the foregoing, it is concluded that the margin of safety against nuclear criticality, structural integrity and material compatibility are consistent with the provision of the LaSalle UFSAR and USNRC regulations. The new worse case maximum bulk pool water temperature is 140 degrees Fahrenheit. This is found to result in a negligible decrease in the time-to-boil stated in the UFSAR. The margin of safety in the pool structure due to thermal loadings is well within the UFSAR specifications.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within thirty (30) days after the date of publication of this notice will be considered in making any final determination. The Commission will not normally make a final determination unless it receives a request for a hearing.

Written comments may be submitted by mail to the Rules and Directives Review Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room P–223, Phillips Building, 7920 Norfolk Avenue, Bethesda, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555. The filing of requests for hearing and petitions for leave to intervene is discussed below.

By February 5, 1993, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555 and at the local public document room located at the Public Library of Illinois Valley Community College, Rural Route No. 1, Oglesby, Illinois 61348.

If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board Panel, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board Panel will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The

contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period, such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish in the **Federal Register** a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1-(800)-325-6000 (in Missouri 1-(800)-342-6700). The Western Union operator should be given Datagram Identification Number N1023 and the following message addressed to Richard J. Barrett: petitioner's name and telephone number; date petition was mailed; plant name; and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to Michael I. Miller, Esquire; Sidley and Austin, One First National Plaza, Chicago, Illinois 60690, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board Panel that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1) (i)-(v) and 2.714(d).

The Commission hereby provides notice that this is a proceeding on an application for a license amendment falling within the scope of section 134 of the Nuclear Waste Policy Act of 1982 (NWPA), 42 U.S.C. 10154. Under section 134 of the NWPA, the Commission, at the request of any party to the proceeding, must use hybrid hearing procedures with respect to "any matter which the Commission determines to be in controversy among the parties." The hybrid procedures in section 134 provide for oral argument on matters in controversy, preceded by discovery under the Commission's rules, and the designation, following argument, of only those factual issues that involve a genuine and substantial dispute, together with any remaining questions of law, to be resolved in an adjudicatory hearing. Actual adjudicatory hearings are to be held on only those issues found to meet the criteria of section 134 and set for hearing after oral argument.

The Commission's rules implementing section 134 of the NWPA are found in 10 CFR part 2, Subpart K, "Hybrid Hearing Procedures for Expansion of Spent Nuclear Fuel Storage Capacity at Civilian Nuclear Power Reactors" (published at 50 FR 41670, October 15, 1985), and 10 CFR 2.1101 *et seq.* Under those rules, any party to the proceeding may invoke the hybrid hearing procedures by filing with the presiding officer a written request for oral argument under 10 CFR 2.1109. To be timely, the request must be filed within 10 days of an order granting a request for hearing or petition to intervene. (As outlined above, the Commission's rules in 10 CFR part 2, subpart G, and 2.714 in particular, continue to govern the filing of requests for a hearing or petitions to intervene, as well as the admission of contentions.) The presiding officer shall grant a timely request for oral argument. The presiding officer may grant an untimely request for oral argument only upon showing of good cause by the requesting party for the failure to file on time and after providing the other parties an opportunity to respond to the untimely request. If the presiding officer grants a request for oral argument, any hearing held on the application shall be conducted in accordance with the hybrid hearing procedures. In essence, those procedures limit the time available for discovery and require that an oral argument be held to determine whether any contentions must be resolved in adjudicatory hearing. If no party to the proceedings requests oral argument, or if all untimely requests for oral argument are denied, then the usual procedures in 10 CFR part 2, subpart G, apply.

For further details with respect to this action, see the application for amendment dated June 5, 1992, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, and at the local public document room, located at the Public Library of Illinois Valley Community College, Rural Route No. 1, Oglesby, Illinois 61348.

Dated at Rockville, Maryland, this 29th day of December 1992.

For the Nuclear Regulatory Commission.

Robert J. Stransky,

Project Manager, Project Directorate III-2, Division of Reactor Projects—III/IV/V, Office of Nuclear Reactor Regulation.

[FR Doc. 93-171 Filed 1-5-93; 8:45 am]

BILLING CODE 7590-01-M

OFFICE OF SPECIAL COUNSEL

Complaints and Disclosures Submitted Under the Whistleblower Protection Act

AGENCY: U.S. Office of Special Counsel.

ACTION: Extension of the expiration date of a currently approved collection.

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act.

SUMMARY: The U.S. Office of Special Counsel has submitted the following proposal for the collection of information to the Office of Management and Budget for approval under provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

OMB APPROVAL NUMBER: 3255–0002.

SUPPLEMENTARY INFORMATION: To fulfill the requirements of 5 U.S.C. 1212(a) of the Whistleblower Protection Act of 1989, the Office of Special Counsel (OSC) must receive complaints of prohibited personnel practices, Hatch Act violations and other matters under the Special Counsel's jurisdiction; whistleblower disclosures must also be received.

Affected Public

Individuals and Federal, State, and local government employees.

Respondent's Obligations

Required to obtain or retain a benefit.

Frequency

One time per complaint or disclosure.

Estimated Completion Time

1 hour.

Annual Responses

1600.

FOR FURTHER INFORMATION CONTACT: Copies of the information collection proposal can be obtained by calling or writing Cathleen M. Sadlo, (202) 653–6005, U.S. Office of Special Counsel, 1730 M Street, NW., suite 300, Washington, DC 20036–4505. Written comments and recommendations for the proposed information collection should be sent to Ms. Sadlo and Joe Lackey, OMB Desk Officer, Office of Management and Budget, room 3002, 725 17th Street, NW., Washington, DC 20503.

Signed on this 30th day of December, 1992.

Leonard M. Dribinsky,

Deputy Associate Special Counsel for Prosecution.

[FR Doc. 93–121 Filed 1–5–93; 8:45 am]

BILLING CODE 7405–01–M

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

[Docket No. 301–90]

Determination Concerning Section 301 Investigation of Indonesian Acts, Policies, and Practices Regarding Pencil Slat

AGENCY: Office of the United States Trade Representative.

ACTION: Notice of determination pursuant to section 304(a) of the Trade Act of 1974, as amended (Trade Act), that acts, policies, and practices of Indonesia concerning pencil slat are not imposing a burden or restriction upon United States commerce within the meaning of section 301(b)(1) of the Trade Act. In light of this determination, the United States Trade Representative (USTR) has terminated this investigation.

SUMMARY: On October 2, 1992, pursuant to section 302(a) of the Trade Act, the USTR initiated an investigation of Indonesia's acts, policies, and practices concerning pencil slat, in response to a petition filed by P&M Cedar Products, Inc. and Hudson ICS. 57 FR 46609 (Oct. 9, 1992). Since the investigation was initiated, the interagency Section 301 Committee has reviewed information submitted by the petitioners, the Government of Indonesia, and interested persons, as well as information already in the United States's possession and obtained from public sources. Additionally, in coordination with the Section 301 Committee, an interagency team led by USTR officials has conducted three rounds of consultations with Indonesian Government officials concerning the allegations set forth in the petition.

Based upon the results of these investigative efforts and the recommendations of the Section 301 Committee, the USTR has determined pursuant to sections 301(b)(1) and 304(a) of the Trade Act that the alleged acts, policies and practices are not imposing a burden or restriction upon United States commerce. Accordingly, the USTR has terminated this investigation.

EFFECTIVE DATE: This investigation is terminated effective December 31, 1992.

ADDRESSES: Office of the United States Trade Representative, 600 17th Street, NW., Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: Peter Collins, Director, Southeast Asian Affairs (202) 395–6813; Joseph Papovich, Deputy Assistant United States Trade Representative for Industry and Labor (202) 395–6160; or Dorothy Balaban, Special Assistant to the Section 301 Committee (202) 395–3432, Office of the United States Trade Representative.

SUPPLEMENTARY INFORMATION:

Summary of the Investigation

On August 18, 1992, P&M Cedar Products, Inc. and Hudson ICS filed a petition pursuant to section 302(a) of the Trade Act alleging that various Indonesian practices concerning pencil slat are unreasonable and burden or restrict United States commerce. Petitioners manufacture pencil slat from incense cedar. Indonesian pencil slat is manufactured from Jelutong, a less expensive and lower quality product.

The petition alleges that the following practices by Indonesia enhance exports of Indonesian pencil slat to third-country markets and are actionable under section 301(b): (1) The imposition of differential export taxes, with a high tax imposed on logs and no tax imposed on finished products such as pencil slat; (2) underpricing of government-owned timber stock; and (3) failure to enforce the terms of timber concession arrangements. The petition contends that these actions are part of Indonesia's plan to target exports of wood products, including pencil slat, a practice which is actionable under section 301(d)(3)(E) of the Trade Act. According to the petition, the combined effect of these practices has resulted in a substantial decline in petitioner' sales in third-country markets.

On October 2, 1992, the USTR initiated an investigation to determine whether the petition's allegations warranted action pursuant to section 301. 57 FR 46609 (Oct. 9, 1992). Immediately thereafter, USTR requested consultations with the Government of Indonesia, as required by section 303(a) of the Trade Act. Additionally, USTR invited comments from interested persons, 57 FR 46609–10, and obtained information and advice from the petitioners in preparing for the consultations. USTR also considered documents already in the possession of the United States concerning the possibility that Indonesia has engaged in or tolerated anticompetitive activities involving wood products.

In coordination with the Section 301 Committee, an interagency team led by USTR officials conducted three rounds of consultations with Indonesian government officials. Two of these rounds were held in Jakarta. On November 15 and 16, 1992, senior USTR officials and the Section 301 Committee met with petitioners and their counsel to discuss the petition's allegations, Indonesia's responses, submissions by interested persons, data gathered during the investigation, and legal and policy issues raised by the petition. The Section 301 Committee and the interagency investigative team also reviewed all available information concerning the practices alleged by the petition, including all comments submitted by interested persons and information obtained from international organizations.

Results of the Investigation

1. Indonesia's Log Export Tax

The investigation revealed that Indonesia maintains high export taxes on virtually all unprocessed and semi-processed wood products. The export tax on Jelutong logs is US$500 per cubic meter, and the export tax on Jelutong lumber is US$250 per cubic meter. The petition alleges that these export taxes "artificially inflate the domestic supply of materials used to make pencil slat, and thus depress their prices within Indonesia. Indonesian pencil slat producers thus obtain far cheaper raw materials."

No evidence was submitted to or uncovered by USTR or the Section 301 Committee during the investigation substantiating that the export tax has resulted in lower prices for Jelutong logs and lumber. In fact, as explained below, the data shows just the opposite—that Indonesian prices for Jelutong logs and lumber have increased notwithstanding the export tax.

2. Pricing of Government-Owned Timber

The petition also alleges that "Indonesia deliberately undervalues its forests, thereby reducing the cost of logging to artificially low levels," and that this undervaluation is evidenced by Indonesia's capture of only one-third of the actual economic "rent" on government-owned timber. Further, the petition claims that, because of extensive vertical integration in this industry, the benefits of any undervaluation flow directly to pencil slat producers. According to the petition, Indonesia captures less rent than the Malaysian state of Sabah. While Sabah captures over three-quarters of its timber rent, Indonesia captures only one-third.

Data obtained during the investigation demonstrates, however, that Indonesia's capture of rent compares favorably with that of a number of other similarly-situated, major timber producing states. These include the Malaysian state of Sarawak, Peninsular Malaysia, and the Philippines, which capture only 18.4 percent, 21.8 percent, and 11 percent, respectfully. This information indicates that Indonesia captures timber rent at a rate comparable to other similarly-situated countries.

3. Enforcement of Terms of Timber Concessions

The petition alleges that Indonesia charges "fire sale" prices for its timber and "turns a blind eye to widespread and notorious smuggling, poaching, early cutting, high grading, and tax evasion with respect to such timber harvests."

During the investigation, the Section 301 Committee obtained the following information concerning these allegations:

- A 1989 Ministerial Decree specifies the types of fines levied on Indonesian concessionaires who violate concession regulations. Out of the 581 concessionaires, 371 have had some type of fine levied against them since 1988; 607 violations have been recorded, for which approximately $21 million (at current exchange rates) in fines have been levied. Since 1988, 66 concession licenses have been revoked.
- In August 1992, Indonesia adopted a new procedure to track trees through the harvesting process to increase collected fees and deter poaching. The form used for this purpose is difficult to forge. If a log arrives at a mill without the required form, a fine of 10 times the royalty fee is assessed.
- Indonesia is making greater use of remote sensing information from satellites to monitor the rate of harvest and the presence of logging roads. An aerial survey is performed of the concession prior to its award, and thereafter an aerial survey is performed annually.
- Both the reforestation and license fees charged to Indonesian concessionaires have been increased.

USTR currently is unaware of any reason to question the validity of this information, which suggests that Indonesia has taken steps in recent years to enforce timber concession terms.

4. Trade Effects of the Alleged Practices

All available data indicates that prices of Jelutong logs in Indonesia actually have increased since the imposition of the export tax. In fact, prices for Jelutong logs appear to have increased more rapidly than other prices in the Indonesian economy. Factors other than the practices alleged in the petition appear to have had a much greater impact on prices than the three practices alleged by petitioners if, in fact, those practices have affected Indonesian prices of Jelutong logs. These factors include (1) exchange rate fluctuations since 1985; and (2) labor and transportation cost advantages enjoyed by Indonesian producers.

Thus, the alleged practices do not appear to be suppressing Jelutong log prices in Indonesia. The petition acknowledges that elimination of the export taxes on Jelutong logs and lumber "would have neither a direct nor an immediate impact on the export prices of Indonesian Jelutong slat." Accordingly, the remedy proposed by the petition is the imposition of an off-setting export tax on pencil slat, rather than the elimination of the export tax on Jelutong logs.

Comments Received From Interested Persons

Comments submitted by interested persons during the investigation suggest that the alleged practices do not exist, are not unreasonable, or are not harming United States commerce. Dixon-Ticonderoga, a United States pencil manufacturer that uses both cedar slat produced domestically and Jelutong slat from Indonesia, claims that Indonesia's ability to produce export-quality pencil slat is largely due to technical assistance provided by Dixon in order to develop an alternative to cedar slat. Dixon further claims that Indonesian Jelutong slat is used to produce lower-quality pencils for sale in markets that do not require the more expensive, higher-quality cedar slat.

According to Dixon, even if Indonesia eliminated all of the practices alleged in the petition, Dixon would continue to purchase Jelutong slat from Indonesia because there would still be a price difference between cedar and Jelutong slat. Thus, Dixon contends that elimination of the Indonesian practices would have no impact on the current mix of pencil slat sales in third-country markets. Accordingly, Dixon asserts that the practices alleged in the petition impose no burden or restriction on U.S. commerce.

The International Hardwood Products Association (IHPA) also submitted comments during the investigation. IHPA is comprised of importers of primarily tropical hardwoods, as well as some foreign exporters and end users. IHPA claims that the petitioners enjoyed a monopolistic position in the pencil slat market until Jelutong became available as an alternative to cedar. IHPA further claims that Indonesia will enjoy a comparative advantage in the pencil slat market as long as U.S. producers use more expensive raw materials (*i.e.*, cedar).

Determination

Section 301(b) of the Trade Act authorizes discretionary action if the USTR determines that an act, policy or practice of a foreign government is unreasonable and burdens or restricts United States commerce. Section 304(a)(1) of the Trade Act requires the USTR to determine whether any act, policy or practice described in section 301(b) exists and, if so, what action, if any, the USTR should take.

The petition contends that the three alleged practices together constitute export targeting, which Congress has specifically defined as an "unreasonable" practice within the meaning of section 301(b) The legislative history indicates that a determination of export targeting under section 301(b) concerns three elements:

(1) There must be a government scheme or plan involving coordinated actions;

(2) Export targeting practices must be involved; and

(3) The targeting must have the effect of assisting a discrete class of companies or industries to become more competitive in their export activities.

Based upon the results of this intensive investigation, and the recommendations of the interagency Section 301 Committee, the USTR has determined that there is no evidence that the alleged practices are having the adverse trade effects asserted by the petition. Thus, even assuming that the alleged practices exist and would otherwise be considered actionable under section 301(b), there is no basis for concluding that they are burdening or restricting United States commerce. Accordingly, the USTR has determined that no action is appropriate in this investigation and that it should be terminated.

The United States will continue to pursue improvements in international trade of wood and wood products through multilateral negotiations with Indonesia and other countries. In terminating this investigation, the USTR has strongly urged the Government of Indonesia to support these initiatives.

Additional information submitted to or obtained by USTR during this investigation is contained in the public file, which is available for public inspection in the USTR Reading Room: Room 101, Office of the United States Trade Representative, 600 17th Street, NW., Washington, DC 20506. An appointment to review the file (Docket No. 301–90) may be made by calling Brenda Webb (202) 395–6186. The USTR Reading Room is open to the public from 10 a.m. to 12 noon and 1 p.m. to 4 p.m., Monday through Friday.

Jeanne E. Davidson,

Chairman, Section 301 Committee.

[FR Doc. 93–180 Filed 1–5–93; 8:45 am]

BILLING CODE 3190–01–M

Identification of Priority Foreign Countries; Request for Public Comment

AGENCY: Office of the United States Trade Representative.

ACTION: Request for written submissions from the public concerning acts, policies to be considered with respect to identification of countries under section 182 the Trade Act of 1974, as amended (Trade Act).

SUMMARY: Section 182 of the Trade Act requires the United States Trade Representative (USTR) to identify countries that deny adequate and effective protection of intellectual property rights or deny fair and equitable market access to U.S. persons that rely on intellectual property protection. (19 U.S.C. 2242.) In addition, the USTR is required to determine which of those countries identified are priority foreign countries. Such priority countries would be subject to initiation of a "special" 301 investigation.

The USTR requests written submissions from the public concerning foreign countries' acts, policies, and practices that are relevant to the decision whether that country partner should be identified under section 182 of the Trade Act.

DATES: Submissions must be received on or before 12 noon on Friday, February 12, 1993.

FOR FURTHER INFORMATION CONTACT: Emery Simon, Deputy Assistant USTR for Intellectual Property (202) 395–6864; Gilbert Donahue at (202) 395–7320; or Catherine Field, Associate General Counsel (202) 395–3432, Office of the United States Trade Representative.

SUPPLEMENTARY INFORMATION: Pursuant to section 182 of the Trade Act of 1974, as amended by the Omnibus Trade and Competitiveness Act of 1988, the USTR must identify those countries that deny adequate and effective protection for intellectual property rights or deny fair and equitable market access to U.S. persons that rely on intellectual property protection. Those countries that have the most onerous or egregious acts, policies, or practices and whose acts, policies or practices have the greatest adverse impact (actual or potential) on relevant U.S. products are to be identified as priority foreign countries.

The USTR may not identify a country as a priority foreign country if it is entering into good faith negotiations, or making significant progress in bilateral or multilateral negotiations, to provide adequate and effective protection of intellectual property rights.

The USTR must decide whether to identify countries as priority foreign countries each year and issue a decision within 30 days after publication of the National Trade Estimate (NTE) report, i.e., no later than April 30, 1993. Priority foreign countries are potentially subject to initiation of an investigation under section 301 of the Trade Act.

Requirements for Submissions

Submissions should include a description of the problems experienced and the effect of the acts, policies, and practices on U.S. industry. Submissions should be as detailed as possible and should provide as a much information on methodology for assessing the effect of the acts, policies and practices. Comments must be filed in accordance with the requirements set forth in 15 CFR 2006.8(b) (55 FR 20593) and must be sent to Dorothy Balaban, Special Assistant to the Section 301 Committee, room 223, 600 17th Street, NW., Washington, DC 20506, no later than 12 noon on Friday, February 12, 1993. Because submissions will be placed in a file open to public inspection at USTR, business-confidential information should not be submitted.

Public Inspection of Submissions

Within one business day of receipt, submissions will be placed in a public file, open for inspection at the USTR Reading Room, in room 101, Office of the United States Trade Representative, 600 17th Street, NW., Washington, DC. An appointment to review the file may be made by calling Brenda Webb, (202) 395–6186. The USTR Reading Room is open to the public from 10 a.m. to 12 noon and from 1 p.m. to 4 p.m., Monday through Friday.

Carmen Suro-Bredie,

Assistant USTR for Intellectual Property and the Environment.

[FR Doc. 93–181 Filed 1–5–93; 8:45 am]

BILLING CODE 3190–01–M

RAILROAD RETIREMENT BOARD

Agency Forms Submitted for OMB Review

SUMMARY: In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35), the Railroad Retirement Board has submitted the following proposal(s) for the collection of information to the Office of Management and Budget for review and approval.

Summary of Proposal(s)

(1) *Collection title:* Financial Disclosure Statement

(2) *Form(s) submitted:* G–423

(3) *OMB Number:* 3220–0127

(4) *Expiration date of current OMB clearance:* Three years from date of OMB approval

(5) *Type of request:* Extension of the expiration date of a currently

approved collection without any change in the substance or in the method of collection
(6) *Frequence of response:* On Occasion
(7) *Respondents:* Individuals or households
(8) *Estimated annual number of respondents:* 2,100
(9) *Total annual responses:* 2,100
(10) *Average time per response:* 1.4166 hours
(11) *Total annual reporting hours:* 2,975
(12) *Collection description:* Under the Railroad Retirement and Railroad Unemployment Insurance Acts, the Railroad Retirement Board has authority to secure from an overpaid beneficiary a statement of the individual's assets and liabilities if waiver of the overpayment is requested.

Additional Information or Comments: Copies of the form and supporting documents can be obtained from Dennis Eagan, the agency clearance officer (312–751–4693). Comments regarding the information collection should be addressed to Ronald J. Hodapp, Railroad Retirement Board, 844 N. Rush Street, Chicago, Illinois 60611–2092 and the OMB reviewer, Laura Oliven (202–395–7316), Office of Management and Budget, room 3002, New Executive Office Building, Washington, DC 20503.

Dennis Eagan,

Clearance Officer.

[FR Doc. 93–177 Filed 1–5–93; 8:45 am]

BILLING CODE 7905–01–M

SECURITIES AND EXCHANGE COMMISSION

Forms Under Review by Office of Management and Budget

Agency Clearance Officer—John J. Lane (202) 272–5407.

Upon written request copy available from: Securities and Exchange Commission Office of Filings, Information, and Consumer Services, Washington, DC 20549.

Extension:

Rules 701, 702, 703 and Form 701—File No. 270–306, Form 8—File No. 270–158, Regulation B—File No. 270–102, Rule 236—File No. 270–118.

Notice is hereby given pursuant to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*), that the Securities and Exchange Commission ("Commission") has submitted for OMB approval extension of the following: Rules 701, 702, 703, and Form 701, Form 8, Regulation B, and Rule 236.

Filings on Form 701 and pursuant to the rules and regulation provide limited exemptions from the registration requirements of the Securities Act of 1933. Form 701 is filed by approximately 500 respondents annually at an estimated one burden hour per response.

Form 8 is used to file amendments to applications for registration of securities pursuant to section 12 of the Securities Exchange Act of 1934, or amendments to annual reports and other reports filed pursuant to sections 13 and 15(d) of that Act. There are approximately 6,856 Form 8 filings annually at an estimated 12 burden hours per response.

It is estimated that approximately five respondents file schedules and forms under Regulation B annually at an estimated 41 burden hours per response.

Approximately 10 respondents make filings pursuant to Rule 236 annually at an estimated 1.5 burden hours per response.

The estimated average burden hours are made solely for purposes of the Paperwork Reduction Act and are not derived from a comprehensive or even a representative survey or study of the costs of Commission rules or forms. General comments regarding the estimated burden hours should be directed to Gary Waxman at the address below. Any comments concerning the accuracy of the estimated average burden hours for compliance with Commission rules and forms should be directed to John J. Lane, Associate Executive Director, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549 and Gary Waxman, (PRA Project Nos. 3235–0093, 3235–0095; 3235–0141 and 3235–0347), Clearance Officer, Office of Management and Budget, room 3208, New Executive Office Building, Washington, DC 20503.

Dated: December 29, 1992.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–126 Filed 1–5–93; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–31668; File No. SR–NYSE–92–34]

Self-Regulatory Organizations; Proposed Rule Change by the New York Stock Exchange, Inc., Relating to Annual Regulatory Fee

December 29, 1992.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on December 11, 1992, the New York Stock Exchange, Inc. ("NYSE" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization.[1] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The New York Stock Exchange is proposing to extend the applicability of the annual regulatory fee imposed pursuant to Rule 129 to all members and member organizations.[2]

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in section (A), (B) and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the proposed rule change is to permit the Exchange to extend the regulatory fee imposed pursuant to Rule 129 to all members and member organizations. The fee was established to help offset expenses incurred by the Exchange for Financial/Operational ("FIN/OP") examinations and surveillance performed pursuant to its responsibilities under the Act.[3] The regulatory fee is presently collected only from members and member organizations for which the Exchange has been appointed the Designated Examining Authority ("DEA") by the

[1] The NYSE has amended the proposed rule change to clarify that the regulatory fee at issue is presently collected from members and member organizations for which the Exchange is the designated examining authority pursuant to Rule 17d–1 rather than 17d–2 of the Act. *See* letter from Mary Furlong, Director of Rule and Interpretive Standards, NYSE, to Cheryl Evans-Dunfee, Staff Attorney, Exchange Branch, Division of Market Regulation, SEC, dated December 29, 1992. See also note 4, infra.

[2] NYSE Rule 129 provides that is Board of Governors may impose charges on members to reimburse the Exchange, in whole or in part, for regulatory oversight services provided for the membership by the Exchange.

[3] *See* Securities Exchange Act Release Nos. 20277 (October 19, 1983), 48 FR 48562, and 20337 (October 31, 1983), 48 FR 51168 (File Nos. SR–NYSE–83–33 and SR–NYSE–83–34).

Commission under Rule 17d-1 of the Act.[4]

Exchange policy is to surveil and examine all members and member organizations irrespective of DEA designation. There are currently 536 Exchange member organizations of which all but 21 have been designated to the Exchange. Imposition of the regulatory fee on the 21 member organizations that have been designated to other SROs will help offset the costs incurred by the Exchange in performing FIN/OP functions for these organizations. These functions include: Field examinations; monthly review and analysis of FOCUS; review of year-end outside audits; preparation of risk assessment packages; and response to interpretive questions.

The NYSE believes that the proposed rule change is consistent with the requirement under section 6(b)(4) of the Act that an exchange have rules that provide for the equitable allocation of reasonable dues, fees and other charges among its members and issuers and other persons using its facilities. The NYSE also believes that the imposition of the regulatory fee to non-DEA organizations will provide for a more equitable allocation among all members and member organizations of regulatory related expenses.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposed rule change will impose no burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments regarding the proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(b) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of the NYSE. All submissions should refer to File No. SR-NYSE-92-34 and should be submitted by January 27, 1993.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93-130 Filed 1-5-93; 8:45 am]

BILLING CODE 8010-01-M

[4] 17 CFR 240.17d-1 (1991). Exchange Act Rule 17d-1 provides that where a member of SIPC is a member of more than one self-regulatory organization ("SRO"), the Commission shall designate responsibility for examining such member for compliance with applicable financial responsibility rules.

[Rel. No. IC-19191; 812-8156]

American Capital Government Target Series, et al.; Application

December 29, 1992.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of Application for Exemption under the Investment Company Act of 1940 (the "Act").

APPLICANTS: American Capital Government Target Series ("Trust") and American Capital Asset Management, Inc. ("Adviser").

RELEVANT ACT SECTIONS: Order requested under section 17(b) for an exemption from section 17(a), and under rule 17d-1(b) to permit a joint transaction otherwise prohibited by section 17(d) and rule 17d-1(a).

SUMMARY OF APPLICATION: Applicants seek an order that would permit one of the Trust's two portfolios to acquire all of the assets and assume all of the liabilities of the Trust's other portfolio.

FILING DATE: The application was filed on November 10, 1992.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on January 25, 1993, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549. Applicants, c/o American Capital Asset Management, Inc., 2800 Post Oak Blvd., Houston, Texas 77056.

FOR FURTHER INFORMATION CONTACT: Barry A. Mendelson, Senior Attorney, at (202) 504-2284, or C. David Messman, Branch Chief, at (202) 272-3018 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch.

Applicant's Representations

1. The Trust was organized on June 24, 1990 as a Massachusetts business trust. The Trust is registered under the Act as an open-end, diversified, management investment company. The Trust is comprised of two investment portfolios: Portfolio '97 and Portfolio '98 (the "Portfolios"). The Adviser provides investment advisory, administrative, and management services to the Portfolios.

2. Portfolio '97 and Portfolio '98 have the same investment objectives and policies, the same fee structure, and similar investment portfolios. Both Portfolios invest at least 80% of their assets in obligations issued or guaranteed by the United States government or its agencies or instrumentalities. The only substantive

difference between the two Portfolios is the liquidation date. Portfolio '97 is scheduled to liquidate on December 16, 1997; Portfolio '98 is scheduled to liquidate on May 1, 1998.

3. In its capacity as custodian of the Portfolios, Amalgamated Bank of New York ("Amalgamated") owned of record, as of October 30, 1992, approximately 21% of the outstanding shares of Portfolio '97 and approximately 47% of the outstanding shares of Portfolio '98.

4. The trustees of the Trust, including a majority of those trustees who are not "interested persons" (as defined in the Act) of the Trust ("Disinterested Trustees") have approved a Plan of Reorganization ("Plan") pursuant to which Portfolio '97 will acquire all of the assets and assume all of the liabilities of Portfolio '98. The net asset value of the shares Portfolio '97 issues in the exchange will equal the net asset value of the shares of Portfolio '98 then outstanding. Each shareholder of Portfolio '98 will receive that number of full and fractional shares of Portfolio '97 equal in value as of the date of the exchange to the value of such shareholder's shares of Portfolio '98.

5. The Trust will submit the proposed Plan to the shareholders of Portfolio '98 for their approval at a meeting called for that purpose to be held on or about March 31, 1993. A majority of the outstanding shares of Portfolio '98 will be required to approve the acquisition.

6. The proposed reorganization will result in an increase in the asset size of Portfolio '97. The Trust expects that, to the extent expenses remain relatively fixed and do not vary with asset size, this increase will result in economies of scale to the benefit of all shareholders of the combined Portfolio. Management will be facilitated by having fewer Portfolios and certain expenses, including brokerage and research costs, audit fees, and general administrative costs, are expected to decrease as a result.

7. The proposed transaction will not have adverse tax consequences for the shareholders. No gain or loss will be recognized by Portfolio '98 or its shareholders as a result of the reorganization, and applicants will receive an opinion of tax counsel to this effect before consummating the reorganization.

8. The Adviser will pay all of the direct and indirect expenses of the proposed transaction.

Applicants' Legal Analysis

1. Section 2(a)(3) of the Act defines the term "affiliated person," in relevant part, as:

(A) any person directly or indirectly owning, controlling, or holding with power to vote, 5 per centum or more of the outstanding voting securities of such other person; (B) any person 5 per centum or more of whose outstanding voting securities are directly or indirectly owned, controlled, or held with power to vote, by such person; (C) any person directly or indirectly controlled by or under common control with, such other person * * *.

The Portfolios would be considered affiliated persons of one another if they are deemed to be under "common control." In this regard, since the Portfolios are part of the same investment company, they have common trustees and officers, and a common investment adviser. In addition, by virtue of its ownership of the Portfolios' stock, Amalgamated, the Portfolios' custodian, arguably is a "5% affiliate" of each Portfolio. If so, Portfolio '97 would be an affiliated person of an affiliated person (*i.e.*, Amalgamated) of Portfolio '98, and vice-versa.

2. Section 17(a) of the Act, in relevant part, prohibits any affiliated person of a registered investment company, or any affiliated person of such a person, from knowingly selling to or purchasing from such investment company any security or other property.

3. Rule 17a–8 under the act exempts from the prohibitions of section 17(a) mergers, consolidations, or purchases or sales of substantially all of the assets involving registered investment companies which may be affiliated persons, or affiliated persons of an affiliated person, solely by reason of having a common investment adviser, common directors, and/or common officers. Because the Portfolios may be affiliated with one another other than through their adviser, directors, and officers, applicants may not rely on rule 17a–8. Nevertheless, applicants have agreed to comply with the substantive requirements of the rule. Specifically, the trustees of the Trust, including a majority of the Disinterested Trustees, have determined that the proposed reorganization will be in the best interests of the shareholders of each Portfolio and will not result in the dilution of the current interests of any such shareholder.

4. Section 17(b) of the Act authorizes the SEC to exempt any transaction from the provisions of section 17(a) if the terms of the transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned; the transaction is consistent with the policy of each registered investment company concerned; and the transaction is consistent with the general purposes of the Act.

5. Applicants contend that the proposed reorganization meets the standards of section 17(b). Among other things, applicants assert that (a) the shareholders of both Portfolios will benefit from the reorganization (as discussed above), (b) the Adviser will bear all costs of the reorganization, (c) the reorganization is subject to approval of the shareholders of Portfolio '98, who will receive a proxy statement containing information about the transaction, (d) the reorganization will have no adverse tax consequences for shareholders of either Portfolio, and (e) the exchange will be made at net asset value and will not result in dilution of the current interests of any shareholder.

6. Section 17(d) and rule 17d–1(a), taken together, prohibit an affiliated person of a registered investment company, or an affiliated person of such a person, acting as principal, from participating in, or effecting any transaction in connection with, any joint enterprise or joint arrangement in which such registered company is a paricipant, unless an application relating thereto has been filed with the SEC and an order approving the joint transaction has been entered.

7. Rule 17d–1(b) provides that in determining whether to grant an order, the SEC must consider whether participation of each Portfolio in the reorganization is consistent with the provisions, policies and purposes of the Act, and the extent to which each Portfolio's participation is on a basis different from or less advantageous than that of other participants.

8. Applicants contend that the proposed reorganization meets the standards of rule 17d–1(b). In particular, they note that each Portfolio will participate in the reorganization on a basis not different from or less advantageous than that of the other Portfolio. Moreover, applicants submit that the participation of Amalgamated (as a shareholder of each Portfolio) in the organization is consistent with rule 17d–1 because Amalgamated will receive no benefit different from an other Portfolio '98 shareholder. Finally, applicants note that although the Adviser and its affiliates may receive some benefits from the reorganization, the Adviser will bear all of the costs thereof.

For the SEC, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93-125 Filed 1-5-93; 8:45 am]

BILLING CODE 8010-01-M

[Rel. No. IC-19185; 812-7498]

First Prairie Money Market Fund et al.; Application

December 29, 1992.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for exemption under the Investment Company Act of 1940 (the "Act").

APPLICANTS: First Prairie Money Market Fund (the "Fund") and The First National Bank of Chicago ("FNBC").

RELEVANT ACT SECTIONS: Exemption requested pursuant to sections 6(c) and 17(b) from section 17(a).

SUMMARY OF APPLICATION: Applicants seek an order to permit the Fund to enter into repurchase agreements with FNBC or an affiliate of FNBC.

FILING DATE: The application was filed March 22, 1990 and amended on January 10, 1992, August 7, 1992, and November 27, 1992. Counsel for the applicants has represented by letter dated December 24, 1992, that another amendment, the substance of which is incorporated herein, will be filed during the notice period.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on January 25, 1993, and should be accompanied by proof of service on the applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 5th Street, NW., Washington, DC 20549. Applicants, First Prairie Money Market Fund, 144 Glenn Curtiss Boulevard, Uniondale, New York 11556-0144; The First National Bank of Chicago, One First National Plaza, Chicago, Illinois 60670-0120.

FOR FURTHER INFORMATION CONTACT: Marilyn Mann, Special Counsel, at (202) 504-2259, or Barry Miller, Senior Special Counsel, at (202) 272-3018 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch.

Applicants' Representations

1. The Fund is an open-end, diversified management investment company. It is a money market fund that maintains a net asset value of $1.00 per share for purchases and redemptions and, pursuant to rule 2a-7 under the Act, uses the amortized cost method of valuing its securities.

2. FNBC is the Fund's investment adviser. FNBC, a wholly owned subsidiary of First Chicago Corporation, a registered bank holding company, is a commercial bank offering a range of banking and investment services. The Bank of New York acts as the Fund's custodian.

3. The Fund is divided into two separate portfolios, the Money Market Series and the Government Series (each, a "Series"). The Money Market Series invests in short-term money market obligations, including repurchase agreements with banks or primary government securities dealers reporting to the Federal Reserve Bank of New York. The Government Series invests only in short-term securities issued or guaranteed as to principal and interest by the U.S. Government, and repurchase agreements with respect to such securities with banks that have total assets in excess of $1 billion or securities dealers that have issued securities rated at least A-1 by Standard & Poor's Corporation.

4. The Fund's shares are purchased primarily by clients of FNBC and its affiliates, including qualified custody, agency, and trust accounts, through their accounts with FNBC and its affiliates. The Fund's shares may be purchased through automatic investment transactions. In these transactions, FNBC, as agent, follows the standing instructions of such clients and automatically invests excess cash balances in the clients' accounts in shares of the Money Market Series or the Government Series.[1] Currently, these "sweep" transactions are effected automatically by computer each Fund business day as of the next determined net asset value (currently, 12 noon, New York time). The machine processing required to tabulate the day's transactions in such clients' accounts and other shareholder accounts, however, is completed later in the day (normally no earlier than 11 p.m., New York time) when the daily processing for FNBC's accounting system is completed (the "Completion Time"). Therefore, total assets to be invested in each Series through the "sweep" program each day are not known until that evening and are invested in each Series at the respective net asset values determined on the following day.

5. The current operation of the "sweep" program makes the Fund materially less attractive to FNBC's clients because they lose a day's income on funds invested through the program and, for "sweeps" accomplished on a Friday, lose a weekend's income.

6. To permit FNBC, as the Fund's investment adviser, to invest anticipated net assets attributable to the "sweep" program on the same day that they are available for investment (despite the fact that the exact amount thereof will not be known until after the time for investment that day), FNBC or an affiliate proposes to enter into overnight repurchase agreements with each Series. Such assets would be invested in Fund shares as of the time the relevant Series determined its net asset value (the "Pricing Time") on the same day the sweep occurs.

7. The Fund proposes to enter into a master repurchase agreement with FNBC or one of its affiliates, which is substantially the same as the industry standard master repurchase agreement promulgated by the Public Securities Association, covering all repurchase agreement transactions (the "Master Repurchase Agreement").

8. Applicants intend to limit the amount of each Series' net assets that may be invested pursuant to the order with FNBC or its affiliates to a percentage upon which applicants from time to time may agree (the "Maximum Purchase Amount"), which percentage may fluctuate but shall not exceed 15%.

9. To facilitate the repurchase transaction where the exact amount of the overnight repurchase agreement and, consequently, the required collateral is not known until the following day, FNBC, at no cost to the Fund, will maintain at all times in a segregated sub-custodian account in the name of the relevant Series collateral at least equal to 102% of the Maximum Purchase Amount. The Fund will promptly notify FNBC of any increase or decrease in a Series' net asset value and

[1] In accordance with the standing instructions of FNBC's clients, the computer program also provides for the automatic redemption of Fund shares held in an account as of the next determined net asset value if the cash balance in the account is less than the minimum balance specified by the client.

FNBC will adjust the amount of collateral maintained in the segregated account daily so that it at least equals 102% of the Maximum Purchase Amount. The relevant Series will have a perfected security interest in the repurchase agreement collateral held in such account.

10. FNBC's Trust Department would act as the Fund's sub-custodian pursuant to a sub-custodian agreement approved by the Fund's Board of Trustees, including a majority of the Trustees who are not "interested persons," as defined in the Act, of either FNBC or the Fund.[2] The Fund's assets held by FNBC's Trust Department would be maintained in a segregated custodial account established on its behalf in accordance with the rules and standards of the Comptroller of the Currency and the Act. FNBC's Trust Department would receive the eligible securities transferred to it in its capacity as sub-custodian for the relevant Series and hold them in a manner complying with the requirements of section 17(f) of the Act. After the Completion Time that evening, for a particular Series, the records maintained by FNBC for its client's accounts and by FNBC's Trust Department in its capacity as the Series' sub-custodian would show:

(i) For FNBC's client accounts, a cash entry for the amount of Series shares purchased or redeemed and a corresponding entry to the client accounts for the number of Series shares purchased or redeemed as of the Pricing Time through operation of the computer "sweep" program; and

(ii) For the Fund's sub-custodian account, all purchase and sale transactions and the net cash proceeds, if any, received by the Series through the operation of the "sweep" (or, conversely, the net redemption proceeds paid or payable by the Series if there were net redemptions). In addition, the relevant Series' sub-custodian account would reflect the specific amount in fact invested in the particular transaction (including the ownership of the securities securing the repurchase agreement). If the "sweep" had resulted in unanticipated net redemptions for the Series, the relevant sub-custodian account would reflect this fact and show no ownership of any of such securities transferred by FNBC or its affiliates to the account, since (contrary to expectations) none of the Fund's assets had been used to purchase the securities. To the extent that transferred securities exceeded the relevant Series' assets that were available for investment (as shown by the results of the day's computer processing), FNBC or the appropriate affiliate would be shown to be the owner of such securities.

11. After the Completion Time, FNBC would transmit to the Fund's transfer agent records relating to these automatic investment transactions. The transfer agent's records would show an entry to each of the corresponding shareholder accounts for the number of Fund shares automatically purchased or redeemed as of the Pricing Time through operation of the "sweep."

12. Each Series will purchase only securities in which it may invest as described in its prospectus and statement of additional information and as limited by rule 2a-7 under the Act. The Master Repurchase Agreement into which the Fund, on behalf of each Series, proposes to enter will be collateralized only by U.S. Treasury Bills, Notes, and Bonds, with a remaining maturity of one year or less and value at least equal to 102% of the repurchase price (including accrued interest). The transactions will comply with the guidelines set forth in Investment Company Act Release No. 13005 (February 2, 1983). The Master Repurchase Agreement will be subject to annual approval by the Fund's Board of Trustees, including a majority of the Trustees who are not "interested persons" (as defined in the Act) of the Fund or FNBC or its affiliates.

13. The transactions would be "repurchase agreements" for purposes of Chapter 11 of the United States Bankruptcy Code and the Financial Institutions Reform, Recovery and Enforcement Act of 1989. These statutes provide that, if the bankruptcy of the counterparty occurs, the repurchase agreement can be liquidated without being subject to the potential delay associated with the automatic stay or similar provisions of those statutes. If the transactions were not "repurchase agreements" as defined under those statutes, the Fund might encounter significant liquidity problems if a large percentage of its assets were invested in repurchase agreements with a bankrupt counterparty.

14. Each of the Money Market Series and the Government Series currently invests a substantial amount of their respective net assets on an overnight basis. The Fund's average daily portfolio maturity customarily is between 20 and 40 days for the Money Market Series and 15 and 25 days for the Government Series. Applicants intend to limit the Maximum Purchase Amount at a level that they believe should avoid reducing average daily portfolio maturity and thus the yield for the Fund.[3]

15. FNBC will continue to solicit independent quotes from third parties for the proposed "sweep" transactions, but to date FNBC has been unable to find any unaffiliated entity willing to engage in such transactions on a basis as favorable to the Fund as the proposed arrangement with FNBC. The repurchase agreement counter-party will not know until the next day the amount, if any, of such transactions. This delay results because the daily processing for FNBC's accounting system normally is completed well into the night of the day the order is placed and the actual amount to be invested in the repurchase transaction is not known and, thus, monies in respect thereof cannot be transmitted until the next morning. Unaffiliated third parties will not agree to operate in this "look back" manner with the Fund on a basis as favorable to the Fund as the proposed arrangement with FNBC.

16. Before any repurchase agreements are entered into pursuant to the exemption, the Fund or FNBC must obtain and document competitive quotations from at least two other dealers with respect to repurchase agreements that are comparable in terms of size, maturity, and collateral, except that if quotations are unavailable from two such dealers only one other competitive quotation is required. In addition, the transactions for which quotations are sought will be conventional overnight repurchase agreements in which the funds would be transferred by the Fund on the same day that the transaction is entered into, and then returned by the counterparty on the following day. Before entering into a transaction pursuant to the exemption, a determination will be required that the income to be earned from the repurchase agreement is at least equal to that available from the other dealers from which quotes were obtained. As set forth in the application, applicants enter into repurchase agreements on an ongoing basis and, therefore, believe they are capable of obtaining such quotes.

Applicants' Legal Analysis

1. Section 17(a) of the Act, among other things, generally prohibits certain entities affiliated with an registered investment company, when acting as principal, from knowingly selling to or purchasing from the investment

[2] The sub-custodian account may be maintained with FNBC's Trust Department or a nominee qualified to act as a custodian pursuant to section 17(f) of the Act and references herein to FNBC's Trust Department shall mean either entity.

[3] Applicants point out that, not infrequently, the overnight rate is as favorable as and, in certain cases, may exceed the rate available for securities with longer maturities.

company any security. Among the entities precluded from dealing as principal with a registered investment company under section 17(a) are any affiliated person of the investment company and any affiliated person of an affiliated person of the investment company. Section 2(a)(3) of the Act defines any investment adviser of such company. Therefore, FNBC, as the Fund's investment adviser, and its affiliates are subject to the prohibitions contained in section 17(a) with respect to the Fund.

2. Section 6(c) of the Act provides in relevant part that "the Commission, * * * by order upon application, may * * * exempt any person, security, or transaction * * * from any provision or provisions of [the Act] or of any rule or regulation thereunder, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of [the Act]."

3. Section 17(b) of the Act provides that "notwithstanding [section 17(a)], any person may file with the Commission an application for an order exempting a proposed transaction * * * from one or more provisions of that subsection. The Commission shall grant such application and issue such order of exemption if evidence establishes that * * * (1) the terms of the proposed transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned; (2) the proposed transaction is consistent with the policy of each registered investment company concerned, as recited in its registration statement and reports filed under [the Act]; and (3) the proposed transaction is consistent with the general purposes of [the Act]."

4. The Fund believes that the relief requested is appropriate and in the public interest because it will permit the Fund to invest at a favorable price net assets attributable to the "sweep" program on the same day that such assets are available for investment. Applicants believe that a more attractive "sweep" program will result in increased assets for the Fund. A larger asset base for the Fund will benefit all Fund shareholders by reducing the amount of Fund expenses indirectly borne by each shareholder, thereby increasing investors' returns.

5. FNBC and its affiliates are aware of the potential conflict of interest inherent in the operation of the "sweep" program if the proposed relief is granted. FNBC, therefore, has established procedures and conditions to be followed by its employees and agents to prevent any overreaching on the part of any person that could act to the detriment of the Fund and to ensure that each transaction is effected on a reasonable and fair basis.

6. The Fund's overnight position should not necessarily reduce its yield. If the operation of the proposed "sweep" program shortens the Fund's average daily portfolio maturity, the effect of such reduction would be minimal because: (i) The Fund currently maintains a relatively short average daily portfolio maturity; (ii) as FNBC develops more experience operating the "sweep" program, FNBC will be able to manage the maturity of that portion of the Fund's assets held outside the sub-custodian account for the program so as to provide optimal liquidity levels; and (iii) upon receipt of such assets currently, the Fund has invested such assets in overnight or very short-term obligations in any event, but such investment occurs one day later. Thus, applicants believe that any effect on yield as a result of the proposed relief would be negligible. In addition, operation pursuant to the independent pricing mechanism set forth in condition 8 should provide yields from "sweep" investments that are no lower than similar non-sweep Fund investments.

7. Based on the arguments set forth above, applicants believe that the requested relief is necessary and appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants also believe that the terms of the proposed transactions, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned, that the proposed transactions are consistent with the policy of each Series, as set forth in the Fund's registration statement and reports filed under the Act, and that the proposed transactions are consistent with the general purposes of the Act.

Applicants' Conditions

Applicants agree that the order of the Commission granting the requested relief shall be subject to the following conditions:

1. No FNBC or affiliate "sweep" account client will be permitted to affect a transaction after the sweep has occurred and the Fund's net asset value has been computed for that day.

2. The legal or compliance department of, and internal and outside auditors for, FNBC or its affiliates will prepare guidelines for FNBC and affiliate personnel to ensure that the transactions described herein comply with the conditions set forth herein and that the integrity of the program is maintained. The Fund's independent public accountants will verify assets held in each sub-custodian account in accordance with rule 17f–2 under the Act. The legal or compliance department and auditors will periodically monitor the activities of FNBC and its affiliates in connection with the operation of the "sweep" program to ensure that the conditions set forth in the application are adhered to.

3. If granted, the terms of the relief would be disclosed fully in the Fund's prospectus and statement of additional information. A schedule of all transactions with FNBC and its affiliates will be filed with each semi-annual report filed by the Fund with the Commission pursuant to sections 30(a) and 30(b)(1) of the Act. FNBC will provide the Fund's Board of Trustees with a full report of the transactions under the "sweep" program, as described herein, no less frequently than quarterly. FNBC also will provide the Board of Trustees with a statement that, as the Fund's investment adviser, it determined the principal transactions to be necessary and appropriate under the circumstances.

4. The Fund and FNBC will maintain such records with respect to those transactions conducted pursuant to the exemption as may be necessary to confirm compliance with the conditions to the requested relief. In this regard, the Fund will maintain an itemized daily record of repurchase agreement transactions entered into pursuant to the exemption, showing for each transaction: the Series that entered into the transaction; the entity with which the Series entered into the transaction; the purchase and repurchase prices; the type and amount of collateral; the date fixed for termination of the transaction; and the time and date of the transaction. For each transaction, such records also shall document the quotations received from other dealers in accordance with condition no. 8, including: The names of the dealers; the prices quoted; and the times and dates the quotations were received. The records required by this condition will be maintained and preserved in the same manner as records required under rule 31a–1(b)(1).

5. The Maximum Purchase Amount will be the percentage of each Series' net assets upon which the applicants from time to time may agree, which percentage may fluctuate but shall not

exceed 15%. As to a particular Series on a particular day, the amount invested pursuant to the exemption will not exceed the amount swept into such Series on such day.

6. All records pertaining to the sweep program will be preserved for a period of not less than six years, the first two years in an easily accessible place, from the end of the fiscal year in which any sweep transaction occurred.

7. In connection with overnight repurchase agreement transactions pursuant to the Master Repurchase Agreement, FNBC will maintain at all times during operation of the "sweep" program in a segregated sub-custodian account in the name of each Series collateral comprised only of U.S. Treasury Bills, Notes or Bonds, with remaining maturities of one year or less, and valued at least equal to 102% of the Maximum Purchase Amount. In addition, FNBC or its affiliates would transfer such collateral through the book entry system of the Federal Reserve and, in connection therewith, the relevant Series' sub-custodian account with FNBC's Trust Department will be designated by Fedwire as the recipient of such securities and FNBC's internal records and written confirmations will indicate that the collateral is being held on behalf and in such Series' name. The relevant Series thereby would acquire a security interest in the collateral.

8. Before any transaction may be conducted pursuant to the exemption, the Fund or FNBC must obtain such information as it deems necessary to determine that the price test set forth below has been satisfied. Before any repurchase agreements are entered into pursuant to the exemption, the Fund or FNBC must obtain and document competitive quotations from at least two other dealers with respect to repurchase agreements comparable to the type of repurchase agreement involved (including size, which would be at least equal to the Maximum Purchase Amount, maturity and collateral), except that if quotations are unavailable from two such dealers only one other competitive quotation is required. In addition, the transactions for which quotations are sought will be conventional overnight repurchase agreements in which the funds would be transferred by the Fund on the same day that the transaction is entered into, and then returned by the counterparty on the following day. Before entering into a transaction pursuant to the exemption, a determination will be required in each instance, based upon the information available to the Fund and FNBC, that the income to be earned from the repurchase agreement is at least equal to that available from the other dealers from which quotes were obtained.

For the SEC, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93-127 Filed 1-5-93; 8:45 am]

BILLING CODE 8010-01-M

[Investment Company Act Rel. No. 19187; International Series Rel. No. 515; 812-8222]

The Park Avenue Portfolio; Notice of Application

December 29, 1992.

AGENCY: Securities and Exchange Commission (the "SEC").

ACTION: Notice of Application for Exemption under the Investment Company Act of 1940 (the "Act").

APPLICANT: The Park Avenue Portfolio.

RELEVANT ACT SECTIONS: Order requested under section 6(c) for an exemption from the provisions of section 12(d)(3).

SUMMARY OF APPLICATION: Applicant seeks a conditional order permitting it to invest in equity and convertible debt securities of foreign issuers that, in each of their most recent fiscal years, derived more than 15% of their gross revenue from their activities as a broker, dealer, underwriter, or investment adviser ("Foreign Securities Companies"), provided that such investments comply with the provisions of proposed amended rule 12d3-1 under the Act.

FILING DATE: The application was filed on December 17, 1992.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on January 25, 1993, and should be accompanied by proof of service on applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request such notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549. Applicant, 201 Park Avenue South, New York, New York 10003.

FOR FURTHER INFORMATION CONTACT: James J. Dwyer, Staff Attorney, at (202) 504-2920, or Elizabeth G. Osterman, Branch Chief, at (202) 272-3016 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee from the SEC's Public Reference Branch.

Applicant's Representations

1. Applicant, a Massachusetts business trust, is registered as a diversified open-end management investment company under the Act. Applicant will consist of seven series upon the effectiveness of a post-effective amendment to its registration statement filed with the SEC on November 20, 1992. Only one of these funds, The Guardian Baillie Gifford International Fund (the "International Fund"), currently intends to invest in equity or convertible debt securities of foreign issuers. Guardian Baillie Gifford Limited acts as the investment adviser for the International Fund. Baillie Gifford Overseas Limited will serve as sub-adviser for the International Fund.

2. Applicant seeks to invest in equity securities and convertible debt securities of Foreign Securities Companies. Applicant seeks conditional relief from section 12(d)(3) of the Act to invest in equity and convertible debt securities of Foreign Securities Companies to the extent permitted in proposed amended rule 12d3-1 under the Act. See Investment Company Act Release No. 17096 (Aug. 3, 1989).

Applicant's Legal Conclusions

1. Section 12(d)(3) prohibits an investment company from acquiring any security issued by any person who is a broker, a dealer, an underwriter, or an investment adviser. Rule 12d3-1 provides an exemption from section 12(d)(3) for investment companies acquiring securities of an issuer that derived more than 15% of its gross revenues in its most recent fiscal year from securities-related activities, provided that these investments comply with certain conditions set forth in the rule.

2. Under rule 12d-1, an equity security of a Foreign Securities Company must be a "margin security" as defined in Regulation T promulgated by the Board of Governors of the Federal Reserve (the "Board") in order for the acquisition of such security by an investment company to be exempt from the prohibition of section 12(d)(3). Accordingly, Applicant may not invest in equity securities of a Foreign Securities Company that are comparable in quality to "margin securities," but

which do not fall within the definition of "margin securities" under Regulation T, because they are not registered in the United States, are not traded in United States over-the-counter markets, and are not included in the List of Foreign Margin Stocks published by the Board.

3. Proposed amended rule 12d3–1 provides that the "margin securities" requirement will be excused if the acquiring company purchases equity securities of Foreign Securities Companies that meet the qualitative criteria comparable to criteria applicable to equity securities of United States securities-related businesses.

Applicant's Condition

Applicant agrees that the proposed exemptive order will be subject to the following condition:

Applicant will comply with the proposed amendments to rule 12d3–1, Investment Company Act Release No. 17096 (Aug. 3, 1989), as they are currently proposed, or as they maybe reproposed, adopted, or amended.

For the SEC, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Security.

[FR Doc. 93–129 Filed 1–5–93; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 35–25722]

Filings Under the Public Utility Holding Company Act of 1935 ("Act")

December 29, 1992.

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated thereunder. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The applications(s) and/or declaration(s) and any amendments thereto is/are available for public inspection through the Commission's Office of Public Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by January 22, 1993 to the Secretary, Securities and Exchange Commission, Washington, DC 20549, and serve a copy on the relevant applicant(s) and/or declarant(s) at the address(es) specified below. Proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. Any request for hearing shall identify specifically the issues of fact or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After said date, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

General Public Utilities Corp. (70–7473)

General Public Utilities Corporation ("GPU"), 100 Interpace Parkway, Parsippany, New Jersey 07054, a registered holding company, has filed a post-effective amendment to its application-declaration pursuant to sections 9(a), 10 and 12(c) of the Act and Rule 42 thereunder.

By orders dated December 29, 1987, (HCAR No. 24550), March 31, 1988 (HCAR No. 24612), August 5, 1988 (HCAR No. 24691) and September 11, 1989 (HCAR No. 24949), the Commission, among other things, authorized GPU to repurchase from time-to-time through December 31, 1992 up to 11 million shares of its common stock, par value $2.50 per share, in the open market, through odd-lot tender offers and/or from shares held under GPU's Tax Credit Act Employee Stock Ownership Plans upon their termination. The timing of those repurchases depends upon existing market conditions and the anticipated capital needs of GPU and its subsidiaries. At December 3, 1992, GPU had repurchased 7,491,432 shares of its common stock, all of which were repurchased prior to a two-for-one stock split effective May 29, 1991. GPU does not expect to repurchase any additional shares during the remainder of 1992.

GPU now requests authority to repurchase up to five million shares of its common stock in the open market, through privately negotiated transactions and/or through odd-lot tender offers from time-to-time from the effective date of the order herein through December 31, 1995. GPU has determined that the current cost of common stock equity is higher than the current cost of borrowed funds used to effect such repurchases. In all other respects, the transactions as previously authorized by the Commission would remain unchanged.

At September 30, 1992, GPU's equity ratio, on a consolidated basis, was 46%. If GPU were to repurchase the entire five million shares of common stock for which authority is requested, GPU's consolidated equity ratio would be reduced to 45%, assuming an average purchase price of $26.00 per share.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–124 Filed 1–5–93; 8:45 am]

BILLING CODE 8010–01–M

[Investment Company Act Rel. No. 19183; 812–8088]

Technology Funding Medical Partners I, L.P., et al.; Application

December 28, 1992.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of Application for Exemption under the Investment Company Act of 1940 ("Act").

APPLICANTS: Technology Funding Medical Partners I, L.P. (the "Partnership"); and Technology Funding Inc. and Technology Funding Ltd. (the "Managing General Partners").

RELEVANT ACT SECTIONS: Order requested under section 6(c) granting an exemption from sections 2(a)(19) and 2(a)(3)(D).

SUMMARY OF APPLICATION: Applicants seek a conditional order determining that: (a) The Independent General Partners (as hereinafter defined) are not "interested persons" of the Partnership, the other general partners, or the principal underwriter of the Partnership solely by reason of their status as general partners of the Partnership and co-partners of the other general partners; and (b) no limited partner owning less than five percent of the units of limited partnership interest in the Partnership is an "affiliated person" of the Partnership or any of its partners solely by reason of being a limited partner of the Partnership and a co-partner of the other limited partners and the general partners.

FILING DATE: The application was filed on September 14, 1992 and amended on December 1, 1992, December 23, 1992, and December 24, 1992.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on January 22, 1993, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the

request, and the issues contested. Persons who wish to be notified of a hearing may request such notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549. Applicants, 2000 Alameda de las Pulgas, suite 250, San Mateo, California 94403.

FOR FURTHER INFORMATION CONTACT: James E. Anderson, Staff Attorney, at (202) 272-7027, or C. David Messman, Branch Chief, at (202) 272-3018 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee from the SEC's Public Reference Branch.

Applicants' Representations

1. The Partnership, organized as a Delaware limited partnership on September 3, 1992, will be governed by an Amended and Restated Limited Partnership Agreement (the "Partnership Agreement"). The Partnership has elected to be a business development company pursuant to section 54(a) of the Act. As a business development company, the Partnership will be subject to sections 55 through 65 of the Act and to those sections of the Act made applicable to business development companies. The Partnership will terminate no later than December 31, 2006. The Partnership has organized as a limited partnership because applicants believe that the partnership form is a more appropriate investment vehicle for a closed-end entity of limited duration seeking long-term capital appreciation by making venture capital investments.

2. On October 30, 1992 the Partnership filed a registration statement on Form N-2 under the Securities Act of 1933 with respect o a proposed public offering of up to 300,000 units of limited partnership interest in the Partnership (the "Units"). The maximum proceeds from the offering will be $30 million.

3. The general partners of the partnership initially will consist of three individual general partners (the "Individual General Partners") and the Managing General Partners. The initial Individual General Partners will act as independent general partners (the "Independent General Partners") (defined to be individuals who are not "interested persons" of the Partnership within the meaning of the Act). The number of Individual General Partners may not be less than three nor more than nine, and a majority of the Individual General Partners must be Independent General Partners. Only natural persons may serve as Individual General Partners. The Partnership Agreement provides that if at any time the number of Independent General Partners is reduced to less than a majority of the Individual General Partners, the remaining Independent General Partners must, within 90 days, designate one or more successor Independent General Partners so as to restore the number of Independent General Partners to a majority.

4. The Individual General Partners will provide overall guidance and supervision with respect to the operations of the Partnership. The Individual General Partners will perform the same functions and have the same duties and responsibilities that the Act imposes on the boards of directors of business development companies organized in corporate form. The Independent General Partners will assume the responsibilities and obligations imposed by the Act upon disinterested directors of a business development company organized in corporate form. In addition to fiduciary duties, the Individual General Partners will, among other things, have responsibilities with respect to the management and underwriting arrangements of the Partnership, the custody arrangements with respect to portfolio securities, fidelity bonding, and transactions with affiliates.

5. The Managing General Partners, Technology Funding Inc. and Technology Funding Ltd., are a California corporation and a California limited partnership, respectively. Both Managing General Partners are registered investment advisers under the Investment Advisers Act of 1940. Under the Partnership Agreement, the Managing General Partners, subject to the guidance and supervision of the Individual General Partners, are responsible for the management of the Partnership's investments and will provide other management and administrative services.

6. As compensation for their services, the Managing General Partners will receive an allocation of 20% of the Partnership's net profits (as defined in the Partnership Agreement, as well as the following fees: a fee equal to 2% of total limited partner capital contributions for each year of partnership operations until six years after the completion of the public offering of Units, and thereafter declining by 10% per year, as compensation for partnership overhead; reimbursement for organizational and offering expenses and operational costs (as defined in the Partnership Agreement) up to a maximum of 5% of total limited partner capital contributions; [1] and a sales commission of up to 8% of the gross proceeds of the offering, of which up to 7% will be reallowed to unaffiliated broker-dealers. The sales commission will be paid to Technology Funding Securities Corporation, a wholly-owned subsidiary of Technology Funding Inc.

7. The limited partners of the Partnership have no right to participate in the control of the Partnership's business. The Partnership Agreement, consistent with the Act, authorizes the limited partners to vote on certain matters, including the election or removal of general partners, approval or termination of certain arrangements with affiliates of the Managing General Partners, ratification or rejection of the appointment of the independent certified public accountants of the Partnership, approval of the sale of all or substantially all of the Partnership's assets, and amendments to the Partnership Agreement. The Partnership will obtain an opinion of counsel that the possession or exercise of these voting rights does not cause the limited partners to be participating in the control of the Partnership's business under the Delaware Revised Uniform Limited Partnership Act. The Partnership does not have an insurance policy which would provide coverage to persons who become limited partners. The Independent General Partners will periodically review the question of the appropriateness of obtaining an errors and omissions insurance policy for the Partnership.

8. The Partnership Agreement provides that any Individual General Partner may be removed either: (a) for cause by the action of two-thirds of the remaining Individual General Partners, including a majority of the remaining Independent General Partners; or (b) with the consent of a majority in interest of the limited partners. The Managing General Partners may be removed either: (a) By a majority of the Independent General Partners, with or without cause; or (b) with the consent of the majority in interest of the limited partners.

9. The Partnership Agreement provides that the Managing General Partners will not resign or withdraw from the Partnership unless a successor managing general partner or partners have been appointed and consented to

[1] Under the Partnership Agreement, overhead, organizational and offering expenses, and operational costs are each distinct categories and do not overlap.

by the limited partners. The Managing General Partners may resign or withdraw voluntarily only if: (a) At least 120 days prior to such withdrawal, all partners are given notice that the Managing General Partners propose to withdraw and that there will be substituted in their place a person or persons designated and described in such notification; (b) each of the proposed successor managing general partners represents that it is experienced in performing the functions that a managing general partner is required to perform under the Partnership Agreement, that it has the net worth required by the Partnership Agreement, and that it is willing to become a managing general partner under the Partnership Agreement and will assume all duties and responsibilities thereunder, without receiving any compensation for services from the Partnership in excess of that payable under the Partnership Agreement to the withdrawing Managing General Partners and without receiving any participation in the withdrawing Managing General Partners' interests other than that agreed upon by the withdrawing Managing General Partner and its successor; (c) there is on file at the principal office of the Partnership certified audited financial statements of each proposed successor managing general partner; (d) a majority in interest of the limited partners consent to the appointment of the successor; (e) the withdrawing Managing General Partner cooperates with the successor managing general partners so that the responsibilities of the withdrawing Managing General Partner may be transferred with as little disruption of the Partnership's business and affairs as practicable; and (f) the withdrawing Managing General Partner pays all expenses incurred as a result of its withdrawal.

Applicants' Legal Conclusions

1. Applicants request that the Independent General Partners be exempted from the provisions of section 2(a)(19) to the extent that the Independent General Partners would otherwise be deemed "interested persons" of the Partnership, the other general partners, or the principal underwriter of the Partnership solely because such Independent General Partners are general partners of the Partnership and co-partners of the Managing General Partners. Section 2(a)(19) excludes from the definition of "interested person" those individuals who would be "interested persons" solely because they are directors of an investment company. The Partnership has been structured so that the Independent General Partners are the functional equivalents of, and will assume the responsibilities and obligations imposed by the Act and the regulations thereunder on, the non-interested directors of an incorporated investment company. Granting the requested exemption from the provisions of section 2(a)(19) is consistent with the purposes, policies, and provisions of the Act.

2. Applicants request further that the SEC exempt all limited partners of the Partnership who own less than 5% of the Units of the Partnership from being deemed under section 2(a)(3)(D) of the Act to be "affiliated persons" of the Partnership or any of its other partners solely because such limited partner is a partner of the Partnership and any of such other persons are partners with one another in the Partnership. Section 2(a)(3)(D) of the Act provides that an "affiliated person" of an entity includes, *inter alia*, any partner or co-partner of such entity. Under section 2(a)(3), persons investing in a corporate entity as mere shareholders would have substantially the same rights to vote on the affairs of the entity as the rights that are accorded to the limited partners under the Partnership Agreement, but would not be thereby deemed "affiliated persons" of the corporate entity unless they held more than 5% of such entity's outstanding voting securities. Granting the requested exemption from the provisions of section 2(a)(3)(D) is consistent with the purposes, policies, and provisions of the Act and places investments in the Partnership on a more equal footing with investments in business development companies organized in corporate form.

Applicants' Conditions

If the requested order is granted, applicants agree to the following conditions:

1. The general partners of the Partnership, except the Managing General Partners, will be natural persons, and a majority of the Individual General Partners will not be interested persons of the Partnership.

2. The Individual General Partners will assume the responsibilities and obligations imposed by the Investment Company Act on directors of a business development company organized in corporate form. The Independent General Partners, all of whom will be Individual General Partners, will assume the responsibilities and obligations imposed by the Investment Company Act on non-interested directors of a business development company organized in corporate form.

3. Neither Managing General Partners will resign or withdraw as a Managing General Partner of the Partnership without two years prior notice unless a successor Managing General Partner has been appointed in accordance with the Partnership Agreement and the provisions of section 15(a), 15(c), and 15(f) of the Investment Company Act.

4. The limited partners will have the right to vote on all matters which would require their approval under the Investment Company Act if they were shareholders of a business development company organized in corporate form, including the right to elect or remove general partners, the right to approve any new or amended investment advisory contract, the right to approve proposed changes in the Partnership's fundamental policies, and the right to ratify or reject the appointment of auditors.

5. If a limited partner transfers his or her units in a manner which is effective under the Partnership Agreement, the general partners will ensure that such assignee, transferee or successor has all of the rights afforded a shareholder under the Investment Company Act.

6. The Partnership will obtain an opinion of counsel stating that the voting rights provided the Limited Partners do not subject the limited partners to liability as general partners under Delaware law.

7. The Partnership will obtain an opinion of counsel that the Partnership should be classified and treated as a partnership for federal income tax purposes.

8. The Partnership will obtain an opinion of counsel that the distributions and allocations provided for in the Partnership Agreement are permissible under section 205 and rule 205–3 under the Investment Advisers Act and under section 15(a) of the Investment Company Act.

9. If, under the Partnership Agreement, the Partnership is or becomes authorized to make in-kind distributions of portfolio securities to its Partners, no such in-kind distributions will be made until such time as the Partnership has obtained a no-action letter from the staff of the SEC or, alternatively, has obtained an order pursuant to section 206A of the Investment Advisers Act of 1940 permitting such distribution.

10. Under the Partnership Agreement, upon the removal of the Managing General Partners, all unrealized gains and losses are deemed realized for purposes of making a final allocation to the Managing General Partners. However, applicants will not deem such unrealized gains and losses realized

until they have received a no-action letter from the staff of the SEC confirming the Partnership's interpretation of section 205 of the Investment Advisers Act (i.e., that such treatment of unrealized gains and losses is appropriate) or, in the alternative, the Partnership has obtained an exemption from section 205 by SEC order issued pursuant to section 206A of the Investment Advisers Act, permitting the Partnership to deem such gains or losses to be realized.

For the SEC, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93-131 Filed 1-5-93; 8:45 am]

BILLING CODE 8010-01-M

[Release No. IC-19188; File No. 812-8172]

Travelers Growth and Income Stock Account for Variable Annuities, et al.; Application

December 29, 1992.

AGENCY: Securities and Exchange Commission (the "Commission" or "SEC").

ACTION: Notice of Application for Exemption under the Investment Company Act of 1940 (the "1940 Act").

APPLICANTS: The Travelers Growth and Income Stock Account for Variable Annuities ("Account GS"), The Travelers Quality Bond Account for Variable Annuities ("Account QB"), The Travelers Fund B for Variable Contracts ("Fund B") and The Travelers Fund B-1 for Variable Contracts ("Fund B-1") (referred to collectively as the "Applicants").

RELEVANT 1940 ACT SECTIONS: Order requested under section 17(b) of the 1940 Act for exemption from section 17(a).

SUMMARY OF APPLICATION: Applicants request an Order of the Commission under section 17(b) of the Investment Company Act of 1940 (the "1940 Act") granting an exemption from the provisions of section 17(a) of the 1940 Act to permit the transfer of portfolio securities from Fund B to Account GS and from Fund B-1 to Account QB.

FILING DATE: The Application was filed on August 19, 1992 and amended on November 9, 1992. Applicants will file another amendment during the notice period to delete references to in kind redemptions by Contract Owners.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving the Applicants with copies of the request, personally or by mail. Hearing requests must be received by the SEC by 5:30 p.m. on January 25, 1993, and should be accompanied by proof of service on the Applicants in the form of an affidavit, or, for lawyers, by certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the Secretary of the Commission.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549. Applicants, One Tower Square, Hartford, Connecticut 06183-1050, Attention: Thomas A. Klee, Secretary.

FOR FURTHER INFORMATION CONTACT: Cindy J. Rose, Staff Accountant, or Wendell M. Faria, Deputy Chief, at (202) 272-2060, Office of Insurance Products, Division of Investment Management.

SUPPLEMENTARY INFORMATION: Following is a summary of the application; the complete application is available for a fee from the Commission's Public Reference Branch.

Applicant's Statements and Representations

1. Accounts GS and QB and Funds B and B-1 are open-end diversified management investment companies, registered under the 1940 Act on Form N-3 (File Nos. 811-1539, 811-2571, 811-1671 and 811-2583, respectively). The Travelers Investment Management Company serves as the investment adviser for Account GS and Fund B. Travelers Asset Management International Corporation serves as the investment adviser for Account QB and Fund B-1.

2. Funds B and B-1 currently serve as the underlying investment vehicles for certain variable annuity contracts (the "old Contracts") issued by the Travelers Insurance Company ("Travelers"). Due to the small asset size of Fund B and Fund B-1, which adversely affects the Funds' ability to diversify, Travelers intends to offer to Contract Owners of the old Contracts the opportunity to exchange their old Contracts for new variable annuity contracts (the "new Contracts") for which Accounts GS and QB serve as the underlying investment vehicles. The exchange offer will be made in compliance with Rule 11a-2 under the 1940 Act (the "Exchange Offer").

3. The proposed transactions will be executed on the effective date of the Exchange Offer if there is 100% participation in the Exchange Offer or all units are otherwise exchanged by the effective date. The transactions will be effectuated by exchanging all units in Funds B and B-1 held under the old Contracts for units of equal value in Accounts GS and QB under the new Contracts. The transactions will be settled by the transfer of all portfolio securities valued on the basis of net asset values as of the date of transfer from Fund B to Account GS and from Fund B-1 to Account QB. Net asset values will be determined in accordance with the methods set forth in the Statement of Additional Information of each of the Applicants. Funds B and B-1 will cease operations when the Exchange Offer and the proposed transactions have been completed.

Applicants' Legal Analysis and Conditions

1. Section 17(a)(1) of the 1940 Act prohibits any affiliated person of a registered investment company, or an affiliated person of an affiliated person, from selling any security or other property to such registered investment company. Section 17(a)(2) of the 1940 Act prohibits any of the persons described above from purchasing any security or other property from such registered investment company.

2. Each Applicant may be deemed to be an affiliated person or affiliated person of an affiliated person of each other Applicant under section 2(a)(3) of the 1940 Act, and the proposed transactions may be deemed to entail one or more purchases or sales of securities or property between the respective Applicants. Therefore, an exemption from section 17(a) of the 1940 Act, pursuant to section 17(b) of the 1940 Act, may be required.

3. Section 17(b) of the 1940 Act provides that the Commission may grant an Order exempting transactions prohibited by section 17(a) of the 1940 Act upon application if evidence establishes that: (a) The terms of the proposed transactions, including the consideration to be paid or received, are reasonable and fair and do not involve over-reaching on the part of any person concerned; (b) the proposed transactions are consistent with the investment policy of each registered investment company concerned, as recited in the registration statements and reports filed under the 1940 Act, and (c) the proposed transactions are consistent with the general purposes of the 1940 Act.

4. Applicants represent that the terms of the proposed transactions and the Exchange Offer, including consideration paid or received, are reasonable and fair and do not involve over-reaching on the

part of any person. Applicants will not pay any of the expenses of the Exchange Offer, as they will be borne entirely by Travelers. The new Contracts will have terms at least as favorable, and in certain respects more favorable, than the old Contracts. There will be no surrender charges or sales charges imposed in connection with the exchange of the old Contracts for the new Contracts, in as much as neither the old Contracts nor the new Contracts provide for a contingent deferred sales charge and the front-end sales charge on the new Contracts has been waived for amounts exchanged in connection with the Exchange Offer. The proposed transactions will be effectuated by exchanging all units in Funds B and B-1 for units in Accounts GS and QB, respectively, and making a corresponding transfer of all portfolio securities from Funds B and B-1 to Accounts GS and QB. The proposed transactions will not be completed if there is not 100% participation by Contract Owners. Without full participation, the Applicants will not be in the position of determining which portfolio securities are to remain in Funds B or B-1 and which are to be transferred to Accounts GS or QB, respectively. The Applicants believe that the proposed transactions are reasonable and fair since they will avoid any transaction costs for any of the Applicants. The portfolio securities will be valued for the purposes of the transfer in the same manner utilized by the Applicants for determining net asset value. Valuing the portfolio securities in this manner will result in consistent values for purposes of the proposed transactions and for determining the net asset values of Accounts GS and QB upon the completion of the proposed transactions.

5. The Exchange Offer will not be a taxable transaction for participants pursuant to section 1035 of the Internal Revenue Code and Revenue procedure 92-26. Deposits made under the old Contracts prior to August 14, 1982 will continue to retain their favorable tax status under the new Contracts.

6. The assets of Funds B and B-1 are declining in size because the old Contracts have not been offered to new customers since 1983. Applicants represent that if Contract Owners exchange their old Contracts for the new Contracts, and their assets are thereby invested in Accounts GS and QB, they will benefit from greater diversification in the portfolios and greater stability as assets are withdrawn.

7 The investment objectives, polices and restrictions of the respective Applicants involved in the proposed transactions are identical. Thus, the transfer of the portfolio securities which will occur between the corresponding funds are consistent with the objectives, policies and restrictions of Accounts GS and QB. Moreover, Accounts GS and QB will be able to retain the portfolio securities received from Funds B and B-1 upon completion of the proposed transactions.

8. Applicants represent that the proposed transactions are consistent with the general purposes of the 1940 Act, as enunciated in the findings and Declaration of Policy in Section 1 of the 1940 Act. Applicants assert that the proposed transactions do not present any of the issues or abuses that the 1940 Act is designed to prevent. Moreover, Applicants represent that the proposed transactions and the Exchange Offer will be effected in a manner consistent with the public interest and the protection of investors. The owners of the old Contracts will be fully informed of the terms of the Exchange Offer through the Prospectus for the new Contracts and explanatory correspondence, including an Exchange Authorization Form. Contract Owners will benefit from increased diversity in the portfolios underlying their new Contracts, and, if the Order is granted, will not incur any expenses in the transfer of portfolio securities.

9. Applicants also note that the proposed transactions fall within the intent of, but not the literal requirements of, Rule 17a-7 under the 1940 Act. Rule 17a-7 generally exempts from section 17(a) certain purchase and sale transactions between registered investment companies which are affiliated persons of each other, provided certain enumerated conditions are met. Applicants represent that, as a condition to any Order under section 17(b), they will comply with the conditions set forth in sub-paragraphs (c), (d), and (e) of Rule 17a-7, namely, that: (c) the proposed transactions are consistent with the policy of the Applicants and the old and new Contracts participating in the Exchange Offer, as recited in the applicable registration statements and reports filed under the 1940 Act; (d) no brokerage commissions, fees (except for customary transfer fees), or other remuneration will be paid in connection with the transactions; and (e) the Boards of Managers, including a majority of the members of the Boards who are not interested persons, have adopted procedures pursuant to which the proposed transactions may be effected, which are reasonably designed to provide that the conditions of paragraphs (c) and (d) of Rule 17a-7 are complied with, and will determine that the proposed transactions are effected in compliance with such procedures.

10. Applicants will not, however, meet the conditions of subparagraphs (a), (b) and (f) of Rule 17a-7. Applicants cannot comply with subparagraph (a) because no cash will be involved in the proposed transactions. Subparagraph (b) will not be complied with since the proposed transactions will be made on the basis of the relative net asset values of the securities to be exchanged, rather than on the basis of "current market price" as defined in subparagraph (b). Subparagraph (f) requires that Funds B and B-1 maintain and preserve permanently in an easily accessible place a written copy of the procedures (and any modifications thereto) described in paragraph (e) of Rule 17a-7, and maintain and preserve for at least six years a written record of each such transaction setting forth a description of the security purchased or sold, the identity of the person on the other side of the transaction, the terms of the purchase or sale transaction, and the information or materials upon which the determinations described in paragraph (e) of Rule 17a-7 were made. Since subparagraph (f) contemplates that each party will have continuing operations after a transaction pursuant to Rule 17a-7 (in order to be able to satisfy the recordkeeping requirements), Funds B and B-1 may not be able to comply if they cease operations upon the completion of the Exchange Offer. However, Accounts GS and QB represent that they will comply with such requirements. Moreover, the records of Funds B and B-1 will be maintained by Travelers for the required periods.

11. Applicants submit that because the proposed transactions involve a transfer of portfolio securities on the basis of net asset values, and because Funds B and B-1 may discontinue operations after the Exchange Offer is complete, the type of potential abuse which Rule 17a-7 was designed to guard against is not present. Applicants state that Rule 17a-7 was designed to permit investment companies to sell securities between themselves at a fairly determined price based on current market prices without incurring costs, including brokerage costs, to the detriment of Contract Owners. Applicants assert that the proposed transactions will be effected at fair market prices, and in substance, are of the type ordinarily exempted by Rule 17a-7

Conclusion

Applicants submit, for all of the reasons stated herein, that their exemptive request meets the standards set forth in section 17(b) of the 1940 Act and that an Order should therefore be granted.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93-128 Filed 1-5-93; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF STATE

Bureau of Oceans and International Environmental and Scientific Affairs

[Public Notice 1749]

United States Man and the Biosphere Program; Request for Proposals for Tropical Ecosystems Directorate

The Tropical Ecosystems Directorate (TED) of the U.S. Man and the Biosphere Program (U.S. MAB) announces a call for proposals addressing the theme of sustainable use of tropical forest resources. A small number of research grants in the range of $5,000 to $12,000 will be awarded in mid-1993. Preference will be given to proposals focusing on the Maya Tri-National Region of Belize, Guatemala, and/or Mexico.

Funding Objectives

U.S. MAB funding should assist research teams to: Add a national researcher to their effort; better integrate conservation and sustainable development; add a particular discipline to an ongoing research project; or explore the application of ongoing site-specific research to an additional site in the Maya Tri-National region. U.S. MAB funding will not be provided for planning purposes.

Focal Issues

Within the broad thematic focus of sustainable use of tropical forest resources in the Maya Tri-National Region, U.S. MAB/TED encourages research projects addressing focal issues such as community-based production systems, tropical forest management for timber and/or non-timber forest products, economic valuation and accounting of tropical forest products and services, benefits and costs of low impact uses such as ecotourism, or integration of biodiversity conservation with production forestry.

Proposal Content

Each proposal should have a title page, a one page synopsis of the existing research project, two pages detailing the proposed use of U.S. MAB/TED funds that would be complementary to the TED core program, and a one-page budget with justification. No funds are available for institutional overhead; only direct costs can be supported.

Evaluation and Review Process

Because of limited available funding, U.S. MAB/TED will give greatest preference to those proposals that directly complement the objectives of the directorate's core program. Proposals will be evaluated for the intrinsic merit of the research, its policy relevance, applicability to promoting sustainable use of tropical forest resources in the May Tri-National Region, and the quality and demonstrated productivity of the principals. All potential proposers are encouraged to contact the Secretariat of the U.S. Man and the Biosphere Program, OES/EGC/MAB, U.S. Department of State, Washington, DC 20522-3706. Tel. (703) 235-2946, to request a description of the TED core program.

Complete proposals must be received by the U.S. MAB Secretariat by close of business February 19, 1993. The U.S. MAB Secretariat will notify all principals of the Directorate's final decisions by the first week of April, 1993. Funds will be committed to the managing institutions identified in the proposals during July, 1993. Principals will receive from the U.S. MAB Secretariat copies of all U.S. MAB/TED review evaluations of their proposal and a written notification of the Directorate's decision on their project.

Submission of Proposals

Mail proposals to: U.S. MAB Secretariat, OES/EGC/MAB, room 608, SA-37, U.S. Department of State, Washington, DC 20522-3706.

Individuals choosing to submit their proposals by Express Mail, Federal Express, UPS, etc., must use the following address: U.S. MAB Secretariat, rm. 608, 1555 Wilson Boulevard, Rosslyn, Virginia 22209.

Deadline for Proposals: 19 February 1993.

Page Limit: 5 pages, single-spaced.

Dated: December 22, 1992.

Roger E. Soles,

Executive Director, U.S. Man and the Biosphere Program, Office of Global Change.

[FR Doc. 93-189 Filed 1-5-93; 8:45 am]

BILLING CODE 4710-09-M

DEPARTMENT OF TRANSPORTATION

Aviation Proceedings; Agreements Filed During the Week Ended December 25, 1992

The following Agreements were filed with the Department of Transportation under the provisions of 49 U.S.C. 412 and 414. Answers may be filed within 21 days of date of filing.

Docket Number: 48568.
Date filed: December 22, 1992.
Parties: Members of the International Air Transport Association.
Subject: Comp Reso/P0810 dated November 10, 1992; Composite Resolutions R-1 to R-15.
Proposed Effective Date: April 1, 1993.

Docket Number: 48569.
Date filed: December 22, 1992.
Parties: Members of the International Air Transport Association.
Subject: TC2 Reso/P 1327 dated November 13, 1992. Within Europe (Some EC Applicability) r-1 to r-4 TC2 Reso/P 1328 dated November 13, 1992. Within Europe (Some EC Applicability) r-5 to r-18 TC2 Reso/P 1329 dated November 13, 1992. Within Europe (No EC Applicability) r-19 to r-41.
Proposed Effective Date: April 1, 1993.

Docket Number: 48570.
Date filed: December 22, 1992.
Parties: Members of the International Air Transport Association.
Subject: Comp Telex—Resolution 024f—Norway.
Proposed Effective Date: January 7, 1993.

Phyllis T. Kaylor,

Chief, Documentary Services Division.

[FR Doc. 93-227 Filed 1-5-93; 8:45 am]

BILLING CODE 4910-62-M

Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart Q During the Week Ended December 25, 1992

The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under subpart Q of the Department of Transportation's Procedural Regulations (See 14 CFR 302.1701 et. seq.). The due date for Answers, Conforming Applications, or Motions to Modify Scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases

a final order without further proceedings.

Docket Number: 48562.
Date filed: December 21, 1992.
Due Date for Answers. Conforming Applications, or Motion to Modify Scope: January 19, 1993.
Description: Application of American Trans Air, Inc., pursuant to section 401 of the Act and subpart Q of the Regulations, applies for a certificate of public convenience and necessity authorizing it to provide scheduled foreign air transportation of persons, property and mail between Indianapolis, Indiana, and Cancun, Mexico.

Docket Number: 48565.
Date filed: December 21, 1992.
Due Date for Answers. Conforming Applications, or Motion to Modify Scope: January 5, 1993.
Description: Application of Morris Air Service, Inc. request the Department for disclaimer of jurisdiction under section 401(h) and issue a new certificate in the name of Morris Air Corporation, pursuant to part 215 of the Department's Regulations.

Docket Number: 48566.
Date filed: December 22, 1992.
Due Date for Answers. Conforming Applications, or Motion to Modify Scope: January 20, 1993.
Description: Application of Lineas Aereas Allegro, S.A. de C.V., pursuant to section 402 of the Act and subpart Q of the Regulations, applies for a foreign air carrier permit for authority to provide charter foreign air transportation of persons and accompanying baggage between points in the United States and points in Mexico.

Docket Number: 48571.
Date filed: December 23, 1992.
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: January 21, 1993.
Description: Application of Skybus, Inc., pursuant to section 401(d)(1) of the Act and subpart Q of the Regulations, applies for a certificate of public convenience and necessity authorizing it to engage in scheduled interstate and overseas air transportation of persons, property and mail between any point in any State of the United States or the District of Columbia, or any territory or possession of the United States, and any other point in any State of the United States or the District of Columbia, or any territory or possession of the United States.

Docket Number: 48572.
Date filed: December 23, 1992.
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: January 20, 1993.
Description: Application of Biman Bangladesh Airlines, pursuant to section 402 of the Act and subpart Q of the Regulations, applies for a Foreign Air Carrier Permit to permit it to commence on March 1, 1993, the transportation of passengers, general cargo, and mail between Dhaka, Bangladesh, and New York, New York, and Newark, New Jersey, and points in between.

Docket Number: 48574.
Date filed: December 23, 1992.
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: January 20, 1993.
Description: Application of American Trans Air, Inc. pursuant to section 401 of the Act and subpart Q of the Regulations, requests a certificate of public convenience and necessity to authorize scheduled foreign air transportation of persons, property, and mail between New York, New York and Riga, Latvia, both nonstop and via the intermediate point of Shannon, Republic of Ireland.

Phyllis T. Kaylor,
Chief, Documentary Services Division.
[FR Doc. 93-226 Filed 1-5-93; 8:45 am]
BILLING CODE 4910-62-M

Federal Railroad Administration

[FRA Docket No. H-92-9]

Petition for Waiver for Test Program; CSX Transportation

In accordance with 49 CFR part 211, notice is hereby given that CSX Transportation (CSXT) has submitted a petition dated November 2, 1992, for a temporary waiver of compliance with specific requirements of certain parts of title 49 Code of Federal Regulations in order to conduct a test of a performance-based method for determining the gage restraint capacity of the track structure, and to further develop this method as a possible alternative to sections of the existing Track Safety Standards.

The proposed test program is designed to evaluate a performance-based method of objectively determining the gage restraint capacity of the crossties and rail fasteners under continuous lateral and vertical loading of the track structure. The applied loads would sufficiently engage and exercise the rail fasteners, but would not permanently damage the track structure. The test program and associated procedures are meant to further develop this approach as an alternative to the present methods of determining adequate gage restraint capacity which are contained in § 213.109, "Crossties" and § 213.127, "Rail Fastenings", of the existing Track Safety Standards (49 CFR part 213).

CSXT and FRA recognize the desirability of improving present methods of determining the adequacy of gage restraint capacity. Present methods rely on visual and manual inspections by both railroad and FRA inspectors. These methods require an inspector to determine the gage restraint capacity of crossties and rail fasteners by observing indications of relative motion and by estimating component strength based on visual appearance. The proposed test program will evaluate a technique which provides a means of testing and objectively measuring the gage restraint capacity by applying controlled loads at the wheel/rail interface and then measuring the resulting deflections. Use of this technique is expected to maintain and enhance safety by detecting and marking safety critical locations so that immediate corrective action can be taken, while simultaneously producing a continuous, objective record of gage restraint capacity.

The test program is proposed to be conducted on the following track segments of the CSXT Florence Division: Aberdeen Subdivision; Hamlet Subdivision; Columbia Subdivision; and Andrews Subdivision. The Aberdeen, Hamlet, and Columbia Subdivisions form a through route between Raleigh, North Carolina and Savannah, Georgia via Hamlet, NC. The Andrews Subdivision is a route between Charleston, South Carolina and Hamlet, NC. The test program is expected to continue for at least three years unless terminated earlier for reasons not foreseen at the present time.

For the purposes of this test program, CSXT Transportation requests temporary relief from the following paragraphs of § 213.109: (b)(1)(i), (b)(2), (b)(3), (c), and (d); and from § 123.127.

FRA is seeking comments on this proposed test program from interested parties. FRA will take these comments into account in arriving at a final specification of conditions governing the conduct of the proposed test program, if conditional approval is granted by FRA'S Railroad Safety Board. Such comments may also have value in supporting FRA's consideration of modifications to the existing Track Safety Standards to incorporate performance-based alternatives.

Interested parties are invited to participate in this proceeding by submitting written views, data, or

comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and must be submitted in triplicate to the Docket Clerk, Office of Chief Counsel, Federal Railroad Administration, Nassif Building, 400 Seventh Street, SW., Washington, DC 20590. Communications received before February 1, 1993, will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) in room 8201, Nassif Building, 400 Seventh Street, SW., Washington, DC 20590.

Issued in Washington, DC on December 30, 1992.

Edward R. English,

Acting Associate Administrator for Safety.

[FR Doc. 93–105 Filed 1–5–93; 8:45 am]

BILLING CODE 4910–06–M

[Waiver Petition Docket Number H–92–7]

Public Hearing

The Union Pacific Railroad Company (UP) has requested a waiver of compliance from certain provisions of the Railroad Power Brakes Regulations (49 CFR part 232) (see FR 59197, December 12, 1992). The UP is seeking a waiver of compliance with § 232.12(b), which stipulates, "Each carrier shall designate additional inspection points not more than 1,000 miles apart where intermediate inspections will be made to determine that—

(1) Brake pipe leakage does not exceed five pounds per minute;

(2) Brakes apply on each car in response to a 20-pound service brake pipe pressure reduction; and

(3) Brake rigging is properly secured and does not bind or foul.

The UP is seeking the waiver for a six (6) month test period.

The FRA has received a request that a public hearing be held. Accordingly a public hearing is hereby set for 10 a.m. on January 15, 1993, in room 8236 of the Nassif Building located at 400 7th Street, SW., in Washington, DC.

The hearing will be an informal one and will be conducted in accordance with Rule 25 of the FRA Rules of Practice (49 CFR 211.25), by a representative designated by the FRA.

The hearing will be a nonadversary proceeding and, therefore, there will be no cross-examination of persons presenting statements. The FRA representative will make an opening statement outlining the scope of the hearing. After all initial statements have been completed, those persons wishing to make brief rebuttal statements will be given the opportunity to do so in the same order in which they made their initial statements. Additional procedures, if necessary for the conduct of the hearing, will be announced at the hearing.

Issued in Washington, DC on December 30, 1992.

Edward R. English,

Acting Associate Administrator for Safety.

[FR Doc. 93–106 Filed 1–5–93; 8:45 am]

BILLING CODE 4910–06–M

DEPARTMENT OF THE TREASURY

Public Information Collection Requirements Submitted to OMB for Review

Dated: December 29, 1992.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

U.S. Customs Service

OMB Number: 1515–0082
Form Number: CF 226
Type of Review: Extension
Title: Record of Vessel Foreign Repair or Equipment Purchase
Description: A 50-percent duty exists on equipment purchases for and repairs made to U.S. flag vessels in foreign ports. Arriving at its first U.S. port, the owner or master of a vessel is required to declare all equipment, parts, or materials purchased, and repairs made outside the U.S.
Respondents: Businesses or other for-profit
Estimated Number of Respondents: 2,000
Estimated Burden Hours Per Respondent: 30 minutes
Frequency of Response: On occasion
Estimated Total Reporting/Recordkeeping Burden: 4,000 hours
Clearance Officer: Ralph Meyer, (202) 927–1552, U.S. Customs Service, Paperwork Management Branch, Room 6316, 1301 Constitution Avenue, NW., Washington, DC 20229.
OMB Reviewer: Milo Sunderhauf, (202) 395–6880, Office of Management and Budget, Room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 93–122 Filed 1–5–93; 8:45 am]

BILLING CODE 4820–02–M

Public Information Collection Requirements Submitted to OMB for Review

December 30, 1992.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

Internal Revenue Service

OMB Number: 1545–1012
Form Number: IRS Form 5305A–SEP
Type of Review: Revision
Title: Salary Reduction and Other Elective Simplified Employee Pension-Individual Retirement Accounts Contribution Agreement
Description: This form is used by an employer to make an agreement to provide benefits to all employees under a salary reduction Simplified Employee Pension (SEP) described in section 408(k). This form is not to be filed with IRS but is to be retained in the employer's records as proof of establishing such a plan, thereby justifying a reduction for contributions made to this SEP. The data is used to verify the deduction.
Respondents: Businesses or other for-profit
Estimated Number of Respondents/Recordkeepers: 100,000
Estimated Burden Hours Per Respondent/Recordkeeper:

Recordkeeping—40 minutes
Learning about the law or the form—56 minutes
Preparing the form—1 hour, 6 minutes
Frequency of Response: On occasion
Estimated Total Reporting/Recordkeeping Burden: 270,000 hours
Clearance Officer: Garrick Shear, (202) 622-3869, Internal Revenue Service, room 5571, 1111 Constitution Avenue, NW., Washington, DC 20224.
OMB Reviewer: Milo Sunderhauf, (202) 395-6880, Office of Management and Budget, room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,
Departmental Reports Management Officer.
[FR Doc. 93-123 Filed 1-5-93; 8:45 am]
BILLING CODE 4830-01-M

DEPARTMENT OF VETERANS AFFAIRS

Veterans' Advisory Committee on Environmental Hazards; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under Public Law 92-463 that a meeting of the Veteran's Advisory Subcommittee on Environmental Hazards will be held on Monday, January 25, 1993, in room 401 at 801 I Street, NW., Washington, DC 20004. The meeting will convene at 9 a.m. and adjourn at 5 p.m.

A full Committee meeting will be held on February 1-2, 1993, in room 946 at 801 I Street, NW., Washington, DC 20004. The meetings will convene at 9 a.m. and adjourn at 5 p.m.

The purpose of the meetings is to review information relating to activities during which significant numbers of veterans were exposed to ionizing radiation before January 1, 1970 (this includes activities other than participation in an atmospheric nuclear test or service with the occupation forces of Hiroshima, or Nagasaki, Japan.)

The meeting is open to the public to the capacity of the room. For those wishing to attend, contact Mrs. Leney Holohan, Department of Veterans Affairs Central Office (026B), 810 Vermont Avenue, NW., Washington, DC 20420, phone (202) 523-3911, prior to January 18, 1993.

Members of the public may direct questions or submit prepared statements for review by the Committee in advance of the meeting, in writing only, to Mr. Frederic L. Conway, Deputy Assistant General Counsel, (026B), Department of Veterans Affairs Central Office, 810 Vermont Avenue, NW., Washington, DC 20420. Submitted material must be received at least five days prior to the meeting. Such members of the public may be asked to clarify submitted material prior to consideration by the Committee.

Dated: December 21, 1992.

Diane H. Landis,
Committee Management Officer.
[FR Doc. 93-107 Filed 1-5-93; 8:45 am]
BILLING CODE 8320-01-M

Sunshine Act Meetings

Federal Register
Vol. 58, No. 3
Wednesday, January 6, 1993

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 57 FR 61965, Tuesday, December 29, 1992.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 2:00 p.m. (eastern time) Tuesday, January 12, 1993.

CHANGE IN THE MEETING:

Open Session

The meeting time will change to 10:00 a.m. (eastern time) Tuesday, January 12, 1993.

CONTACT PERSON FOR MORE INFORMATION: Frances M. Hart, Executive Officer, on (202) 663–4070.

Dated: January 4, 1993.

Frances M. Hart,

Executive Officer, Executive Secretariat.

This Notice Issued January 4, 1993.

[FR Doc. 93–319 Filed 1–4–93; 3:14 pm]

BILLING CODE 6750–06–M

FEDERAL RESERVE SYSTEM BOARD OF GOVERNORS

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 57 FR 61966, December 29, 1992.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 11:00 a.m., Monday, January 4, 1993.

CHANGES IN THE MEETING: Addition of the following closed item(s) to the meeting: Federal Reserve Bank and Branch director appointments.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204.

Dated: January 4, 1993.

Jenifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93–314 Filed 1–4–93; 2:27 pm]

BILLING CODE 6210–01–M

SECURITIES AND EXCHANGE COMMISSION

Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94–409, that the Securities and Exchange Commission will hold the following meeting during the week of January 4, 1993.

A closed meeting will be held on Tuesday, January 5, 1993, at 1:30 p.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c) (4), (8), (9)(A) and (10) and 17 CFR 200.402(a) (4), (8), (9)(i) and (10), permit consideration of the scheduled matters at a closed meeting.

Commissioner Schapiro, as duty officer, voted to consider the items listed for the closed meeting in a closed session.

The subject matter of the closed meeting scheduled for Tuesday, January 5, 1993, at 1:30 p.m., will be:

Settlement of injunctive actions.
Institution of injunctive actions.
Regulatory matter bearing enforcement implications.
Institution of administrative proceedings of an enforcement nature.
Settlement of administrative proceeding of an enforcement nature.
Opinions.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: Paul Atkins at (202) 272–2000.

Dated: January 4, 1993.

Jonathan G. Katz,

Secretary.

[FR Doc. 93–290 Filed 1–4–93; 12:47 pm]

BILLING CODE 8010–01–M

Corrections

Federal Register
Vol. 58 No. 3
Wednesday, January 6, 1993

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[OACT-042-N]

RIN 0938-AF94

Medicare Program; Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for 1993

Correction

In notice document 92-28717 beginning on page 56345 in the issue of Friday, November 27, 1992, make the following corrections:

1. On page 56346, in the 1st column, in the 21st line, "recognizes" should read "recognize".

2. On the same page, in the same column, in the 28th line, "any" should read "may".

BILLING CODE 1505-01-D

POSTAL RATE COMMISSION

[Docket No. C93-2 and Order No. 953]

Parcel Post Rate Complaint: Notice and Order on Filing of Complaint of United Parcel Service

Correction

In notice document 92-29727 appearing on page 58033 in the issue of Tuesday, December 8, 1992, the Docket No. should read as set forth above.

BILLING CODE 1505-01-D

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-31601; File No. SR-NSCC-92-08]

Self-Regulatory Organization; National Securities Clearing Corporation; Order Approving a Proposed Rule Change Relating to Index Receipts

Correction

In notice document 92-31051 beginning on page 61136 in the issue of Wednesday, December 23, 1992, make the following correction: On page 61136, in the heading, "File No. SR-NSCC-92-09" should read "File No. SR-NSCC-92-08".

BILLING CODE 1505-01-D

DEPARTMENT OF TRANSPORTATION

Coast Guard

46 CFR Part 28

[CGD 88-079a]

RIN 2115-AD12

Commercial Fishing Industry Vessel Regulations

Correction

In proposed rule document 92-25895 beginning on page 48670 in the issue of Tuesday, October 27, 1992, make the following corrections:

1. On page 48670, in the 1st column, in the 16th and 17th lines, delete "and outside the Boundary Line".

2. On page 48672, in the second column, in the fourth paragraph, in the eighth line, several words of text were omitted. The eighth and subsequent lines, after "trade", should read "before September 8, 1990, and enters into that service before June 1, 1992, and it has not had a load line assigned at any time before November 16, 1990."

3. On page 48676, in the third column, in the third full paragraph, in the second line, "requirement" should read "requirements".

4. On page 48677, in the first column, in the first line, "codified" should read "modified".

5. On the same page, in the 3rd column, in the 13th line, "pat" should read "part".

6. On page 48678, in the 2nd column, in the 2nd full paragraph, in the 29th line, insert the word "a" between "of" and "bulkhead's".

§ 28.65 [Corrected]

7. On page 48681, in the third column, in § 28.65(b)(1)(ii), in the first line, "of" should read "or".

§ 28.600 [Corrected]

8. On page 48685, in the third column, in § 28.600(d)(1), in the third line a numerical notation was omitted. The third line should read "(2) Flooding through these hatches does".

BILLING CODE 1505-01-D

federal register

Wednesday
January 6, 1993

Part II

Department of Agriculture

Food Safety and Inspection Service

9 CFR Parts 317, 320, and 381
Nutrition Labeling of Meat and Poultry Products; Final Rule

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317, 320, and 381

[Docket No. 91-006F]

RIN 0583-AB34

Nutrition Labeling of Meat and Poultry Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat and poultry products inspection regulations by permitting voluntary nutrition labeling on single-ingredient, raw meat and poultry products, and by establishing mandatory nutrition labeling for all other meat and poultry products, with certain exceptions. FSIS is committed to providing consumers with the most informative labeling system possible. FSIS's nutrition labeling final regulations for meat and poultry products will parallel to the extent possible, as authorized by the Federal Meat Inspection Act and the Poultry Products Inspection Act, FDA's nutrition labeling regulations promulgated under the Nutrition Labeling and Education Act (NLEA).

EFFECTIVE DATE: July 6, 1994. The incorporation by reference of the "Official Methods of Analysis" of the Association of Analytical Chemists (AOAC) International, contained in this regulation, is approved by the Director of the Federal Register as of July 6, 1994.

FOR FURTHER INFORMATION CONTACT: Charles Edwards, Director, Product Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, (202) 205-0080. Copies (printed or on 3.5" high-density diskettes) of the final rule may be obtained from the Policy Office, Linda Carey, FSIS Hearing Clerk, room 3171, South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, (202) 720-7163.

SUPPLEMENTARY INFORMATION:

Executive Order 12291 and Effects on Small Entities

This final rule has been reviewed under USDA procedures established to implement Executive Order 12291 and has been classified as a major rule pursuant to section 1(b)(1) of that order because it is likely to result in an annual effect on the economy of $100 million or more. The Department reported its review in its Final Regulatory Impact Analysis (FRIA), which includes an analysis of the costs and benefits of nutrition labeling. FSIS estimates that the final rule will result in net societal benefits of $1.5 billion during the first 20 years after required nutrition labeling is available to consumers. For the purpose of this rule, net societal benefits are the estimated health benefits minus the compliance costs. The $1.5 billion represents the present value of net benefits, recognizing that changes in nutrition labeling requirements generate both costs and benefits that will occur in future years. All costs and benefits have been converted to a present value using a discount rate of 7 percent. Total 20-year health benefits were estimated to be $1.75 billion. Total 20-year compliance costs were estimated to range from $218 to $272 million.

To estimate future costs and benefits, it is necessary to use a specific time frame. The optimum time period is unknown. The Department selected 20 years, recognizing that 15 years or 25 years may also have been appropriate.

The final rule exempts products from required labeling if annual production of the product is less than 100,000 pounds and the producing firm has 500 or fewer employees. The Small Business Administration's definition of a small meat and poultry processing firm is one having 500 or fewer employees (13 CFR part 121). Thus, products produced by small businesses are exempt if they are produced at levels below 100,000 pounds. Without the small business and 100,000 pound exemption, 20-year costs would rise to $767 to $999 million. The exemption reduces benefits by $138 million. Thus, without the exemption, total benefits would be $1,892 million and estimated net benefits would range from $0.9 to $1.1 billion. The reduction in benefits is based on the estimate that the exemption applies to 7.3 percent of the volume of meat and poultry products that would require nutrition labeling without the exemption. Benefit estimates are directly related to the volume of products that are labeled. Therefore, the exemption reduces estimated benefits by 7.3 percent.

Without the exemption, the estimated compliance cost increases of $767 to $999 million are not the only type of costs that would be incurred. The Department believes that without the exemption many small businesses would have to close or substantially reduce the variety of products they now offer. Reductions in purchase options are a cost to consumers that could not be quantified for the Department's analysis.

The final rule allows processors of meat and poultry products the flexibility to base labeling information on laboratory analyses, recipe analyses using nutrition information from available data bases, or any combination of both. The rule does require that firms maintain a record of supporting information. The net benefit estimates are based on an assumption that 30 percent of the required nutrition information will be based on recipe analyses using data base values. The 30 percent estimate reflects concerns that (1) products using proprietary mixes as ingredients may not be able to make use of recipe analysis, and (2) some manufacturers might feel greater confidence in using laboratory analysis. The final 20-year cost estimates are reduced by from $32 to $50 million based on the estimate that 30 percent of required information will be supported by recipe analyses using data base values. When the predicted use of recipe analyses varied from 15 to 60 percent, the cost savings ranged from $16 to $100 million. Thus, if 60 percent of the required nutrition information was supported by recipe analyses, net benefits could increase by as much as $50 million.

Three alternatives to the final rule were considered. The first alternative was to allow for the voluntary nutrition labeling of all meat and poultry products. All voluntary labeling would have to be consistent with the regulations that FDA issues to implement the NLEA.

Based on responses to a 1992 survey of federally inspected firms, the Department now believes that earlier estimates that 40 percent of packaged processed products have nutrition labeling were high. It is possible that 40 percent of products in large supermarkets have nutrition labeling, but the overall level for all grocery stores is now estimated to be far lower. The Department has three serious concerns with the option of voluntary nutrition labeling on processed products. First, the analytical costs are going up substantially because of the nutrients/food components that will be required. Today, a large portion of voluntary labeling consists of an abbreviated format. The average cost of single laboratory analysis is estimated to be $231. To be consistent with revised FDA regulations, the average cost would rise to $406 per analysis. This voluntary option would not include the testing requirements associated with the current Nutrition Labeling Verification (NLV) program. The NLV program requires 26 analyses over a 20-year period. Based on public comments, the

cost estimates for both mandatory or voluntary labeling use a range of 7 to 13 total analyses per product over the 20-year period. Since the type and amount of testing will be determined by the producer, there is no reason to believe that analytical costs would differ between voluntary labeling and mandatory labeling.

The Department has three major reservations concerning the viability of the voluntary alternative. First, if all nutrition labeling were voluntary, the Department is concerned that higher analytical costs per analysis could result in fewer products having voluntary labeling than currently exists, a level that is already far lower than previously believed. Second, the Department has always been concerned that under a voluntary program, products containing large amounts of fat, saturated fat, cholesterol, or sodium are less likely to be labeled. Third, firms with relatively low levels of nutrition labeling responding to the USDA survey conducted in 1992, did not indicate that, under a voluntary program, they would be increasing nutrition labeling for the new products they plan to introduce over the next three years. These same firms indicate they have substantially more nutrition information on file than they are currently providing on product labels.

The second alternative was to change the exemption criterion on production per product. One variation would lower the exemption criterion on production to 50,000 pounds per year. The change in the 20-year estimated costs when including these products is very close to the change in 20-year projected benefits, thus, including these products between 50,000 and 100,000 pounds results in a minimal change in net benefits. When the impact on individual products and small businesses was considered, the Department decided against lowering the exemption level. Requiring nutrition labeling on the many small-firm products having between 50,000 and 100,000 pounds in annual production would most likely lead to many of those products no longer being produced, with a consequent loss of benefits to consumers. In small firms, these are not generally new or developmental products. They are more likely to represent stable, low production levels for limited markets.

On considering whether to raise the level of exemption from 100,000 to 250,000 pounds, the analysis also indicates little change in net benefits. However, as production increases, the lower relative impact on individual products greatly reduces the possibility that product lines will be unprofitable. The Department has chosen to allow extra time to implement nutrition labeling on products produced at levels between 100,000 and 250,000 pounds. The extra time reduced 20-year compliance costs by $8 to $10 million.

The third alternative was to remove the exemption criterion for employees and exempt all products produced at levels under 100,000 pounds. This option reduces estimated total benefits by $32 million to $1,722 million. Estimated total costs are reduced by from $39 to $47 million to a revised level of from $179 to $225 million. Net benefits remain at $1.5 billion, no change after rounding. To decide whether or not to accept this alternative, the Department had to look beyond the estimates of net benefits.

In developing a comprehensive economic impact for the final analysis, it is useful to view the meat and poultry processing industry as two separate industry sectors. There are medium to large firms that distribute most products regionally and nationally to supermarkets and other grocery stores. There are also a far larger number of small processors that sell most of their products in small specialty stores, locker plants, and butcher shops. Many also sell products through retail counters at production facilities. These small producers, however, market very little product through grocery stores and supermarket chains. In contrast, the Department believes that most products from firms with more than 500 employees are marketed through supermarkets.

This third alternative would result in a substantial increase in the number of exempt products sold in supermarkets. This becomes a concern when viewed in the context of the methodology used to estimate benefits. With the methodology used, overall health benefits come from having a high portion of volume labeled. There is, however, an implicit assumption that a sufficient number of products are labeled so that consumers are able to transfer information to like products. While the analysis cannot explicitly account for the reduction in the prevalence of labels in benefit estimates, each additional exemption weakens their reliability. The Department rejected this alternative in order to assure that both a high volume of products are labeled and the number of labeled products is above a subjective threshold that assures that consumers have sufficient information. Because compliance costs are a very small portion of total production costs for large firms, rejecting this alternative is not viewed as creating an economic hardship for large firms.

The Department developed the final rule with the goal of providing nutrition labeling on the maximum volume of packaged, processed retail product while assuring that small businesses producing small volumes of specialty products for limited markets are not at risk of going out of business or materially reducing the variety of products they deliver to their customers. Ensuring that a high percentage of total production is subject to nutrition labeling is important because that is what accounts for consumer purchases, consumption, and potential health effects.

This final rule achieves the goal. The Department estimates that 99 percent of the pounds of processed products distributed through approximately 24,000 supermarkets will be labeled. Likewise, approximately 95 percent of the volume of processed product marketed through an estimated 170,000 total supermarkets, grocery stores, and smaller convenience stores will be labeled. Finally, over 90 percent of the total production of packaged, processed product marketed through all retail outlets will include nutrition labeling for consumers.

The Department acknowledges that the benefit estimates are based on the total contribution of meat and poultry products to dietary fat, saturated fat, and cholesterol. Labeling will be required on most processed products purchased by consumers in retail stores. Together, with the voluntary program for retail store information on fresh products, consumers will have nutrition information on most of the meat and poultry products purchased for consumption at home. The Department believes that over time consumers will be able to transfer their knowledge gained through such labeling to meals eaten away from home. For that reason, benefits have not been reduced to account for the portion of meat and poultry consumed away from home.

The costs developed for the final analysis are the costs required to comply with the final rule. This analysis does not address the opportunity costs of alternative labeling schemes which would require different label information. It also excludes an analysis of the economic impact if firms choose to reformulate products or produce alternative products rather than comply with the labeling requirements of the rule.

The FRIA is available for public review in the office of the FSIS Hearing Clerk, room 3171, South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. Copies are available from the

Hearing Clerk, without charge. The FRIA also satisfies the analysis requirements of the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601 *et seq.*), which deals with the effect on small entities.

Executive Order 12778

This final rule has been reviewed pursuant to Executive Order 12778, Civil Justice Reform. This rule provides provisions for: (1) Voluntary nutrition labeling on single-ingredient, raw meat and poultry products; and (2) mandatory nutrition labeling for all other meat and poultry products, with the exceptions of (a) certain products produced by small businesses; (b) products used for further processing; (c) products that are not for sale to consumers; (d) products in small packages weighing less than ½ ounce; (e) products custom slaughtered or prepared; (f) products intended solely for export; (g) ready-to-eat products packaged at the retail level; and (h) multi-ingredient products processed at the retail level.

This final rule concerns labeling of meat and poultry products. States and local jurisdictions are preempted under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) from imposing any marking, labeling, packaging, or ingredient requirements on federally inspected meat or poultry products that are in addition to, or different from, those imposed under the FMIA or the PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat and poultry products that are outside official establishments for the purpose of preventing the distribution of meat or poultry products that are misbranded or adulterated under the FMIA or PPIA, or, in the case of imported articles, which are not at such an establishment, after their entry into the United States. Under the FMIA and the PPIA, States that maintain meat and poultry inspection programs must impose requirements on State inspected products and establishments that are at least equal to those required under the FMIA or PPIA. These States may, however, impose more stringent requirements on such State inspected products and establishments.

Upon its adoption, no retroactive effect will be given to this final rule, and applicable administrative procedures must be exhausted before any judicial challenge to its provisions or their application. Those administrative procedures are set forth in the rules of practice governing proceedings for labeling determinations at 9 CFR parts 335 and 381, subpart W.

Paperwork Requirements

This final rule requires manufacturers to maintain records supporting the validity of nutrient information on the labels of meat and poultry products, and to make such records available to FSIS upon request. This final rule requires most currently approved labels for all meat and poultry products, except for single-ingredient, raw products, to be revised and submitted to FSIS for approval, which will impact substantially on all such manufacturers. Manufacturers of single-ingredient, raw meat and poultry products opting to use nutrition labeling on the label will also be required to revise their labels and comply with requirements of the mandatory program.

The final rule also requires that manufacturers desiring to use (1) a new nutrient content claim not currently provided in the regulations, (2) a synonymous term to a term defined by regulation, or (3) an implied nutrient content claim in a brand name, or to amend the table for Product Categories and Reference Amounts, to submit to FSIS a standard labeling application, along with additional supporting information. The supporting information includes statements that (1) identify the term, (2) explain why the term is not false or misleading, (3) set forth the importance of the term and its relation to consumer nutrition or health, and (4) analyze the potential effect of the use of the proposed term on food consumption. The supporting information required to accompany the labeling application is a new paperwork burden being imposed upon manufacturers.

The paperwork requirements contained in this final rule have been submitted to the Office of Management and Budget for approval under the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). If you wish to comment on the paperwork burden of this proposed rule, send your comments to: Office of Management and Budget, Desk Officer for FSIS, Office of Information and Regulatory Affairs, room 3208, New Executive Office Building, Washington, DC 20503 and to the Clearance Office, room 404–W, Administration Building, Washington, DC 20250.

Background

Introduction

The FMIA (U.S.C. 601 *et seq.*) and the PPIA (21 U.S.C. 451 *et seq.*) authorize the Secretary of Agriculture to establish and maintain inspection programs designed to assure consumers that meat and poultry products distributed in commerce or within designated States are wholesome, not adulterated, and are properly marked, labeled, and packaged.

FSIS regulates the labeling of meat and poultry products while FDA has responsibility for all other food labeling. FSIS conducts a prior label approval program under which labeling to be used on, or in conjunction with, meat and poultry products must be approved by the Agency prior to their use. FDA, on the other hand, relies primarily upon food manufacturers to comply with prescribed labeling regulations and to ensure that information contained on food labels is truthful and not misleading.

FSIS also develops standards of identity or composition for certain meat and poultry products under section 7(c) of the FMIA (21 U.S.C. 607(c)) and section 8(b) of the PPIA (21 U.S.C. 457 (b)). Under these authorities, FSIS has promulgated regulations prescribing definitions and standards of identity or composition (9 CFR part 319 and § 381.155 *et seq.*). FSIS also has promulgated regulations prescribing the content and design of labels (9 CFR part 317 and § 381.115 *et seq.*).

In 1973, FDA adopted a regulation, recodified in 1977 as 21 CFR 101.9, prescribing a specific labeling format to be included on food product labels when voluntary or mandatory nutrition information is provided. Currently required components that must be addressed include: calories, protein, carbohydrates, fat, sodium, two mineral elements (calcium and iron), and five vitamins (vitamin A, vitamin C, thiamin, riboflavin, and niacin). FSIS disseminates its nutrition labeling guidelines for meat and poultry products through the issuance by its Food Labeling Division of various policy memoranda. Copies of FSIS policy memoranda on nutrition labeling are available for public review in the FSIS Hearing Clerk's office.

The policy memos that relate in whole or in part to nutrition related issues will need to be rescinded or revised because of this final rule. Policy Memo 74A, dated November 1986, Exemptions from Nutrition Label Verification (NLV) Procedures or Partial Quality Control (PQC) Programs, and Policy Memo 85B, dated January 1988, NLV Procedures will no longer be in effect upon publication of this final rule. The following policy memoranda will remain in effect during the 18-month period between the date of publication and the effective date of this final rule, except that the provisions relating to data requirements and requirements for

an NLV procedure or PQC Program will not be enforced: Policy Memo 86, dated May 1985, Nutrition Labeling; Policy Memo 49C, dated June 1984, Sodium Labeling Guidelines; Policy Memo 70B, dated November 1987, Fat and Lean Claims; Policy Memo 71A, dated March 1986, Lite and Similar Terms; and Policy Memo 78, dated November 1984, Potassium Labeling Guidelines. These memoranda will be rescinded upon the effective date of this final rule. Policy Memo 16A, dated March 1981, Combinations of Ground Beef or Hamburger and Soy Products; Policy Memo 46, dated April 1982, Percent Fat Free Label Declarations; Policy Memo 7, dated August 1980, Information Panel; Policy Memo 39, dated January 1982 Caloric Claims/Weight Reduction; and Policy Memo 121, dated May 1991, Low Fat Ground Beef and Low Fat Hamburger with Added Ingredients, will remain in effect during the interim period but will be rescinded upon the effective date of this final rule. Policy Memo 69, dated March 1984, Labeling for Substitute Products; Policy Memo 19A, dated May 1987 Negative Labeling; and Policy Memo 114, dated July 1988, Point of Purchase Materials, will remain in effect during the interim period but will be revised upon the effective date of this final rule. Thus, companies desiring to continue declaring nutrition related information on labels in accordance with existing policy memoranda may do so until the effective date of this final rule. During this interim period, labels must conform either to policies established in the cited policy memorandum or these regulations, but not both. No combinations will be allowed. The policy memoranda discussed in this section reflect those listed in the proposal, and the addition of Policy Memo 7, Policy Memo 16A, Policy Memo 19A, and Policy Memo 121. These latter two policy memoranda have been added because FSIS agrees with the comments that stated these policy memoranda would also be impacted by the regulation.

Marketing Trends

Consumers are becoming increasingly aware of diet, health, and nutrition, and are concerned about the nutrient content of their foods. As a result, food manufacturers are adding nutrient content claims to allow consumers to make more informed food purchases. Claims such as "lean," "low fat," and "low cholesterol" have become common in today's marketplace. The use of such terms is subject to various interpretations and may mislead the consumer when purchasing products so labeled.

Nutrition Labeling Endeavors

The issue of providing consumers with more accurate and informative labeling prompted a series of undertakings by various segments of the Federal government to provide more nutrition information on the labels of all foods.

1. Congressional Action

On November 8, 1990, the Nutrition Labeling and Education Act of 1990 (NLEA), which amended certain provisions of the Federal Food, Drug, and Cosmetic Act, was enacted (Pub L. 101.535; 104 Stat. 2353). The NLEA requires mandatory nutrition labeling for most FDA-regulated packaged food products. It also requires FDA to issue voluntary nutrition guidelines to food retailers for providing nutrition information on 20 of each most frequently consumed, during a year, varieties of raw vegetables, raw fruits, and raw fish. Should food retailers fail to comply substantially with the guidelines, the NLEA requires FDA to issue mandatory requirements for these commodities.

2. FDA Regulatory Initiatives

In August 1989, FDA issued an advance notice of proposed rulemaking (ANPR) requesting comments on a wide range of labeling issues to determine what changes, if any, should be made on the labeling of foods regulated by FDA (54 FR 32610). In September 1989, FDA issued a notice of an extension of the comment period on the ANPR and announced a series of public hearings to be held throughout the Nation on food labeling (54 FR 38806). FSIS participated in these hearings, which were conducted by FDA in the fall of 1989. Issues discussed at the hearings related to nutrition labeling, ingredient labeling, descriptions of food, health messages, and nutrition label format.

After consideration of various comments received, FDA published a reproposed rule on February 13, 1990, on health messages (55 FR 5176), and three proposed rules on July 19, 1990, that would establish provisions on daily values for use in declaring nutrient content in nutrition labeling (55 FR 29476), require mandatory nutrition labeling on most food products that are meaningful sources of calories or nutrients (55 FR 29487), and define serving and portion sizes (55 FR 29517). FDA also published a tentative final rule on July 19, 1990 (55 FR 29456), prescribing regulations that define and provide for the use of the terms "cholesterol free," "low cholesterol," and "reduced cholesterol" in the labeling of foods.

The NLEA, as previously discussed, was enacted in November 1990, several months after FDA published its proposed rules and tentative final rule on food labeling. As a result, on January 11, 1991, FDA published a notice in the **Federal Register** (56 FR 1151) recognizing the impact of the NLEA on its pending rulemaking proceedings dealing with food labeling. FDA announced its plans to obtain comments in some form, or issue reproposals or supplemental proposals in some form, to ensure that all such regulations are consistent with the NLEA. These reproposals and supplemental proposals are discussed throughout this document.

3. NAS Study

In 1989, FSIS and the Public Health Service, U.S. Department of Health and Human Services (HHS), which includes FDA, jointly sponsored a study by the Institute of Medicine of the National Academy of Sciences (NAS) to provide options for improving food labeling. In its 1990 final report, NAS recommended that FSIS and FDA mandate nutrition labeling for all packaged foods under their respective jurisdictions, except for certain exemptions.[1] In addition, NAS presented recommendations on various facets of nutrition labeling including: Nutrition label content, serving sizes, U.S. Recommended Daily Allowances, adjectival descriptors, and ingredient labeling.

4. Advance Notice of Proposed Rulemaking (ANPR)

On April 2, 1991, FSIS published an ANPR in the **Federal Register** to solicit comments and recommendations from consumers, industry, public health officials, and other interested parties to assist the Agency in developing proposed regulations for nutrition labeling of meat and poultry products (56 FR 13564). In the ANPR, the Agency announced its intent to propose mandatory nutrition labeling regulations for most processed meat and poultry products and a voluntary program for fresh meat and poultry products. FSIS identified the following eight major food labeling issues that are of particular concern to the Agency: (1) Mandatory nutrition labeling, (2) nutrition label content, (3) U.S. Recommended Daily

[1] The NAS final report titled "Nutrition Labeling: Issues and Directions for the 1990s" is available for public review in the FSIS Hearing Clerk's office. Copies of the report are available for sale from the National Academy Press, 2101 Constitution Avenue, NW., Washington, DC 20418.

Allowances, (4) serving size, (5) descriptors and health messages, (6) food ingredients and standards of identity, (7) compliance and analytical methods, and (8) economic impact.

FSIS received 197 comments in response to the ANPR. After review and consideration of the comments received on the ANPR, FSIS issued a proposed rule in the **Federal Register** (56 FR 60302) on November 27, 1991, which is discussed in the following section.

5. Proposed Rules

On November 27, 1991, FSIS published a proposed rule in the **Federal Register** (56 FR 60302) to solicit comments and recommendations from consumers, industry, public health officials, and other interested parties to assist the Agency in developing the final regulations for nutrition labeling of meat and poultry products. In the proposed rule, the Agency announced its intent to amend the Federal meat and poultry products inspection regulations by permitting voluntary nutrition labeling on single-ingredient, raw meat and poultry products, and by establishing mandatory nutrition labeling for all other meat and poultry products, with the exception of products used for further processing.

FSIS received 1109 comments in response to the proposed rule. The majority of these comments (586) were submitted by food manufacturers and distributors, while 296 comments were received from consumers and consumer groups; 94 from trade associations; 24 from State governments; 15 from congressional offices on behalf of small businesses; 15 from food retailers; 10 from expediters and consultants; 10 from academia; 9 from the Federal Government; 9 from health professionals; 8 from foreign governments; 4 from professional organizations; 4 from financial institutions; 4 from meat and poultry associated industries; 4 from computerized database companies; 3 from food service organizations; 3 from health promotional groups; 2 from local governments; 2 from food ingredient developers; 2 from food industry technical advisors; and 1 each from a weight loss service, laboratory, oven and smokehouse supplier, and pharmaceutical official. One comment received did not address the scope of the proposed regulations. All comments submitted with respect to the proposed regulation were given due consideration and are discussed further in this document.

On March 25, 1992, FSIS published a supplemental (57 FR 10298) to the November 1991 proposed rule in the **Federal Register** regarding nutrition labeling of meat and poultry products. This supplemental proposed rule would (1) allow for the use of data bases and recipe analyses using data bases, as well as the proposed laboratory analyses, on which to base the nutrition information on processed meat and poultry product labels, and (2) provide a small business exemption from mandatory nutrition labeling. This action was taken because of the Agency's concern that its proposed rule not impose undue cost burdens and that its proposal be implemented in the most cost-effective manner possible while providing consumers with the same high quality nutritional information. FSIS received 247 comments in response to the supplemental proposed rule. The majority of these comments (161) were submitted by food manufacturers/distributors, while 29 comments were received from trade associations; 14 from congressional members; 13 from State governments; 10 from academia; 9 from consumers and consumer groups; 2 from labeling consultants; and 1 each from a health professional, professional organization, food retailer, Federal Government Agency, and a computerized database company. Full and careful consideration was given to all written comments received. In view of these comments and the comments received at the public forums, the Agency is providing a small business exemption and the use of databases which are discussed later in this document.

On August 28, 1992, FSIS published a proposed rule in the **Federal Register** (57 FR 39332) regarding the adoption of a standard format for use in presenting nutrition information on the labels of meat and poultry products. In its proposal, FSIS proposed to establish the CONTROL WITH DIETARY GUIDANCE or the CONTROL WITH RECOMMENDED DAILY INTAKE RANGE as the standard format. The Agency also requested comments on the proposed formats, as well as other options. A discussion of the comments received is provided later in this document.

6. Implementation Date

On March 25, 1992, FSIS published a notice in the **Federal Register** (57 FR 10298) announcing the intended implementation date of its rulemaking for nutrition labeling of meat and poultry products. FSIS advised that, based upon a careful review of the comments received from the proposed rule (56 FR 60302) published on November 27, 1991, the Agency has decided that the nutrition labeling regulations concerning meat and poultry products will be implemented 18 months from the date of publication of the final rule. Thus, the nutrition labeling regulations shall become effective on July 6, 1994.

7. Public Forums

a. On April 4, 1991, FSIS participated in a FDA public meeting on food labeling to discuss issues related to serving size: (1) The basis for determining serving size, (2) units of measure to be used, (3) deviation allowed from standard serving sizes, (4) dual nutrition labeling with the second column on the basis of uniform weight, and (5) the definition of single-serving container. One recommendation expressed by all the participants was that USDA and FDA should work in harmony to establish uniform serving sizes for the foods the agencies regulate. In response to this, FSIS participated as a member of an Interagency Committee on Serving Sizes formed by FDA to ensure consistency in serving size requirements for all foods. The committee's recommendations and objectives are discussed in this document under section VI, Serving Sizes;

b. On January 23, 1992, FSIS published a notice in the **Federal Register** (57 FR 2692) announcing its participation in FDA's "Food Labeling Hearing" on January 30 and 31, 1992, in Bethesda, MD. The hearing provided an additional opportunity for interested persons to present their views on the proposed rulemaking entitled, "Nutrition Labeling of Meat and Poultry Products" (56 FR 60302). The hearing addressed several subject areas including mandatory nutrition labeling, nutrient content claims, and health claims;

c. In April 1992, FSIS issued a notice in the **Federal Register** (57 FR 14499) announcing three public forums on the small business exemption issues raised in its nutrition labeling supplemental proposed rule published March 25, 1992, as well as other issues of public concern specific to exempting small businesses from nutrition labeling. The public forums were held May 12 in Kansas City, MO; May 14 in Atlanta, GA; and May 21 in San Francisco, CA. Issues discussed at the hearings related to defining a small business, criteria for a small business exemption, the potential economic impact of nutrition labeling on small businesses, and the ramifications of exempting small businesses from nutrition labeling regulations;

d. On July 23, 1992, FDA issued a notice in the **Federal Register** (57 FR

32750) announcing a public hearing on the notice of proposed rulemaking on the format for the nutrition label that it published in the **Federal Register** of July 20, 1992. The public hearing, held on August 17 and 18, 1992, in Bethesda, MD, provided an opportunity for interested persons to present their views on the issues raised by the proposal. FSIS participated in the hearing.

Major Issues

The following discussion provides background information on the major issues of nutrition labeling and a summary of the comments received on FSIS's proposed rule, the supplemental rule, the format proposal, and the small business forums, and highlights of the Agency's final rule on nutrition labeling.

I. Codified Language

In response to the proposed rule, FSIS received many comments that suggested that the Agency should include all the codified language for meat and poultry products in the regulations under 9 CFR parts 317 and 381. The commenters stated that it is very difficult to go back and forth between FDA and FSIS regulations to look up different provisions for the nutrition labeling regulations.

FSIS agrees with the comments. However, FSIS and FDA desire to ensure as much harmonization as possible of the nutrition labels for all food products, including simultaneous publication of final regulations. Harmonization will ensure consistency of format and content for consumers and, thereby, will encourage the use of the new labels, while minimizing the cost of compliance on the food industry.

The NLEA dictates for FDA the timeframe for publication of the final regulation. In order for FSIS to issue nutrition labeling regulations simultaneously with FDA, FSIS must meet this same publication timeframe. The codified portion of FSIS's final regulations will cross reference all the provisions of FDA's regulations where the provisions are identical, and provide codified language only for those provisions where there are variations from FDA because of the different products that FSIS regulates. FDA's final rule on nutrition labeling, portions of which are cross referenced in this final rule, is published elsewhere in this issue of the **Federal Register**. FSIS plans to publish, in the near future, the codified language as it applies to meat and poultry products in its entirety in 9 CFR parts 317 and 381.

The implementation date for FSIS's regulations is July 6, 1994. The future codification of the regulations for nutrition labeling of meat and poultry products into 9 CFR part 317 and 381 does not postpone the implementation of nutrition labeling set by this final rule.

II. Mandatory Nutrition Labeling

FSIS requires food manufacturers to obtain prior approval for the content and design of labeling for meat and poultry products before the products may be marketed. FSIS permits and encourages voluntary nutrition labeling using formats set forth in Agency policy memoranda. Many processed, packaged meat and poultry products currently bear nutrition labeling. FSIS requires manufacturers to provide nutrition data to substantiate nutrition claims. Additional information, when necessary to facilitate consumer understanding of these claims, is required.

NAS recommended that FSIS promulgate regulations which would require nutrition labeling for most packaged foods under FSIS's jurisdiction, including institutional-size packages and commodities distributed through USDA food programs, and the 20 to 30 top items of fresh/frozen meat and poultry products. NAS suggested that values for the latter be provided by using point-of-purchase information developed from data base values.

FSIS's rulemaking activities addressed several issues surrounding mandatory nutrition labeling, such as: (1) Statutory authority, (2) exemptions from mandatory nutrition labeling, and (3) voluntary nutrition labeling for single-ingredient, raw meat and poultry products.

1. *Statutory Authority.* In the proposed rule, FSIS stated that it had statutory authority to require nutrition labeling based on the Secretary of Agriculture's determination that meat and poultry products, other than single-ingredient, raw products, would be misbranded in the absence of such information under section 1(n) of the FMIA (21 U.S.C. 601(n) (1)) and section 4(h) of the PPIA (21 U.S.C. 453 (h) (4)).

There was considerable opposition to mandatory nutrition labeling from food manufacturers and trade associations. Much of the opposition centered around anticipated increased costs. These commenters indicated that they preferred a strictly voluntary program, citing that supply and demand in the marketplace would provide the nutrition information wanted by consumers.

FSIS has concluded that consumers should be provided nutrition labeled products to the extent possible for all foods. Because the nutrient values of single-ingredient, raw meat and poultry products are not modified through various stages of preparation, such as cooking and heat processing, FSIS believes that consumers have reasonable expectations as to the nutritional qualities of such products. Therefore, FSIS is establishing mandatory nutrition labeling for most processed meat and poultry products, such as pumped turkey, chicken franks, corned beef and meat burritos. FSIS addresses cost concerns in the following section with provisions for a small business exemption and allowance for the use of data bases.

2. *Exemptions.* Many comments on the Agency's November 1991 proposal supported the need for nutrition labeling of meat and poultry products, but had concerns about the absence of an exemption from mandatory nutrition labeling for small businesses for which the cost impact may be excessive. Therefore, FSIS published a supplemental proposed rule in the March 25, 1992, **Federal Register**, which asked for comments on small business exemptions and on the use of data bases and recipe analyses using data bases. In the supplemental proposal, FSIS sought input on the appropriate criteria for determining a small business exemption for meat and poultry product manufacturers, such as annual sales by dollars, pounds of product, or units of product, and the relationship between the level of exempted meat and poultry products.

On April 21, 1992, FSIS published a notice in the **Federal Register** (57 FR 14499) asking for participation in three public forums on the small business exemption issues raised in the March 25 supplemental proposal. Forum participants were asked to focus on specific issues regarding viable criteria for a small business exemption, the feasibility of compliance with various exemption criteria, and the effect of specific exemption criteria on nutrition labeling of the total food supply. Participants were free to also comment on other relevant issues relating to a small business exemption.

Public comments have indicated that, without an exemption, the cost burden for small businesses would be excessive. Some manufacturers have contended that unless an exemption is established for meat and poultry products, they will be forced out of business or will be forced to drop unprofitable product lines. These manufacturers further stated that their volume of sales or the size of their product lines do not make it feasible for them to incur the additional costs of nutrition labeling.

The majority of trade association and industry representatives responding to the supplemental rule advocated a small business exemption based on pounds of product, with 100,000 pounds as the suggested amount. Also, most commenters favored an exemption that would be implemented on a product-by-product basis to allow a company to stay diverse and to encourage production of unique and innovative products.

Numerous commenters also suggested that each official establishment be considered a separate business. Many trade associations and industry comments defined a product as one that is approved on a single label request. However, identical products with different weights would be considered the same product. The majority of comments suggested that the daily production records be used to evaluate a company's eligibility.

In addition, commenters suggested that an average of 2 years of data be used to establish eligibility. Numerous commenters suggested that the time period allowed to implement the nutrition labeling requirement, when a company exceeds the exemption limits, should be 6 months to 1 year.

In May 1992, public meetings were held in Kansas City, MO, Atlanta, GA, and San Francisco, CA. At the Kansas City forum, the consensus of the group was that the exemption should be based on pounds of product. The most important factor in favor of the pounds per product option is that a product will be exempted based on each product's contribution to the diet; the level of the exemption may be tied directly to the percentage of the diet that may not be nutrition labeled. Furthermore, each exempted product is likely to be a small part of an individual's annual diet.

In Atlanta, the concept of a unit-based exemption was introduced. The unit concept is similar to the pound-per-product option and may be better for FDA-regulated products because of their wide variation in weight.

In San Francisco, a representative of the Small Business Administration suggested using an exemption that included a pound/unit concept in combination with the small business definition of 500 employees or less. The majority of people attending the meeting contended the exemption should be based on pounds and/or units.

FSIS believes an exemption for small business is necessary because mandatory nutrition labeling requirements will create undue economic hardship and serve as a disincentive for development of more nutritious food products. Furthermore, the burden of mandatory nutrition labeling may force some small firms to drop product lines that would become unprofitable because of the cost of nutrition labeling and eventually force some small firms out of business. Therefore, after reviewing comments received in response to the 1990 amendment proposal, comments at the nutrition labeling hearings, the public forums held for the small business exemption, and written comments supplied to the Agency, FSIS is establishing a small business exemption for meat and poultry processing firms based on the volume of production in combination with the number of employees working at a firm. To qualify for the small business exemption, a processor must produce less than the annual production poundage level of a single food product and must employ no more than a specified number of employees. For purposes of the small business exemption, a "food product" is defined as a formulation, not including distinct flavors which do not significantly alter the nutritional profile, sold in any size package in commerce.

FSIS evaluated several options in establishing a poundage limit for the small business exemption, as discussed in the Agency's FRIA. This evaluation was based on two objectives: (1) Setting the limit high enough so that the risk that any small business would have to close would be minimal, and (2) setting the limit low enough so that the maximum volume of total production would bear nutrition labeling. FSIS believes that a maximum annual production poundage level between 100,000 and 250,000 pounds appears to best satisfy these two stated objectives.

Accordingly, FSIS has determined that the cutoff for the annual production level should be 100,000 pounds, phased in over a 3-year period. The 3-year phase-in period will minimize the impact of compliance costs to the industry, while also minimizing the impact of additional purchasing costs to consumers. The maximum annual production poundage level is set at 250,000 pounds per food product for the first year of implementation of nutrition labeling, lowered to 175,000 pounds per food product for the second year of implementation, and lowered finally to 100,000 pounds per food product for the third and subsequent years. The 3-year phase-in period ultimately achieves the 100,000-pound limit suggested by industry and trade association representatives. In addition, FSIS estimates an average food product line has a 3-year life. Therefore, the 3-year phase-in period will accommodate the many firms that will be relabeling their products during the normal course of business because of changed formulations.

The limit on the number of employees at a firm is set at 500 or fewer employees, which is the Small Business Administration's definition of a small meat or poultry processing firm. This approach will allow the Small Business Administration to assist in determining which firms would qualify for exemption based on the number of employees.

For purposes of a small business exemption, FSIS defines "business" as a single-plant facility or a company that owns multiple facilities. Although most meat and poultry firms are single-plant facilities, a significant number of firms are multi-plant companies. These multi-plant companies tend to make labeling decisions for all facilities under their ownership or management in a centralized manner. The qualification of a multi-plant company for exemption from nutrition labeling entails the total annual production and the total number of employees for all facilities under that multi-plant company, not for each individual facility. Thus, if a multi-plant company as a whole meets both criteria set forth in the small business exemption, all facilities under that centralized company may be exempt from nutrition labeling. Conversely, if the multi-plant company does not meet both criteria in the small business exemption, no facility under that company qualifies for exemption from nutrition labeling.

Given this combination approach for exemption from nutrition labeling, FSIS estimates that over 90 percent of all meat and poultry products, under the mandatory nutrition labeling provisions, will bear nutrition labeling after the 3-year phase-in, when the maximum annual production level has reached 100,000 pounds. FSIS further expects, that nutrition labeling will be included on as much as 99 percent of all nationally distributed meat and poultry products available to consumers through supermarkets. Again, this figure takes into account all products that are regulated under the mandatory nutrition labeling regulations, and do not include single-ingredient raw meat and poultry products that are under voluntary nutrition labeling.

In its November 1991 proposal, FSIS proposed to exempt from nutrition labeling foods used for further processing. For very small packages (less than ½ ounce) and other than consumer-size packages, FSIS proposed to allow nutrition information to be provided by labeling means other than a nutrition panel on the package.

Although there were relatively few comments addressing this issue, the majority of those that did comment on exemptions supported a blanket exemption for foods used in further processing and other than consumer-size packages.

FSIS believes that there is little value in requiring nutrition information where the consumer will not see it. Since other than consumer-size packages can be purchased by the consumer at the retail level, FSIS believes it is more appropriate to exempt products that are not for sale to consumers, regardless of size, and allow industry to determine when the product is to be used for further processing and not to be sold, at that point, to consumers. (The term "consumers", as used throughout this document refers only to household consumers.) Since consumers will not see the nutrition information on products used for further processing or products that are not for sale to consumers, these products are exempt from nutrition labeling.

For very small packages, some commenters recommended a blanket exemption, while others recommended an increase in the net weight for small package exemptions. Several commenters recommended that FSIS follow FDA's definition for very small packages (i.e., surface area available to bear labeling of less than 12 square inches). FSIS believes that it is appropriate to retain the definition of very small packages as individually wrapped packages of less than ½ ounce net weight. The Agency does not currently require packages of meat or poultry products weighing less than ½ ounce to bear a net weight statement (9 CFR 317.2(h)(9)(ii) and 381.121(c)(9)(ii)). In order to provide consistency with this net weight labeling policy, FSIS is adopting the proposed definition of very small packages as individually wrapped packages of less than ½ ounce net weight. However, since these products are such an insignificant part of the diet, FSIS is exempting very small packages from nutrition labeling requirements, provided that no nutrition claim is made on the labeling. If a nutrition claim is made on the label of very small packages, all nutrition labeling requirements must be satisfied by printing the information on the labeling.

Based on comments it received on its proposal, FDA concluded that there was adequate justification for allowing some flexibility for food in an intermediate size package group of between 12 and 40 square inches. In this intermediate size package range, FDA is allowing for the use of a linear format, making the daily reference values (DRV's) optional, allowing for abbreviations, and allowing for required information to appear on other label panels adjoining the principal display panel or the information panel. FSIS has reviewed FDA's summary of the comments received on this issue, and agrees that there may be situations that warrant a modified nutrition label. Accordingly, FSIS will allow a modified nutrition label for packages with a total surface area available to bear labeling of 40 or less square inches. In addition, on a case-by-case basis, FSIS will consider allowing a modified nutrition label for packages larger than 40 square inches that have a surface area which precludes the presentation of the full nutrition label.

Numerous commenters raised the issue of custom services and were concerned about the status of these services with respect to nutrition labeling products. FSIS has determined that custom services, such as custom slaughter or custom processing, should be exempt from nutrition labeling requirements since such services are performed solely for individuals.

Several commenters stated that products intended for export should be exempt from nutrition labeling requirements. Such products are not covered under this final rule because they are labeled according to the requirements of the country where the product is to be exported. This final rule sets forth this exception to mandatory nutrition labeling.

Although the FSIS proposal did not specifically address the issue of food products served in restaurants, the Agency did receive several comments from trade associations and retailers. Restaurant menus generally do not constitute labeling or fall within the scope of these regulations.

FSIS has historically provided for certain retail exemptions, as prescribed in 9 CFR 303.1 and 381.10. However, the adulteration and misbranding provisions of the FMIA and PPIA, as well as related regulations, still apply to such retail exempted product. FSIS has determined, based on experience and on comments, that it would be impractical to enforce nutrition labeling requirements on products prepared or served at retail. In addition, FSIS has concluded, based on review of National Food Consumption Survey (NFCS) data, the average person's diet consists of an insignificant proportion of ready-to-eat, retail packaged or processed products.

Accordingly, FSIS is exempting from mandatory nutrition labeling (1) ready-to-eat products, such as sliced bologna, that are packaged or portioned at a retail store or similar retail-type establishment; and (2) multi-ingredient products, such as sausage, that are processed at a retail store or similar retail-type establishment, provided the labels or the labeling of these products bear no nutrition claims or nutrition information.

FSIS anticipates that most meat and poultry products in gift packs will fall under the small business exemption. FSIS also believes that gift packs play a very minor role in the overall diet. Although FSIS does not agree with those commenters who stated that gift packs should be exempt from nutrition labeling, this final rule provides that nutrition information for gift packs may be shown at a location other than on the gift pack label, unless a nutrition claim is made on the labeling of such products. For example, nutrition information may be provided on a package insert.

3. *Voluntary Nutrition Labeling.* FSIS proposed to permit voluntary nutrition labeling on single-ingredient, raw meat and poultry products, including those that have been previously frozen. Products such as ground beef, chicken breasts, and whole turkeys would be in the voluntary program. Under the proposed rule, manufacturers electing to provide nutrition information on the label of these products would be subject to all requirements of the mandatory nutrition labeling program, except that nutrition labeling for the voluntary program could be declared on the basis of "as consumed" or "as packaged", rather than required to be declared on an "as packaged" basis as is the case for products under the mandatory nutrition labeling program.

Several commenters requested clarification of whether single-ingredient, raw kosher meat and poultry products would be included in the voluntary program. These products are considered to fall within the definition of single-ingredient, raw products, and, thus, are included in the voluntary program. Commenters tended to support a voluntary program similar to FDA's voluntary program for raw fruit, raw vegetables, and raw fish. After reviewing the various comments received, FSIS believes that a voluntary nutrition labeling program for single-ingredient, raw meat and poultry products is the best approach.

Commenters supported the Agency's proposal to incorporate point-of-purchase materials in the voluntary program. Examples of the use of point-of-purchase materials to display nutrition information may include large placards (e.g., wall posters, signs, and aisle hangings). The nutrition

information may be supplemented by videos, live demonstrations or other media. If a nutrition claim is made on point-of-purchase materials that are labeled under the FMIA and the PPIA, all of the requirements of the mandatory nutrition labeling program apply. However, if only nutrition information—and not a nutrition claim—is supplied on point-of-purchase materials: (a) The requirements of the mandatory nutrition labeling program, apply but the nutrition information may be supplied on "as packaged" or "as consumed" basis; (b) the listing of DRV's is voluntary; and (c) the point-of-purchase materials are not subject to any of the format requirements. FSIS will not require the listing of DRV's on point-of-purchase materials which do not make nutrition claims because there will be limited space in grocery stores and supermarkets to display such nutrition information. Also, the Agency does not believe there is one most effective format for the presentation of nutrition information in point-of-purchase materials. Currently point-of-purchase nutrition information materials have many different formats. The Agency is not aware of any studies that show one format to be more effective than another.

FSIS proposed to survey food retailers on actions taken to provide consumers with nutrition information on products described in the voluntary program. FSIS will survey for "significant participation" rather than follow FDA's review of "substantial compliance" of the voluntary guidelines. Because FSIS does not have a statutory mandate as provided to FDA under the NLEA, FSIS proposed different terminology to refer to its review of the voluntary program. FSIS will follow FDA's planned 2-year evaluation cycle of the voluntary program, and will issue its first report of survey findings on the voluntary program by May 1995. FSIS initially proposed to implement both the voluntary and the mandatory nutrition labeling programs in May of 1993. However, FSIS has delayed the effective date of the nutrition labeling programs until 18 months from publication of this final rule. Therefore, FSIS will not begin surveying for significant participation until the effective date of this final rule. FSIS will reevaluate for significant participation every 2 years thereafter. If the Agency determines, during any evaluation of its voluntary guidelines, that significant participation does not exist, the Agency will initiate proposed rulemaking to determine whether it would be beneficial to require nutrition labeling on single-ingredient, raw meat and poultry products. The guidelines will remain in effect, however, as long as significant participation exists.

Individual stores selected for evaluation of the guidelines will be found to be participating at a significant level if (1) the store provides nutrition labeling information for at least 90 percent of the major cuts of single-ingredient, raw meat and poultry products that it sells, such as those listed in Table 1, including those that have been previously frozen; and (2) nutrition labeling information is in accordance with the guidelines described in the regulations.

FSIS will use a representative sample of stores to obtain the information necessary to assess participation. The distribution of the sample of stores shall cover all chain companies and a representative sample of independent companies. FSIS further proposed that significant participation by food retailers exists if at least 60 percent of the companies that are evaluated are participating in accordance with the guidelines.

There were few comments addressing the proposal for measuring significant participation. Several commenters supported the Agency's proposal, while those that disagreed with the proposal did not support measuring for significant participation. Two consumer groups that disagreed with the proposal expressed a different viewpoint, i.e., the Agency should require a higher percentage of participation than the proposed 60 percent.

FSIS believes it is important to provide nutrition information to consumers and, to the extent possible, harmonize with FDA's voluntary program for raw fruit, raw vegetables, and raw fish. To meet the 60 percent criterion, over half of the covered stores will provide nutrition information. In addition, FSIS believes that, by allowing for the use of point-of-purchase materials, retailers will be able to provide consumers with the necessary nutrition information. Therefore, FSIS is adopting the proposed standard for significant participation.

The FSIS proposal identified 45 major cuts of meat and poultry that would be used to measure significant participation in the voluntary program and requested comments on the list. Very few commenters addressed this issue. However, those that commented generally supported the proposed list. One commenter that generally disagreed with the proposed list suggested that the list omitted several of the more popular, fattier cuts and included leaner, less popular cuts of meats. FSIS attempted to identify representative cuts based on USDA nutritional studies, Poultry Nutri-Facts and Meat Nutri-Facts programs. The list in no way restricts retailers from providing additional nutrition information on other cuts of meat and poultry. FSIS encourages retailers to provide nutrition information on other cuts of meat and poultry to meet changing consumer needs.

One company requested that necks and giblets be excluded from the whole bird nutrient profile listing, stating that consumers frequently do not prepare these items nor do they consume them as part of the bird. In addition, it was requested that, at the manufacturer's option, the whole bird nutrient profile for turkeys be listed as white and dark meat.

Manufacturers currently label turkeys with two nutrient panels—one for white meat and one for dark meat. FSIS believes it is reasonable to exclude the necks and giblets from the whole bird when listing the nutrient profile. FSIS will permit manufacturers to continue the option of labeling turkeys with two panels. These minor revisions are reflected in Table 1 and in the final rule.

TABLE 1.—MAJOR CUTS OF MEAT AND POULTRY

1. Whole Chicken [1]
2. Chicken Breast
3. Chicken Wing
4. Chicken Drumstick
5. Chicken Thigh
6. Whole Turkey [2]
7. Turkey Breast
8. Turkey Wing
9. Turkey Drumstick
10. Turkey Thigh
11. Beef Chuck Blade Roast
12. Beef Loin Top Loin Steak
13. Beef Rib Roast Large End
14. Beef Round Eye Round Steak
15. Beef Round Top Round Steak
16. Beef Round Tip Roast
17. Beef Chuck Arm Pot Roast
18. Beef Loin Sirloin Steak
19. Beef Round Bottom Round Steak
20. Beef Brisket (Whole, Flat Half, or Point Half)
21. Beef Rib Steak Small End
22. Beef Loin Tenderloin Steak
23. Ground Beef Regular, w/o added seasoning
24. Ground Beef Extra Lean, w/o added seasoning
25. Pork Loin Chop
26. Pork Loin Country Style Ribs
27. Pork Loin Top Loin Chop Boneless
28. Pork Loin Rib Chop
29. Pork Spareribs
30. Pork Loin Tenderloin
31. Pork Loin Sirloin Roast
32. Pork Shoulder Blade Steak
33. Pork Loin Top Roast Boneless
34. Ground Pork
35. Lamb Shank
36. Lamb Shoulder Arm Chop
37. Lamb Shoulder Blade Chop
38. Lamb Rib Roast
39. Lamb Loin Chop
40. Lamb Leg (Whole, Sirloin Half, or Shank Half)
41. Veal Shoulder Arm Steak
42. Veal Shoulder Blade Steak
43 Veal Rib Roast

TABLE 1.—MAJOR CUTS OF MEAT AND POULTRY—Continued

44 Veal Loin Chop
45. Veal Cutlets

[1] Without neck and giblets.
[2] Without neck and giblets. Separate nutrient panels for white and dark meat permitted as an option.

III. Nutrition Label Content

The NLEA mandates that the amount of the following food constituents be included on the labeling of nonexempted food products: Calories derived from any source, calories derived from the total fat, total fat, saturated fat, cholesterol, total carbohydrate, complex carbohydrates, sugars, dietary fiber, protein, and sodium. Also required to be included is any mineral, vitamin, or other nutrient required to be placed on the label or labeling before October 1, 1990, if the Secretary of Health and Human Services (HHS) determines that such information will assist consumers in maintaining healthy dietary practices. The NLEA allows FDA, by regulation, to add other nutrients to the list of nutrients that should be included on the labeling of foods subject to the NLEA, if this will help consumers to maintain healthy dietary practices. It allows FDA, by regulation, to remove nutrients required to be listed, if the Secretary of HHS determines that the information relating to the nutrient is not necessary to assist consumers in maintaining healthy dietary practices. The NLEA specifies that a simplified nutrition label format is to be used when a food contains insignificant amounts of more than one-half of the nutrients required to be listed.

In its November 1991 proposal, FSIS proposed to establish a list of 15 required nutrients which are: Calories, calories from total fat, total fat, saturated fat, cholesterol, total carbohydrate, complex carbohydrate, sugars, dietary fiber, protein, sodium, vitamin A, vitamin C, calcium, and iron. In addition, FSIS proposed to adopt FDA's proposed list of nutrients as mandatory or voluntary components of nutrition labeling, definition of nutrients, definition of insignificant amounts, and increments for declaring nutrients, in the interest of harmonizing with FDA. FSIS and FDA received numerous comments on these issues. Both agencies reviewed and discussed all comments, and after consideration, based their decisions regarding the list of nutrients on the agencies' discussion of comments. The following discussion addresses comments received concerning various nutrients.

1. *Saturated fat.* In the proposal, FSIS defined saturated fat as the sum of lauric (C12), myristic (C14), palmitic (C16), and stearic (C18) acids. FSIS requested comments on the inclusion of stearic acid in the definition of saturated fat.

Most of the comments received on the definition of saturated fat supported excluding stearic acid, stating that the proposed definition would be detrimental to red meat products and would serve no health benefit to consumers. A manufacturer supporting the inclusion of stearic acid in the definition of saturated fat stated that it has not been confirmed that stearic acid lowers serum cholesterol.

FDA also received a number of comments concerning the definition of saturated fat. There is substantial evidence that diets low in saturated fatty acids are associated with decreased levels of blood cholesterol, reduced risks of coronary heart disease and atherosclerotic disease and may help to lower total fat intake, which may be associated with risks of cancer and obesity. For these reasons, FSIS and FDA agreed with the comments supporting the definition of saturated fat as the sum of all fatty acids, including stearic acid, without double bonds. Although the definition for saturated fat includes stearic acid, a near consensus has been reached that stearic acid does not have the same serum cholesterol-raising effect as the three other saturated fatty acids—myristic, palmitic, and lauric acids. To provide consumers with factual information concerning saturated fats that do not have a cholesterol-raising effect, FSIS is allowing for the voluntary declaration of stearic acid as a subcomponent of saturated fat.

2. *Dietary fiber.* Food manufacturers and trade associations strongly objected to requiring the declaration of dietary fiber content. These commenters contended that, because meat and poultry products are generally not meaningful sources of dietary fiber, disclosure would be of limited value to consumers.

While whole muscle cuts may contain no dietary fiber, FSIS believes that some breaded and meal-type products may contain substantial amounts of dietary fiber. FSIS is requiring the declaration of total dietary fiber content, based on the well documented role of dietary fiber in maintaining normal bowel function. Different physiological effects are associated with soluble and insoluble dietary fibers, and consumers have expressed an interest in knowing these types of fibers in foods. However, no quantitative guidelines for daily intakes of soluble and insoluble fiber components have been provided. Therefore, FSIS is permitting the voluntary declaration of insoluble and soluble fiber components unless a nutrient content claim on fiber is made.

3. *Total carbohydrate.* FSIS proposed to define total carbohydrate to exclude dietary fiber. Because dietary fiber includes components of carbohydrate that cannot be digested by humans, the proposed definition of total carbohydrate did not include the components of carbohydrate that generally do not contribute calories to the diet. One comment stated that there was no justification for excluding dietary fiber from total carbohydrate values.

Based on comments, FSIS and FDA concluded that excluding dietary fiber from carbohydrate is inconsistent with established methods of reporting food composition, confuses the issue of calculating energy content, and will decrease consumer understanding of label information. Therefore, dietary fiber is included in the definition of total carbohydrate.

4. *Complex carbohydrate and sugars.* Food manufacturers and trade associations opposed the mandatory listing of complex carbohydrate and sugars (including sugar alcohols) on the label. These commenters stated that in most meat and poultry products, complex carbohydrate and sugars are present in small amounts or not at all.

In the interest of harmonization with FDA, FSIS is requiring the declaration of grams of sugars. Additionally, FSIS is limiting the definition of sugars to free mono- and disaccharides.

FSIS proposed that complex carbohydrate be defined as the sum of dextrins and starches. Thus, complex carbohydrate, as defined, includes those carbohydrate components that contain 10 or more saccharide units (exclusive of dietary fiber).

There was opposition to the proposed definition of complex carbohydrate. One manufacturer commented that excluding dietary fiber from the definition of complex carbohydrate has no scientific rationale, since dietary fiber is, by chemical composition, a complex carbohydrate. Several commenters were concerned that currently there is insufficient methodology for determining sugars and complex carbohydrates.

FSIS believes that the inclusion of dextrins and saccharide units of 10 or more within the definition of complex carbohydrate may inappropriately classify the relatively low molecular weight carbohydrates in some nutritive sweeteners as complex carbohydrate.

Additionally, from a compliance perspective, available and widely used laboratory methods provide for the analysis of carbohydrate in foods in a manner that may not be sufficiently specific for regulatory purposes.

Based on review of the comments submitted, FSIS concurs with FDA that it is more appropriate to replace the term "complex carbohydrate" with the term "other carbohydrate" which would be defined as the difference between total carbohydrate and the sum of dietary fiber and sugars, or if sugar alcohol is declared, the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol. In harmonization with FDA, FSIS is allowing for the declaration of other carbohydrate on a voluntary basis.

FSIS proposed to define "sugars," including sugar alcohol, as free mono- and oligosaccharides (and their derivatives) that contain four or fewer saccharide units. This definition includes tri- and tetrasaccharides. Most of the comments on this issue objected to the proposed definition of sugars, stating that sugars should be defined to include only mono- and disaccharides. One opposing commenter stated that the definition differed from that used by Canada, the Codex Alimentarius Commission and the European Economic Community. Two commenters suggested that including sugar alcohols in the definition of sugars is inappropriate because sugar alcohols do not have the nutritional and metabolic effects of sugars, such as glucose.

FSIS is aware that the proposed definition differs from that used by Canada, the Codex Alimentarius Commission, and the European Economic Community, all of which limit the definition of sugars to mono- and disaccharides. FSIS agrees that it is more appropriate to exclude sugar alcohols from the definition of sugars. FSIS is allowing, on a voluntary basis, the separate declaration of the number of grams of sugar alcohols or, alternatively, if only one sugar alcohol is present in the food, the name of the specific sugar alcohol. If sugar alcohols are present but not listed, they are included in other carbohydrates. Declaration of sugar alcohols is mandatory when claims are made relative to sugar alcohols or to sugars when sugar alcohols are present.

5. *Protein.* FSIS proposed to require that the label for any food contain the statement "not a significant source of protein" immediately adjacent to the protein content regardless of the actual amount of protein present if the food (a) intended for adults and children 4 or more years of age, has a protein quality value that is a protein digestibility-corrected amino acid score of less than 20 expressed as a percent, (b) intended for children greater than 1 but less than 4 years of age, has a protein digestibility-corrected amino acid score of less than 40 percent of casein, or (c) intended for infants, has a protein quality, as measured by protein efficiency ratio, of less than 40 percent of the reference standard (casein).

Based on comments received, FDA concluded that the amino acid pattern for children 1 to 4 years of age should be the same as the amino acid reference pattern for 2- to 5-year old children. FSIS agrees, and is removing casein as a reference standard for foods intended to be for children older than 1 year but younger than 4 years of age.

One commenter stated that it was important to harmonize with FDA on protein quality. Another company opposed use of the statement "not a significant source of protein" citing that there is no evidence of protein malnutrition in the United States.

The Agency is retaining this requirement because there is a need to protect the consumer, especially a young child, from inadequate nutrition from the use of poor quality protein.

FSIS proposed that declaration of protein content calculated as a percent of the recommended daily intake (RDI) be voluntary for foods intended for consumption by adults and children 4 or more years of age unless a protein claim is made for the food. However, the Agency also proposed that nutrition labeling on foods intended for infants and children less than 4 years of age contain a mandatory statement of protein content expressed as a percent of the RDI.

The label reference value for protein for adults and children 4 or more years of age has been established as a DRV rather than a RDI because the label reference value for protein for this age group is now being based on percent of calories. However, because FDA did not propose DRV's for infants, children less than 4 years of age, pregnant and lactating women, the protein label reference values for these groups remain as RDI's.

One commenter recommended that protein expressed as a percentage of RDI be voluntary for all foods unless a protein claim is made. Another commenter disagreed stating that the mandatory listing of protein as a percent of RDI would provide consumers with knowledge of when protein requirements are met and also exceeded.

Because current evidence suggests that the diet typically within the U.S. provides for an adequate intake of protein of sufficiently high biological quality, FSIS is allowing but not requiring the voluntary declaration of protein content calculated as a percent of the DRV for foods represented for consumption by adults and children 4 or more years of age unless a protein claim is made for the food. Furthermore, the Agency is requiring that nutrition labeling on foods represented for use by infants and children less than 4 years of age contain a mandatory statement of protein content expressed as a percent of the RDI.

6. *Vitamins and minerals.* Public concern for thiamin, riboflavin, and niacin has lessened considerably in the last 20 years. The Agency received only one comment stating that these vitamins should be required. Therefore, the Agency is making the declaration of thiamin, riboflavin and niacin voluntary, unless a claim is made for them.

7. *Nutrient components.* FSIS and FDA received numerous comments on a variety of issues concerning nutrient components. Both agencies have carefully reviewed and assessed the comments and discussed the merit of these comments. Accordingly, FDA has made changes in its final rule published elsewhere in this issue of the **Federal Register**. FSIS is adopting the agreed upon changes since both agencies are committed to providing consumers with the most consistent food labeling system possible. The following tables list the voluntary and mandatory nutrient components.

TABLE 2.—MANDATORY/VOLUNTARY NUTRIENTS

Nutrients	Mandatory (M), Voluntary (V)	Core nutrient	Units	Increments rounding	Insignificant amount	Definition	Other
Calories	M	X	Calories	5 cal <=50 cal 10 cal >50 cal	<5 cal		May be listed on label as kilojules (k) or (energy) in addition to calories.
Calories from fat	M		Calories	5 cal <=50 cal 10 cal > 50 cal	<5 cal		
Calories from sat fat.	V		Calories	5 cal <=50 cal 10 cal > 50 cal	<5 cal		
Total Fat	M	X	gm	Nearest .5 gram below 3 grams nearest gram above 3 grams.	<.5 gm	Total lipid fatty acids	
Saturated Fat	M		gm	Nearest .5 gram below 3 grams nearest gram above 3 grams.	<.5 gm	Sum of all fatty acids without double bonds.	
Stearic Acid	V		gm	Nearest .5 gram below 3 grams nearest gram above 3 grams.	<.5 gm		
Polyunsaturated fat and monounsaturated fat.	V		gm	Nearest .5 gram below 3 grams nearest gram above 3 grams.	<.5 gm		
Cholesterol	M		mg	Nearest .5 mg	<2 mg		2–5 mg may state "Less than 5 mg".
Sodium	M	X	mg	5 mg <=140 mg 10 mg>140 mg	<5 mg		
Potassium	V		mg	5 mg <=140 mg 10 mg >140 mg	5 mg		
Total Carbohydrate.	M	X	gm	Nearest gram	<1 gm	All carbohydrates including dietary fiber.	
Dietary Fiber	M		gm	Nearest gram	<1 gm	Sum of soluble and insoluble fiber.	
Soluble Fiber	V		gm	Nearest gram	<.5 gm		
Insoluble Fiber	V		gm	Nearest gram	<.5 gm		
Sugars	M		gm	Nearest gram	<.5 gm	Sum of all free mono and disaccharides.	
Sugar Alcohols	V		gm	Nearest gram	<.5 gm	Sum of all approved sugar alcohols.	
Other Carbohydrates.	V		gm	Nearest gram	<.5 gm	All carbohydrates except sugars, sugar alcohols (if not declared), and dietary fiber.	
Protein	M	X	gm	Nearest gm	<1 gm	Voluntarily state as % of RDI or DRV, becomes mandatory for foods for infants and children less than 4 years.	
Vitamin A	M		% RDI	Nearest 2% <=10% Nearest 5% > 10% <=50% Nearest 10% >50%	<2% RDI		
Vitamin C	M		% RDI	Nearest 2% <=10% Nearest 5% > 10% <=50% Nearest 10% >50%	<2% RDI		
Calcium	M		% RDI	Nearest 2% <=10% Nearest 5% > 10% <=50% Nearest 10% >50%	<2% RDI		
Iron	M		% RDI	Nearest 2% <=10% Nearest 5% > 10% <=50% Nearest 10% >50%	<2% RDI		

Note: All voluntary nutrients become mandatory if a claim is made regarding the nutrient or one of its subcomponents.

TABLE 3.— MANDATORY/VOLUNTARY RDI CHART

Nutrient	Mandatory (M), voluntary (V)	Unit of measurement	RDI
Vitamin A	M	International Units	5000
Vitamin C	M	Milligrams	60
Calcium	M	Gram	1.0
Iron	M	Milligrams	18
Vitamin D	V	International Units	400
Vitamin E	V	do	30
Thiamin	V	Milligrams	1.5
Riboflavin	V	do	1.7
Niacin	V	do	20
Vitamin B6	V	do	2.0

TABLE 3.— MANDATORY/VOLUNTARY RDI CHART—Continued

Nutrient	Mandatory (M), voluntary (V)	Unit of measurement	RDI
Folate	V	do	0.4
Vitamin B12	V	Micrograms	6.0
Biotin	V	Milligrams	0.3
Pantothenic Acid	V	do	10
Phosphorus	V	Gram	1.0
Magnesium	V	Milligrams	400
Zinc	V	do	15
Iodine	V	Micrograms	150
Copper	V	Milligrams	2.0

Notes:
- All voluntary nutrients are required if a claim is made regarding that nutrient.
- The declaration of all vitamins and minerals will be as a percent of the RDI.

IV. Nutrition Label Format

In its November 27, 1991, proposal, FSIS announced its intent to issue a separate proposed rule on format. At that time, FDA had initiated a pilot program to test alternative nutrition label formats. On July 20, 1992, FDA proposed to adopt a new nutrition label format. Its proposal was based on the findings of four consumer research studies, and other label research being conducted by industry. FDA described its intent in revising the current nutrition label so that the information included in the nutrition panel would enable consumers to understand its relative significance in the context of a total daily diet.

On August 28, 1992, FSIS issued a separate proposed rule adopting a standard format for use in presenting nutrition information on the labels of meat and poultry products. FSIS proposed to establish the CONTROL WITH DIETARY GUIDANCE or the CONTROL WITH RECOMMENDED DAILY INTAKE RANGE as the standard format. The Agency tentatively concluded that these formats would: (1) Enable consumers to select foods that fit into a healthier diet that meets their individual needs; (2) provide consumers with the most accurate information on which to base their dietary decisions; (3) promote and reinforce a nutrition education message that is familiar to consumers and well accepted by health professionals; and (4) allow the Agency flexibility to adapt to ever changing scientific findings without publishing new regulations. FSIS requested comments on whether the CONTROL WITH DIETARY GUIDANCE or the CONTROL WITH RECOMMENDED DAILY INTAKE RANGE format enables consumers to apply the nutrition information in the context of a total daily diet. FSIS also requested comments on certain label format elements, such as changes in terminology, graphic presentation, and highlighting.

To be consistent with FDA, FSIS proposed the use of an abbreviated format in its November 1991 proposal. The proposed abbreviated format was to be used if a meat or poultry product contained insignificant amounts of more than one-half of the nutrients required in the full nutrition label format. The term "insignificant amount" was proposed as meaning "that amount which may be rounded to zero in nutrition labeling."

Trade associations and food manufacturers expressed opposition to the requirements for use of an abbreviated format stating that virtually every meat and poultry product will have significant amounts of more than one-half of the required nutrients. Many commenters supported some type of shortened format for which meat and poultry products could qualify.

In the August 28, 1992, proposal on format, the Agency stated that it was unable to find meat or poultry products that would qualify for the proposed simplified format ("abbreviated" format was changed to "simplified" format). Therefore, FSIS did not propose FDA's simplified format. FSIS requested comments on a simplified format, with differing criteria for meat and poultry products. When any of the required nutrients, other than the core nutrients or food components, are present in insignificant amounts, FSIS proposed that they may be omitted from the tabular listing, provided that the following statement is included within the nutrition label: "Not a significant source of _____." The blank would be filled in with the appropriate nutrient or food component. In addition, at a minimum, the simplified format would include calories, total fat, total carbohydrate, protein, and sodium.

FSIS received 70 comments on the format proposal from trade associations (25), food manufacturers and distributors (22), consumers (5), colleges and universities (4), consumer advocacy organizations (3), foreign governments (2), professional organizations (2), a health promotion organization (1), and others (3).

Although there was some support for both the CONTROL WITH DIETARY GUIDANCE and the CONTROL WITH RECOMMENDED DAILY INTAKE RANGE formats, commenters thought, in general, that these formats needed testing prior to any consideration for adopting them. There was general agreement among those opposing FSIS's proposed formats that these formats do not meet the NLEA provision which requires that nutrition information be provided in a manner that is understandable and informative. (Although FSIS is not bound by the NLEA, as FDA is, nutrition labeling is a harmonization effort on the part of both agencies.)

Strong objections were voiced on the CONTROL WITH DIETARY GUIDANCE format, suggesting that the dietary guidance would be too general to be informative or would require too much label space. Further objections included: (1) Consumers would not have time to calculate the dietary guidance into meaningful information; (2) the dietary guidance offered no frame of reference; and (3) the order of ingredients should reflect the CONTROL format.

Those opposing the CONTROL WITH RECOMMENDED DAILY INTAKE RANGE format did not believe consumers would be able to apply the information to their individual needs. Many believed that nutrition education would be needed in order for consumers to understand this format, and that this format also utilizes too much label space.

Commenters opposed the CONTROL WITH DAILY GUIDE FOR MEN AND WOMEN format because they thought consumers would focus on one number for each nutrient and assume that this number would be right for them. This format was also criticized for not allowing space for other groups, such as children.

Many commenters voiced support for the CONTROL format. These

commenters cited simplicity, minimal label cutter, and consumer familiarity to support their viewpoint. Several companies commented that the CONTROL format should be required as a base, but allow the expansion of the CONTROL format to include recommended daily intake ranges and expanded dietary guidance on a voluntary basis.

There was some support for the CONTROL/DRV, PERCENT DV WITH DRV, and PERCENT DV WITHOUT DRV formats. Commenters contended that the DRV's represent an estimate of the daily needs for the average consumer or that DRV's provide consumers a framework based on the total daily diet.

No comments supported the ADJECTIVE, HIGHLIGHTING, and GROUPING formats.

Commenters repeatedly stressed that, whatever format is ultimately selected, it is critical for FSIS and FDA to adopt a uniform format. They believed that consistency in labeling format should be the main concern to achieve the ultimate goal of providing useful nutrition information to consumers for all foods.

FSIS and FDA have extensively reviewed and discussed all comments submitted, and have determined that the PERCENT DV WITH DRV format best meets the intent of the NLEA and serves the needs of consumers. The required elements of the nutrition label format include: the fourteen mandatory nutrients and their quantitative amounts, the percent of the daily value based on a 2,000 calorie diet, the DRV's for both a 2,000 calorie and a 2,500 calorie diet, and caloric conversion information. Both FSIS and FDA believe that establishing one uniform format for all foods is in the consumers' best interest. Accordingly, FSIS is adopting all of the mandatory and voluntary elements of the PERCENT DV WITH DRV format.

Commenters expressed strong support for the simplified format with differing criteria for meat and poultry products. Commenters agreed that the FSIS proposed simplified format was appropriate for meat and poultry products. Therefore, FSIS is adopting the simplified format as proposed.

V. U.S. Recommended Daily Allowances

In its November 1991 proposed rule, FSIS proposed to require that daily reference values (DRV's) become part of nutrition labeling. FSIS also proposed to adopt FDA's proposed format for the "daily value", as presented in the proposed 21 CFR 101.9(c)(12)(i).

The majority of commenters opposed the use of DRV's on the label because they believe that:

(1) DRV's are based on an extremely high calorie intake that is not a representative sample of the average population;

(2) DRV's would only serve to confuse consumers;

(3) DRV's do not have universal acceptance by health professionals, and are not in common usage by the scientific and academic communities;

(4) DRV's will not apply uniformly to all consumers due to variations in individual diets; and

(5) DRV's would clutter the food label.

Those commenters that supported the use of DRV's on the label believe that using DRV's gives consumers a gauge for the nutrient amounts on the label and aids consumers in understanding how individual foods fit into the total diet. Most of the supporters of the DRV concept believe that its use should be voluntary.

There were varying opinions among commenters regarding the Agency's proposal to head the list of vitamins and minerals with the single term "Daily Value." Some commenters were concerned that the term "Daily Value" could be interpreted as goals to be achieved rather than reference levels. Other commenters agreed with the FSIS proposal, while others said Daily Value intakes should be eliminated or postponed until they are better defined, justified by a consensus of the scientific community, and understood by industry and consumers. The terms "Percent of Daily Values" and "Reference Value" were suggested as alternatives to the proposed "Daily Value" term. Some commenters thought "Daily Value" should be voluntary and recommended that it be allowed as an additional column in the main nutritional panel.

The majority of the commenters opposed the adoption of the Recommended Daily Intakes (RDI's) and supported the continued use of the U.S. Recommended Daily Allowances (RDA's). Commenters opposed the adoption of RDI's because they believe RDI's would mislead and confuse consumers and understate or ignore the nutritional needs of many population groups. Some commenters suggested that the method used to derive the RDI's and DRV's undermines the usefulness and effective accuracy of the nutrition panel for most consumers. Another commenter believes that the 2,350 calories level would be misinterpreted by consumers as goals to achieve.

Those commenters supporting the continued use of U.S. RDA's believe that U.S. RDA's are currently accepted as the established and up-to-date reference standard for vitamins and minerals for healthy Americans. Also, there is a history of recognition and use of the U.S. RDA's by consumers.

Some commenters concurred with FSIS's decision to adopt FDA's RDI's and stated that the current U.S. RDA's are the appropriate standards to use in developing the RDI's. The commenters suggested that the age adjusted mean is a reasonable method for establishing the level for each nutrient and food component. Commenters also stated that the five sets of RDI's that FDA proposed should provide adequate standards for foods specifically designed for infants, children, and pregnant and lactating women.

Several commenters addressed the issue of updating RDI's and RDA's. The commenters pointed out that the current proposal makes no provision for incorporating a mechanism to update the RDI's at regular intervals as the population changes and as new evidence for recommended nutrient requirements (RDA's) changes. Another commenter supported updating of the U.S. RDA's to reflect the 10th edition of the RDA's.

Most of the commenters suggested that FSIS and FDA be consistent in the use of RDI's and DRV's.

FSIS will parallel FDA and adopt the format for the "Daily Value." "Daily Value" will be the means of placing the nutrition information on the label in the context of a total daily diet. As the FDA and FSIS have worked to standardize the nutritional labels under their respective jurisdictions, it remains in the interest of consumers that FSIS and FDA be consistent.

After extensive discussions over format, the Administration decided that the DRV's should be shown for both a 2,000 calorie diet and a 2,500 calorie diet. For the 2,000 caloric level the DRV's are: 65 g fat, 20 g saturated fat, 300 mg cholesterol, 2,400 mg sodium, 300 g total carbohydrate and 25 g fiber. For a 2,500 caloric level the DRV's are: 80 g fat, 25 g saturated fat, 300 mg cholesterol, 2,400 mg sodium, 375 g total carbohydrate and 30 g fiber.

VI. Serving Sizes

To make nutrition information on food labels meaningful, the NLEA requires FDA to establish standards to ensure that nutrition labeling provides the serving size which is an amount customarily consumed and is expressed in a common household measure appropriate to the food. NAS recommended that FDA and FSIS jointly establish sizes for limited, broad categories of foods to help consumers

make product comparisons. NAS suggested basing them on standard serving sizes as specified by dietary guidance recommendations to make their use in educational programs less difficult and to permit consistency among serving sizes shown in dietary guidance material and on the food label. NAS also advocated a petition process for desired deviations from the serving size set by FDA and FSIS or for creation of different food subcategories with new serving sizes.

In its November 1991 proposal, FSIS proposed the following regulations specific to serving sizes:

(1) Creating Reference Amounts for serving sizes for 23 food Product Categories;

(2) Establishing guidelines for converting Reference Amounts to serving sizes;

(3) Defining serving sizes for meal-type products and food products in pieces or units;

(4) Requiring presentation of nutrition information based on serving size "as packaged" for the mandatory labeling program and allow nutrition information for single-ingredient, raw meat and poultry products to be declared "as packaged" or "as consumed" under a voluntary nutrition labeling program;

(5) Requiring the use of both common household and metric measures to declare serving size;

(6) Defining serving size and single-serving container;

(7) Establishing guidelines for declaring the number of servings per container;

(8) Requiring the use of serving size and Reference Amounts to evaluate nutrition claims; and

(9) Allowing for labeling applications for changes in Product Categories and Reference Amounts.

1. *Reference Amounts for serving sizes for 23 food Product Categories.* a. Product Category. Through the work of the Interagency Committee on Serving Sizes, FSIS proposed to establish 23 food Product Categories for meat products, and 22 food Product Categories for poultry products regulated by FSIS. These Product Categories would provide consumers with a uniform food labeling system that categorizes similar foods by the same reference standard. Each Product Category has an accompanying Reference Amount which is based on food consumption data. These Reference Amounts are to be used by food companies as the basis for determining the serving sizes for nutrition labeling of their products.

Opposition to this approach came from manufacturers who contend that all products should have a 1-ounce or 100-gram standard Reference Amount. Although FSIS discussed this option in the proposed rule, it was not the option proposed because:

(a) The NLEA requires that the serving size be based on the "customarily consumed amount";

(b) Consumers may not realize that multiplication is necessary to arrive at the consumed amounts; and

(c) FSIS seeks harmonization with FDA to allow ready product comparisons.

There was strong support from a variety of industry representatives, industry associations, cattle associations, consumer advocacy groups, and individuals in favor of retaining the proposed approach to serving sizes. These commenters believe that a single, uniform set of nutrition labeling regulations for all foods will be in the consumers' best interest, easiest to understand, and prevent consumer confusion.

b. Three-ounce serving size. Several consumer advocacy groups contended that a 3-ounce serving size for single-ingredient, raw meat and poultry products is too small and the data used to determine the serving size were seriously flawed. They believed that the serving size should be determined using only 1977–78 Nationwide Food Consumption Survey (NFCS) data.

FSIS has decided to retain the 3-ounce serving size for single-ingredient, raw meat and poultry products. This is supported by many commenters who believe it is appropriate from an educational standpoint, and it is based on realistic data on food consumption. Food consumption survey data, such as NFCS, provide objective estimates of amounts of food customarily consumed. The NFCS is nationally representative of the most comprehensive data on food consumption practices of the U.S. population that are available to the Agency. Additionally, the 3-ounce serving size for fresh meat and poultry products is supported by dietary recommendations and the work of the Interagency Committee on Serving Sizes.

c. Weight-loss products. Many producers of weight-loss products, which are part of a weight loss program, have asked to be allowed to develop their own serving sizes based on their program. FSIS believes that the serving sizes for all foods available to the retail consumer should be based on the Reference Amount, including those intended for weight-control or weight-reduction. However, the Agency believes that it is in the best interest of participants of a weight-control program, which provides product only through the program, to have labeling which is consistent with the program meal plan. Therefore, the Agency will allow these programs to have serving sizes based on their meal plan. To avoid any confusion with retail products, manufacturers of product that will be used only through weight-control programs will be required to label their products "for sale only through the _____ program." The blank will be filled in with the appropriate weight control program (e. g., Smith's Weight Control).

d. Specific changes to Reference Amounts and Product Categories. Many manufacturers and industry representatives expressed confusion concerning which Reference Amount would apply to their product. Also, commenters had questions about the examples used for specific product categories. Manufacturers will decide the intended use of their product(s), which in turn will determine the appropriate Product Category and Reference Amount (e. g., ham that is intended for use in sandwiches would fit under the Product Category "Luncheon Meats" with a Reference Amount of 55 grams). Examples listed under Product Category are not all inclusive or exclusive, and are provided to assist manufacturers in identifying the appropriate Product Category for their products. FSIS believes this clarification will alleviate most concerns along with a few changes made to Product Category examples in this final rule.

Other comments focused on the lack of a specific Product Category and Reference Amount or a change in the proposed Reference Amount. Comments were received requesting a change in the Reference Amount but were not accompanied by food consumption data. Therefore, no change is being made to the Reference Amount. Comments asking for Product Category changes for specific markets or foods for specific eating occasions will not be granted at this time (e.g., toddler finger foods and breakfast burritos). Labeling applications requesting Product Category or Reference Amount changes will be accepted after the final regulation is published.

Several comments requested a range rather than a fixed Reference Amount. FSIS encourages manufacturers to use the optional second column of nutrition values based on either 100 grams, 100 milliliters, or 1 ounce.

Comments requested different Reference Amounts for products which

are sold at retail and food service products which are served at restaurants, schools, and other such facilities. FSIS believes consumers would be confused by two different Reference Amounts for the same product regardless of where it is sold.

Some comments requested Reference Amount changes based on the mode of the NFCS data. These requests are being denied because all Reference Amounts were calculated based on the mean and the median "consumed serving size" (CSS). The mode of the CSS was determined not to be useful as the sole criterion for determining the Reference Amount because most food groups had two or more modes, and there usually was no obvious or rational basis to choose one over the other. However, the mode did provide additional guidance in determining the Reference Amount. Therefore, FSIS used all three values (i.e., the mean, median, and the mode) in determining the amount customarily consumed.

e. Volume vs. weight. Some commenters stated that all Reference Amounts should be expressed in grams. Some of the specific Product Categories originally expressed in volume-based Reference Amounts have been changed to weight-based Reference Amounts. However, the Agency does not agree that it is appropriate or desirable to do so for all Product Categories, including some of those specifically mentioned in comments. As explained above, when products within a Product Category differ widely in density, the use of a fixed gram Reference Amount would result in a serving size that is too large for some products in the category and too small for others, even though the volume amounts consumed are similar for all products within the category. For example, although the Reference Amount for "mixed dishes measurable with a cup" is 1 cup, the gram-weights of different types of products within the category differ widely (e.g., about 180 grams for chili with beans and about 225 grams for beef stew). Thus, in this final rule, FSIS uses weight-based Reference Amounts in most cases but is retaining volume-based Reference Amounts for a limited number of categories with products that vary greatly in density (e. g., mixed dishes measurable with a cup).

f. Foods that are Packed or Canned in Liquid. Foods such as canned meats may be packed in water, brine, or oil, but food consumption data have shown that the liquid is not customarily consumed. FDA received comments requesting that foods packed or canned in liquid bear nutrition labeling based on the drained solids. FSIS agrees with the commenters that the label serving size most meaningful for these products would be the serving size based on drained solids. Therefore, FSIS will require that the declaration of nutrient and food components for foods that are packed or canned in water, brine, or oil be based on the drained solids.

g. Labeling applications. FSIS shall allow labeling applications to be submitted to amend the Reference Amount and/or Product Category through the rulemaking process. Any such labeling applications for changes to the Reference Amount and/or Product Category for meat and poultry products would be submitted to the Director, Food Labeling Division, FSIS, with specific information supporting such use. The supporting information includes statements that (1) identify the Reference Amount and/or Product Category; (2) explain why the Reference Amount and/or Product Category is not false or misleading; and (3) describe the product and the form the product will be used in. Such labeling application is required to be signed by the applicant or by the applicant's responsible officer or agent.

Upon receipt and review of the labeling application and supporting documentation, FSIS will notify the applicant, in writing, that the labeling application is either being considered for further review or that the labeling application has been denied by the Administrator. If the Administrator summarily denies the labeling application, he or she would notify the applicant, in writing, as to the reason(s) for the denial, including why the proposed Reference Amount and/or Product Category was determined by FSIS to be false or misleading, and would afford the applicant an opportunity to submit a written statement by way of answer to the notification, and a right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed Reference Amount and/or Product Category. If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator would file with the Hearing Clerk of the Department the notification, answer, and the request for hearing, which would constitute the complaint and answer in the proceeding, which would thereafter be conducted in accordance with the Department's Uniform Rules of Practice. The hearing would be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who is delegated the authority to make the final determination for the Secretary. Any such determination by the Secretary will be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

If the Administrator does not summarily deny the labeling application, he or she would publish in the **Federal Register** a proposed rule to amend the regulations to authorize the use of the Reference Amount and/or Product Category. The proposal would also summarize the labeling application, including where the supporting documentation could be reviewed. The Administrator's proposed rule would seek comments from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the proposed Reference Amount and/or Product Category. After public comment has been received and reviewed by the Agency, the Administrator will make a determination on whether the proposed Reference Amount and/or Product Category will be approved for use on the labeling. If the Reference Amount and/or Product Category is denied, the Agency would notify the applicant by letter of the basis for the denial, including the reason why the Reference Amount and/or Product Category was determined by the Administrator to be false or misleading. The applicant would have an opportunity to appeal this decision by instituting a proceeding which would be conducted under the same procedures specified above if a labeling application were summarily denied by the Administrator during the initial review. If the Reference Amount and/or Product Category is approved by the Administrator, the Agency would notify the applicant by letter and would also publish in the **Federal Register** a final rule regarding the approval of the Reference Amount and/or Product Category. The final rule would amend the regulations to authorize the use of the Reference Amount and/or Product Category in the labeling of meat and poultry products.

2. *Procedures for converting Reference Amounts to serving sizes.* As part of the Interagency Committee on Serving Sizes, FSIS fully participated in establishing the criteria for converting the Reference Amounts to serving sizes in common household measures. These procedures will help to assure

uniformity in the declared serving size within a Product Category and allow flexibility in the serving size to account for differing characteristics of diverse food products. The following are guidelines for converting Reference Amounts to Serving Sizes for: (a) Products in discrete individual units, (b) products in large discrete units that are usually divided for consumption, and (c) non-discrete bulk products.

a. Products in discrete individual units. FSIS proposed that serving sizes for products in discrete units be the number of units that most closely approximates the Reference Amount applicable to the product. Under this provision, if a unit weighs 67 percent or more, but less than 200 percent of the Reference Amount, serving size shall be one unit. If a unit weighs 200 percent or more of the Reference Amount, the manufacturer may declare the whole unit as one serving if the whole unit can reasonably be consumed at a single-eating occasion.

Several commenters opposed the lower limit of the proposal because a single-serve unit of many products in discrete units fall in the 50–67 percent range and one unit is customarily consumed. FSIS has decided to change the lower limit to >50 percent of the Recommended Amount Customarily Consumed (RACC). Products which are exactly 50 percent of the RACC will not be included because 50 percent is exactly half of the RACC. Therefore, two units of a product weighing 50 percent of the RACC per unit is exactly one serving.

Commenters also recommended that FSIS allow voluntary listing of nutrient contents per unit for products that come in discrete units (e.g., chicken nugget, chicken wing, cocktail frank), when the declared serving size of a multi-serving package is more than one unit. FSIS believes this would be beneficial for consumers, because many products in discrete units come in small units and consumers who consume one single unit would benefit from per-unit labeling.

b. Products in large discrete units that are usually divided for consumption. The proposal would require that the serving size for products in large discrete units (e.g., pizza) be the fractional slice of the food that most closely approximates the RACC. Commenters pointed out that the serving size may be 1/7 of the product. However, the product cannot be easily cut into 7 even slices; it can only be cut into fractions of multiples of 2 or 3. Therefore, FSIS will allow manufacturers to use 1/2, 1/3, 1/4, 1/5, 1/6, or higher fractions of multiples of 2 or 3. This does not include 1/28 because it involves a division by 7.

3. *Serving sizes for meal-type products.* In the proposed rule, FSIS defined meal-type products as any product that is intended for consumption by one person. There was strong support from commenters for nutrition labeling of meal-type products in their entirety. Because meal-type products are typically consumed by one person and make up the major portion of a meal, it is more meaningful to provide consumers with nutrition information on these products in terms of the entire product. A consumer will have nutrition information on exactly what he or she purchases and typically consumes. Therefore, the consumer will be able to evaluate how the product fits into his or her total diet.

FSIS will require nutrition labeling for meal-type products, based on the contents of the entire package. Meal-type products must also meet the definition of a single serving container. FSIS addresses the definitions of meal-type products elsewhere in this final rule with a provision for the use of nutrient content claims with meal-type products.

4. *Nutrition information based on serving size "as packaged" vs. "as consumed".* To maintain consistency with FDA's mandatory and voluntary nutrition labeling scheme, FSIS proposed to require nutrient values "as packaged" for products under the mandatory program with an option of also presenting "as consumed" values. Products under the voluntary program may list nutrient values on an "as consumed" or an "as packaged" basis. The preparation method used for the "as consumed" values must be clearly indicated on the package.

The Agency proposed that the RACC for products which require further preparation before consumption be the amount required to make one RACC of the prepared form. Commenters stated that they are unable to identify raw product serving sizes to produce the cooked RACC.

Therefore, FSIS has developed yields for Product Categories which contain products that require further preparation (e.g., bacon, raw meat and poultry cuts). These yields are based on yields used in the Nationwide Food Consumption Surveys (NFCS) and USDA Handbook #8. These yields will appear as an additional column in the RACC tables found in §§ 317.312(b) and 381.412(b). These yields will only be used for the determination of Reference Amounts.

Some commenters opposed the labeling of fresh or raw, ready-to-cook food products on an "as packaged" basis. They believe the labeling on an "as consumed" basis would allow consumers to directly compare ready-to-cook and ready-to-serve or heat-and-serve products. However, this would only be the case if the consumer prepared the fresh or raw, ready-to-cook product exactly as the manufacturer stated on the label. There are varieties of cooking methods that affect the nutrient values of food products differently. Therefore, there is no method to assure the accuracy or measure compliance of the nutrient values of a food labeled on an "as consumed" basis.

Several commenters stated that special case products (e.g., bacon, breakfast sausage, and raw marinated meat or poultry products) undergo extreme composition changes prior to consumption. If labeled "as packaged", these products would provide the consumer with essentially useless information. FSIS strongly encourages manufacturers who believe the consumer would benefit from "as consumed" nutrition values to voluntarily provide this information. Manufacturers of special case products who believe their products should be labeled on an "as consumed" basis and not "as packaged" should submit a labeling application to the Agency.

FSIS believes that the addition of another column to the Reference Amount table based on NFCS yields and USDA Handbook #8 will provide the additional information needed by manufacturers to determine Reference Amounts for their products. Also, FSIS believes that "as consumed" nutrient values must be accompanied by preparation and cooking instructions. To retain harmonization of labeling between the FSIS and FDA, FSIS will require "as packaged" nutrient values for products covered under the mandatory program. "As consumed" nutrient values may voluntarily be added, provided that preparation and cooking instructions are clearly stated. Products covered by the voluntary program may list nutrient values either on an "as packaged" or "as consumed" basis.

5. *Units of measure for declaring the serving size.* FSIS proposed to require the use of common household and metric measures to declare serving sizes. In addition, FSIS proposed that serving sizes may be declared in ounces and fluid ounces (U.S. measure), in parenthesis, following the metric measure where other common household measures are used as the primary unit for serving size (e.g., 1 cup (28 g) (1 oz)). FSIS also proposed rules

for expressing serving size in common household measures. These rules are intended to ensure as much uniformity as possible in label serving sizes within a Product Category. The rules are as follows:

a. Whenever possible, cups, tablespoons or teaspoons should be used. Cups should be expressed in ¼ cup increments; tablespoons in whole numbers for quantities less than ¼ cup but equal to or greater than 1 tablespoon; teaspoons in whole numbers for quantities less than 1 tablespoon but equal to or greater than 1 teaspoon; and in ¼ teaspoon increments for quantities less than 1 teaspoon.

b. If cups, tablespoons or teaspoons are not applicable, units such as piece, slice, tray, jar, and fraction of the whole piece or package should be used. These units are the common household measures that are most appropriate for food products not measurable by a cup, tablespoon, or teaspoon.

c. If neither of the above is applicable, ounces may be used. Ounce measurements should be expressed in 0.5 ounce increments most closely approximating the Reference Amount.

Several commenters stated that they believe that some foods would be more precisely measured in ⅓ cup increments and would like this option added to the final rule. FSIS believes this is an acceptable change. Parenthetical metric measure is required and has been standardized; therefore, uniformity in the common household measure is not as critical. In addition, allowing ⅓ cup increments is likely to reduce potential manipulation of the label serving size for measurements that fall between ¼ and ½ cup (e.g., ¼, ⅓, ½, ⅔, ¾, and 1).

Several commenters stated that when declaring serving size, the U.S. measure should be mandatory, in addition to, or instead of the metric measure. Other commenters objected to voluntary declaration of the U.S. measure in addition to the common household measure, arguing that it was unnecessary, would crowd the label, and would be confusing to consumers. Because the comments indicated such varied views on the listing of the U.S. measure, FSIS has decided to make the listing of the equivalent U.S. measure after the metric measure voluntary.

Several comments opposed requiring the rounding of the ounce unit of measure to the nearest 0.5 ounce. They expressed that the ounce measurement should be rounded to the nearest 0.1 ounce increment. Listing ounce measure in 0.5 ounce increment would result in a large discrepancy between metric measure. Since listing gram quantities will be mandatory, commenters believe that more exact declaration of ounce measures should be used.

FSIS will require 0.5 ounce increments to be used when the primary serving size (household measure) is expressed in ounces [e.g., beef fillet 3 oz. (85 g)], to be meaningful to consumers. This does not apply to the voluntary ounce serving size (U.S. measure) declarations [e.g., chicken wing, 2 wings (80 g) (about 2.8 ounces)]. The ounce measure in this case can be a decimal quantity rounded to 0.1 increments. FSIS believes that the more exact ounce measures are justified because they will reduce the error in gram-to-ounce conversions and reduce consumer confusion.

Commenters opposed the requirement that products whose common household measure is an ounce must also bear an appropriate visual representation of the serving size. They contended that the ounce is a unit of measure that is well understood by the public and that the visual representation requirement will only serve to confuse the consumer; therefore, no artificial comparisons need be made. FSIS believes that a visual representation requirement is unnecessary and may be confusing to consumers. Therefore, FSIS will no longer require a visual representation of serving size for products whose common household measurement is in ounces.

Commenters expressed concern that the use of several parentheses within the serving size statement (e.g., 2 slices (28 g) (1 oz)) would make the statement more difficult to understand. The commenters recommended that FSIS allow flexibility to use commas and slashes. FSIS believes that allowing such flexibility would result in non-uniformity in the declaration of label serving sizes. For example, the serving size for sliced luncheon meat could be expressed five different ways: 2 slices (28 g) (1 oz) by brand A; 2 slices (28 g, 1 oz) by brand B; 2 slices (28 g / 1 oz) by brand C; 2 slices, 28 g, 1 oz by brand D; and 2 slices 28 g / 1 oz by brand F. The use of various formats for this declaration would be confusing.

After examining all possible combinations of the formats for the declaration of label serving size, FSIS finds that the most desirable format is to require the presentation of all serving size information other than the mandatory common household measure, in one set of parenthesis with the different serving size statements separated by a slash (i.e., 2 slices (28 g / 1 oz)).

FSIS also proposed to allow an additional column of figures to be declared on the nutrition label based on 100 grams, 100 milliliters, or 1 ounce of the food as packaged or purchased. Commenters were opposed to limiting the optional second column to 100 grams or 100 milliliters. Manufacturers believe they should be able to determine the unit of measure used in the optional second column. They believe that they are in the best position to determine which unit will best serve their consumers.

The purpose of the optional second column is to provide consumers with another means of comparing products. The advantage would be lost if each manufacturer listed its own unit of measure on the label. Therefore, FSIS will limit the optional second column to 100 grams, 100 milliliters, or 1 ounce.

6. *Definition of serving size and single-serving container.* The FSIS proposed definition for a serving or serving size was "an amount of food customarily consumed per eating occasion by persons 4 years of age or older, which is expressed in a common household measure that is appropriate to the food." If the article were represented to be for infants or for toddlers, the proposed definition of a serving or serving size was "an amount of food customarily consumed per eating occasion by infants through 12 months of age or by children 1 through 3 years of age."

FSIS proposed to define a single-serving container as a container or package containing less than 200 percent of the Reference Amount. The nutrition profile on the single-serving container will be declared on the total content of the container. Some comments stated that the upper limit on single-serving containers should be rolled back to 150 percent of the RACC because the 200 percent cut off level is too high for some products (e.g., entrees, mixed dishes not measurable with a cup, salads, soups). Other comments suggested allowing the manufacturer to decide the single-serving status of a package that contains between 150 percent and 200 percent of the RACC.

FSIS has found that products whose Reference Amounts are 100 grams or larger are less likely to be consumed at a level twice that of the Reference Amount. Therefore, FSIS will allow manufacturers to determine whether there are 1 or 2 servings in packages that contain more than 150 percent, but less than 200 percent of the Reference Amount, if the food in the package has a Reference Amount of 100 grams (or milliliters) or larger, and if the entire content of the package can reasonably

be consumed at a single-eating occasion. The determination should be based on food consumption data under actual conditions of use. Manufacturers should be prepared to provide FSIS with the data that supports the single-serving claim upon request. The Agency is aware that this allowance has a potential for misuse and products that are obviously intended to be consumed in one serving must be labeled as such or they would be considered misleading. The Agency intends to consider regulatory action for misuse of this allowance on single-serving containers.

An industry comment stated that the parenthetical listing of the equivalent metric weight of the serving size is unnecessary on single-serving containers when the net quantity of contents includes the metric weight and is provided on the principal display panel.

FSIS agrees with this comment. However, for some products the metric quantity for serving size and the metric quantity for net weight may differ. For example, the serving size for products packed or canned in liquid that is customarily consumed (e.g., canned meat or poultry), where the serving size is expressed on the drained weight. Therefore, FSIS believes it is reasonable to exempt single-serving containers from the parenthetical metric measure requirement, if the metric quantity for net weight and serving size are the same.

7. *Declaration of number of servings her container.* FSIS proposed that the number of servings per package or container be declared to the nearest whole or approximate whole number. Several comments opposed requiring a whole number and requested that the number of servings per container be rounded to the nearest 0.5 servings.

Commenters stated that rounding to the nearest whole serving would significantly distort a container's contents, especially for packages containing between 1.5 and 4.5 servings. Industry commenters agree that many consumers do not like to see a fractional number of servings in the nutrition information. However, they believe, and the Agency agrees, that the basis for this dislike is from the use of decimal fractions (e.g., 2.7 servings) and a decimal fraction number of servings on containers that are obviously single-serving containers. Commenters believe that rounding to the nearest 0.5 servings will be understood by all consumers.

FSIS believes that this is an acceptable change. FSIS does not believe that a half serving is necessary or meaningful for large containers (e.g., 8.5 servings) or is desirable on small packages containing less than 200 percent of the Reference Amount. Therefore, manufacturers will be allowed to round to the nearest 0.5 serving for packages containing between 2 and 5 servings. Products containing less than 200 percent of the Reference Amount must follow the rules for single-serving containers. Products containing 5 servings or more per container will be rounded to the nearest whole serving.

Additionally, the proposed rule provided two options for declaring number of servings per container: (a) Declare serving size as the approximate whole household measure that results in a whole number of servings in the container (e.g., serving size: approximately ½ cup; number of servings per container: (10) or (b) declare serving size in exact household measure and approximate the number of servings per container (e.g., serving size: ½ cup; number of servings per container: approximately 10) (see 21 CFR 101.9(b) (8) (i) and (ii)).

Several comments opposed the two options in the proposal. They recommended that manufacturers list the exact serving size and approximate number of servings per container. They believe it is more important for the consumer to know the exact serving size, which is the basis for the nutrition information.

FSIS recognizes that allowing the two options as proposed would result in nonuniformity, and would make nutrition comparisons of different brands of the same food difficult. Therefore, FSIS will require the exact serving size and the approximate number of servings.

The proposed rule made an exception for random weight products from the requirement for number of servings per container. For random weight products such as kielbasa, manufacturers would have problems in declaring the number of servings per package. FSIS proposed to accommodate random weight packages by allowing manufacturers to declare the number of servings per container as "varied", provided the nutrition information was based on the Reference Amount expressed in ounces.

The comments supported the option of listing the servings per container of random weight packages as "varied," but also suggested allowing an optional statement describing the typical number of servings per base weight unit when "varied" is used to declare the number of servings per container (e.g., varied (approximately 8 servings per pound)). FSIS believes this is a reasonable option that will provide further clarification for consumers.

VII. Nutrient Content Claims

To alleviate widespread public confusion associated with descriptors, the NLEA contains requirements regarding nutrient content claims. It precludes, except for specified limited exceptions, the use of any nutrient content term that characterizes the level of any nutrient that has not been defined by FDA by regulation, and requires FDA to define "free," "low," "light" or "lite," "reduced," "less," and "high." The NLEA places limitations on cholesterol, saturated fat, and dietary fiber claims for a food by requiring these claims to be accompanied by prominent disclosure of the food's level of fat or saturated fat, cholesterol, and total fat, respectively, on the label. The NLEA does not address the use of cholesterol claims based on threshold criteria for fat or saturated fat content.

The Food Labeling Division of FSIS has issued several policy memoranda in connection with its label approval system, outlining quantitative criteria for permitting the use of selected descriptors such as "low calorie," "low sodium," "low fat," and "lean." (Copies of these policy memoranda are available for public review in the FSIS Hearing Clerk's office.) For many years, the Agency's definition for "lean", except as applied to ground beef, hamburger, and products containing added substances, such as water or extenders, has been no more than 10 percent fat content. The memoranda currently require at least a 25 percent reduction from specific reference points for comparative expressions such as "lower." FSIS also uses informal working policies for nutrient content claims for some food constituents, such as cholesterol in meals and fiber. FSIS has no current regulatory definitions for any nutrient content claims.

FSIS proposed the adoption of most of FDA's proposals, published in the **Federal Register** simultaneously with FSIS's proposed rule, for 21 CFR 101.13, Nutrient Content Claims—General Principles; 21 CFR 101.54, Nutrient Content Claims for "Source" and "High"; 21 CFR 101.56, Nutrient Content Claims for "Light" or "Lite"; 21 CFR 101.60, Nutrient Content Claims for the Calorie Content; 21 CFR 101.62, Nutrient Content Claims for the Fat, Fatty Acids, and Cholesterol Content of Foods; and 21 CFR 101.69, Petitions for Nutrient Content Claims. In addition, FSIS proposed definitions for the terms "lean" and "extra lean" as unique descriptors for meat and poultry products. In the above documents, FDA

set forth proposals required by the NLEA. The FSIS proposals were an effort to harmonize food labeling regulations with FDA's and were in response to the comments received from FSIS's ANPR on nutrition labeling.

FSIS's proposal specifically included a discussion on the use of descriptive terms in brand names, since many products regulated by FSIS contain descriptive terms in the brand name ("brand name" is a generic term used to define a fanciful name, trademark, etc.). The proposal provided for the use of a descriptive term in a brand name, provided the product met the prescribed definition for the term. The proposal stated that nutrient content claims not defined by regulation that appeared as part of a brand name, could be used if they were not false or misleading, and only if the brand name was in use prior to November 27, 1991, the date of the proposal. A list of brand names that included descriptive terms was compiled from labels on file with the Food Labeling Division, and included to provide specific examples of some of the products that may be affected by the proposals.

FSIS proposed definitions for "lean" and "extra lean" based on fat, saturated fatty acids, and cholesterol thresholds suggested by the American Heart Association (AHA) in response to the ANPR. FSIS found merit in AHA's suggested values, and proposed the quantitative values per 100 grams of product by extrapolating the 1 ounce values AHA suggested, yielding the following values:

TABLE 4

	Fat	Saturated fatty acids	Cholesterol
Lean	<10.5 g	<3.5 g	<94.5 mg
Extra Lean	<4.9 g	<1.8 g	<94.5 mg

These values for the fat content of 10.5 and 4.9 grams approximated the Agency's current definitions for the terms "lean" and "extra lean."

FSIS proposed the values for "lean" and "extra lean" as descriptors for use in all meat and poultry products. Accordingly, the terms could be used on multi-ingredient, meal-type products as well as muscle cuts of meat, ground beef, and hamburger. Currently, FSIS extends special exception to ground beef and hamburger for the purposes of "lean" and "extra lean" labeling. "Lean" and "extra lean" ground beef and hamburger can contain up to 22.5 percent fat, a 25 percent reduction from the regulatory standard of 30 percent fat for these products.

Specifically mentioned in the proposal were the "_____ percent fat free" claims. FDA proposed to prohibit the claim in those circumstances in which it would be misleading. The FDA criteria was for the product to meet the definition for "low fat" and for the label or labeling to disclose the amount of total fat per serving of the product. The Agency reviewed FDA's proposal on this issue and fully agreed with FDA, and therefore proposed the same criteria for meat and poultry products.

There was overwhelming support in response to the proposal for FSIS to proceed with the adoption of FDA defined nutrient content claims (the term "nutrient content claim" is replacing "descriptor" for consistency with FDA). The majority of parties commenting on the FSIS proposal have primary interest in the products regulated by the Agency. Therefore, the majority of comments relating to nutrient content claims focused directly on the areas of the proposal that were unique to FSIS, namely the terms "lean" and "extra lean."

Trade associations, industry, and consumer groups supported the Agency's proposal to provide the unique descriptors "lean" and "extra lean." Several trade associations and manufacturers disputed the total fat and saturated fatty acids numbers as extrapolated to 100 grams, arguing that inherent to ruminant muscle, the saturated fatty acids to fat ratio is 40 percent.

Trade associations and manufacturers believe that the AHA values presented per 3 ounces cooked represented attainable values for meat. Many commenters suggested that including a saturated fatty acid criterion in the definition of "lean" and "extra lean" was too restrictive.

Trade associations believe that AHA, in its original presentation of "lean" and "extra lean" to the industries it represents, did not intend to discriminate against the inherent saturated fatty acid content of ruminant muscle.

TABLE 5 is a review of AHA's quantitative values, showing the saturated fatty acids to fat ratio:

TABLE 5

	Fat	Saturated fatty acids	Ratio (%)
Lean:			
1 oz. cooked.	<3 g	<1 g	33.3
3 oz. cooked.	<8 g	<3 g	37.5

TABLE 5—Continued

	Fat	Saturated fatty acids	Ratio (%)
Extra Lean:			
1 oz. cooked.	<1.4 g	<0.5 g	35.7
3 oz. cooked.	<4.3 g	<1.4 g	32.5

In response to the ANPR, AHA provided tables of meat and poultry that would be included in its proposed definitions of "lean" and "extra lean." As a parameter for determining the meat and poultry products that would meet the definitions, AHA factored a rounding margin of 0.4 grams for the 3 ounce cooked values (i.e., 8.4 could be rounded to 8.0 grams). Table 6 represents the ratios of the saturated fatty acids to fat for the 3 ounce values factoring in the rounding margins used by AHA:

TABLE 6

	Fat	Saturated fatty acids	Ratio (%)
Lean:			
3 oz. cooked.	<8.4 g	<3.4 g	40.5
Extra Lean:			
3 oz. cooked.	<4.4 g	<1.4 g	31.8

Many trade associations and industry comments suggested that the 3 ounce cooked numbers, when rounded to the according values in TABLE 5, would further provide an appropriate ratio of saturated fatty acids to total fat that meat could achieve. FSIS's proposal did not specify the rounding for the fat, saturated fat, and cholesterol values. Numerous commenters requested that FSIS clarify the rounding that would apply to the proposed values, and asked that the values be rounded to the whole gram.

The Agency's intention was to provide the unique nutrient content claims "lean" and "extra lean" specifically for use on meat and poultry products. As a result of the Agency's use of the 1 ounce cooked numbers to extrapolate to 100 grams, the "lean" and "extra lean" definition contained a saturated fatty acids to total fat ratio of 33.3 percent and 36.7 percent, respectively. As discussed earlier, some meat and poultry products will not utilize many of the descriptive terms included in FDA's nutrient content claims regulations. The Agency's resolve is to furnish meat and poultry products with equitable descriptive terms through the use of the terms "lean" and "extra lean." In light of the overwhelming comments indicating that adherence to the saturated fat to total fat

ratios are impossible for meat, FSIS is withdrawing the qualitative values proposed.

FSIS believes, and is supported by commenters, that the AHA 3 ounce cooked values have merit. The Agency also believes that "lean" and "extra lean" definitions that recognize and allow for the inherent saturated fatty acid content of meat can easily include a saturated fatty acid criterion in the definition.

The Agency further believes that defining the terms "lean" and "extra lean" with fat, saturated fatty acids, and cholesterol values per 3 ounces is difficult to apply to any definition. FSIS proposed the "lean" and "extra lean" values solely per 100 grams. It was the Agency's intent to propose a dual criteria, per 100 grams and per labeled serving.

To maintain as much consistency with the criteria for nutrient content claims as possible, the Agency is modifying in the definitions of "lean" and "extra lean," the dual criteria of per RACC and 100 grams for individual foods and per 100 grams and per labeled serving size for meal-type products. The Agency is retaining the 100 gram requirement for individual foods because the RACC for the same food may vary depending on the use of the food (e.g., ham used as a luncheon meat RACC is 55 grams, ham used as an entree RACC is 85 grams).

The effect this would have on nutrient content claims is the luncheon meat could have approximately ⅓ more of a nutrient (such as fat, saturated fatty acids, cholesterol, or sodium) to qualify for a claim such as "low". The Agency believes this would be false and misleading for consumers.

To facilitate the use of the 3 ounce values for the terms "lean" and "extra lean", the values were converted to a percentage (100 gram) basis. The following values are a result of extrapolating AHA's proposed 3 ounce cooked values to 100 grams (conversion factor 1 ounce=28 grams):

	Fat	Saturated fatty acids	Cholesterol
Lean	9.5 g	3.6 g	95.2 mg
Extra Lean	5.1 g	1.6 g	95.2 mg

The Agency took these numbers and rounded them to the nearest whole number:

	Fat	Saturated fatty acids	Cholesterol
Lean	10 g	4 g	95 mg
Extra Lean	5 g	2 g	95 mg

The ratio of saturated fatty acids to fat is 40 percent for both "lean" and "extra lean". The numerical rounding for these numbers will be the rounding proposed for the fat, saturated fatty acids, and cholesterol on the nutrition label after compliance considerations are taken into account. Fat and saturated fat will be rounded to the nearest 0.5 gram (i.e., 10.24 grams is rounded to 10 grams) and cholesterol to the nearest 5 milligrams.

The Agency's proposal to apply the "lean" and "extra lean" definitions to all meat and poultry products, including ground beef and hamburger, received divided comments. Many commenters supported the use of the terms to describe processed meat and poultry products while some commenters did not. Many ground beef and hamburger manufacturers urged the Agency to reconsider the exemption for ground beef and hamburger.

The criterion for some of the nutrient content claims defined by FDA will not allow many meat and poultry products to qualify for their use. The Agency is offering "lean" and "extra lean" as alternatives for meat and poultry products, including meal-type products, injected products, pumped products, and breaded and battered products. Offering these terms to muscle products exclusively would bring disparity to meat and poultry products. FSIS believes that a meat and poultry product meeting the definition for "lean" or "extra lean" should be permitted to label that product as such, regardless of whether the product has added ingredients or is a muscle meat. Carrying that belief further, the Agency believes that applying these definitions across all product categories would best benefit the consumer and aid in nutrition education. By granting ground beef and hamburger an exemption, there would be a dual criteria pertaining to these definitions. The Agency believes it cannot permit this confusion in the marketplace nor in the education of consumers. Therefore, the definitions of "lean" and "extra lean" will be applied categorically across all meat and poultry products.

Commenters also recommended the term "_____ percent lean" to be allowed on the labeling of muscle meats which contain 20 percent or less fat, especially as an alternative for ground beef and hamburger. The agency has given this recommendation careful consideration and believes that, in light of the "_____ percent fat free" regulation discussed below, "_____ percent lean" would be a viable alternative for meat and poultry. The Agency received comments in support of unified nutrient content claims, and, therefore, will adopt the definition for "_____ percent fat free" claims. The "_____ percent fat free" and "_____ percent lean" claims must meet the definition for "low fat."

Inadvertently omitted in the proposed codified language for "lean" and "extra lean" were the general requirements that accompany all the nutrient content claims. The general requirements provide that the product be labeled in compliance with § 317.309 or § 381.409, and the nutrient content claims comply with the requirement of § 317.313 or § 381.413. The Agency has corrected that oversight in this final rule.

The comments received by FDA, in response to its nutrient content claims proposals, specifically addresses the definitions of terms. Responses to the FSIS proposals that commented on nutrient content claims would, in some instances, include responses written to FDA, along with a brief comment expressing support for harmonization between FSIS and FDA.

In response to the comments it received, FDA has made modifications to its proposals. Since FSIS is adopting most of the FDA nutrient content claims proposals, the two Agencies have been working closely on the resolution of key issues raised by comments, and the modifications to the proposals. A brief discussion of six key issues related to nutrient content claims follows:

1. *Nutrient density.* FDA proposed for nutrient content claims the criteria of per RACC, per labeled serving size, and per 100 grams of food for individual foods. Commenters expressed concerns that the 100 gram criterion would inappropriately prohibit "low" claims on many foods, and that the 100 gram criterion, in addition with the RACC criterion, was excessive.

Weight based criterion was proposed to prevent "low" claims on certain foods that are dense in a nutrient on a weight basis yet still qualify for a low claim because of their small serving size.

This final regulation will be modified by applying a weight-based criterion for "low" claims and "very low sodium" claims only to foods with small serving sizes (i.e., 30 grams or less or 2 tablespoons or less). These foods will be evaluated on a per RACC and 50 gram requirement. All other individual foods will be evaluated on a per RACC basis only.

2. *Comparative claims.* Comments received in response to FDA's proposals suggest that consumers do not differentiate between the terms "less" ("fewer") and "reduced," and, therefore, the terms should be considered synonymous. Commenters also opposed

the minimum (quantitative) reduction requirement, stating that this criterion is overly restrictive, would prevent claims on small serving sizes, and would penalize foods that have already been nutritionally improved.

This final rule has been modified to permit the use of "reduced" and "less" ("fewer") as synonymous terms referring to a reduction of at least 25 percent in a nutrient. In order that reductions not be trivial, claims will be prohibited if the reference food already meets the criteria for "low." Disclosure of the percent reduction and the reference food will be required with a claim.

3. *"Light" or "lite".* Many comments to FDA's proposals contended that certain products would not be able to make a "light" claim under the proposed definition. Comments questioned the feasibility of creating an acceptable product reduced both in calories and fat (fat substitutes often contain a significant number of calories) or, in the case of products with small serving sizes, unable to make sufficient reductions due to the small amount of nutrients in the regular product. The proposed definition was based on the belief that consumers equated the use of the term "light" with calories. To support this belief, FDA cited data contained in (1) FDA's 1982 Health and Diet Survey and (2) Calorie Control Council's January 9, 1990, New Release, "Americans Finding 'light' to Their Liking." The Calorie Council's survey showed that consumers associate the term "light" with calories, as well as with fat. A National Consumers Survey by the Gallop Organization showed that 8 out of 10 consumers of "light" products use these products to reduce fat. Therefore, the "light" definition has been modified to include a fat and calorie reduction requirement. To satisfy the "light" definition, foods with greater than 50 percent calories from fat must reduce fat by 50 percent. Foods with less than 50 percent calories from fat must reduce the fat by 50 percent and the calories by one-third. FSIS and FDA believe that "light" for sodium can be nutrient specific, and has modified this final rule to provide for the use of the term "light in sodium." "Light in sodium" will mean 50 percent reduction in sodium.

4. *Implied claims.* FDA proposed that an "implied" claim was a statement that would lead a consumer to assume: (a) That a nutrient is absent or present in a certain amount, and (b) that a food, because of its nutrient content, is useful in achieving a total daily diet conforming to dietary guidelines (e.g., "healthy"). Healthy was not defined. Therefore, under the proposal, healthy could not be used, except in "grandfathered" brand names.

Health professionals, consumer organizations, States, and a segment of industry suggested that such claims should either be prohibited entirely or be defined. Many industry comments stated that terms such as "healthy," "nutritious," and "wholesome" are not implied claims under the NLEA.

Many comments proposed definitions for the term "healthy", ranging from "low in fat, saturated fat, cholesterol and sodium plus high in at least two key micronutrients," to "not exceeding the levels of fat, saturated fat, cholesterol and sodium that would be inconsistent with dietary guidelines"; e.g., the disclosure/disqualifier levels.

Before the term "healthy" can be defined, FSIS will seek public comment on this issue by publishing a proposed rule with request for comments.

5. *Meal-type products.* FDA's proposal included the definition of meal-type product as a food that: (a) Makes a significant contribution to the diet either by providing at least 200 calories per serving or by weighing at least 6 ounces per serving; (b) contains ingredients from two or more of the four food groups; and (c) is represented as a meal, main dish, entree or pizza. Claims for these meal-type products generally would be based on nutrient levels per 100 grams.

Industry comments generally supported the proposed definition of meal-type products whereas health professional and consumer advocacy groups found it too broad, and the 200 calorie requirement much too low. Some of these groups also found the requirement for a minimum of two ingredients (as opposed to two servings) too liberal, and would not meaningfully distinguish meal-type products from individual foods.

The responses FSIS received to the definition of meal-type products overwhelmingly supported, rather than opposed, the Agency's proposed definition. FSIS believes the majority of meal-type products fall under the Agency's purview, and does not believe the comments received warrant major changes in the definition proposed. Comments received suggest that a 200 calorie level is an insufficient amount of food for a meal-type product, even for those on a reducing diet and that a number of individual foods would meet this minimum caloric level. Increasing the caloric level substantially might exclude a number of meal products appropriate for weight maintenance or weight reduction.

Comments support the weight requirement of 6 ounces. Nielson Scantrack 1990 through 1991 Data, provided to the Agency, show that 78.7 percent of the frozen dinners (6.0 ounces—24.0 ounces) surveyed fall between 6 ounces and 12 ounces.

The Agency is convinced by comments that the 200 calorie requirement is insufficient. The Agency believes a weight requirement is necessary to ensure that products represented as meals contain adequate amounts because of their contribution to the overall diet. Therefore, the Agency is modifying the meals definition to exclude a minimum calorie requirement, but include a minimum and maximum weight requirement of 6 ounces and 12 ounces respectively.

The definition proposed will remain, with criterion (a) modified to: "Makes a significant contribution to the diet by weighing at least 6 ounces, but not more than 12 ounces." Meal-type products weighing more than 12 ounces will be evaluated on a case-by-case basis.

The term "source" for meal-type products was proposed to be used when a product contained 10–19 percent of the RDI or DRV for the nutrient per 100 grams of product. The term "high" was proposed for use on meal-type products that contained equal to or greater than 20 percent of a nutrient per 100 grams. Comments stated that the per 100 gram basis would result in inappropriately high nutrient levels to make products eligible for "high" or "good source" claims. For example, to make a "high in Vitamin C" claim, a 10-ounce dinner would be required to contain over one half of the DRV. Comments also stated that products that contain a smaller percent of the DRV still may be considered excellent nutrient sources. Therefore, the final regulation has been modified to provide for the use of the terms "source" and "high" on meal-type products that contain an individual food that meets the definitions of "source" and "high." For example, the label or labeling claim for a meal-type that contained carrots could state "Carrots are a source of Vitamin A."

6. *Brand to brand comparisons.* As a basis for comparative terms, the FSIS proposal provided as reference foods:

(1) An industrywide norm, i.e., a composite value weighted according to a national market share on a unit or tonnage basis for all the foods of the same type as the food for which the claim is made;

(2) A manufacturer's regular product that has been offered for sale to the public on a regular basis for a substantial period of time in the same geographic area by the same business

entity or by one entitled to use its trade name; or

(3) A food or class of food whose composition is reported in a current valid data base.

Many industry comments objected to only a manufacturer's own brand for use as a reference food. The Agency believes that use of a competitor's products has the potential for unwarranted inferences. Therefore, this final rule does not permit competitors' products as reference foods.

For easy reference, the following two tables contain the nutrient content claims definitions which have been modified from the proposed definitions.

TABLE 7.—NUTRIENT CONTENT CLAIMS FOR FOODS

Nutrient	Free	Low	Reduced/less/fewer	Other
	Synonyms for "Free": "Free of", "No", "Zero", "Without", "Trivial source of", "Negligible source of", "Dietarily insignificant source of".	Synonyms for "Low": "Contains a small amount of", "Low source of", "Low in".	Synonyms for "Reduced/Less/Fewer": "Reduced in", "Lower", "Lower in".	
	Exception: "Sugarless", "Nonfat"	Exception: "Little sodium", "Few" for calories, "Little fat", "A little saturated fat", "Little cholesterol".	.....	
Calories	<5/RACC	Reference Amount: >30g or >2T: <=40 cal/RACC.	>=25% fewer	
		Reference Amount: <=30g or <=2T: <=40 cal/RACC & /50 grams.	.....	
Sodium	<5mg/RACC	Reference Amount: >30g or >2T: <=140 mg/RACC.	>=25% fewer	"Very Low Sodium", "Very Low in Sodium".
	"Salt Free" may be used if food is "Sodium Free".	Reference Amount: <=30g or <=2T: <=140 mg/RACC & 50 g.	.....	Reference Amount >30g or >2T: <=35 mg/RACC, <=30 g or <=2T: <=35 mg/RACC & 50 g.
Total Fat	<0.5g/RACC	Reference Amount: >30g or >2T: <=3 g/RACC <=30% calories from fat.	>=25% fewer	"____% Fat Free" must meet "low fat" criteria.
				"____% Lean" must meet "low fat" criteria.
Saturated Fat	<0.5 g/RACC & Level of trans fatty acids.	Reference Amount: >30g or >2T: <=1 g/RACC <=15% calories SFA.	>=25% fewer	
	<1% of total fat	Reference Amount: <=30g or <=2T: <=1 g/RACC & /50 g <=15% calories SFA.	.....	
Cholesterol	<2mg/RACC <=2 g SFA/RACC	Reference Amount: >30g or >2T: <= 20 mg/RACC <= 2 g SFA/RACC.	>=25% fewer and <=2 g SFA/RACC.	
		Reference Amount: <=30g or <=2T: <=20 mg/RACC & 50 g <=2 g SFA/RACC.	.....	
Sugar	<0.5 g sugar/RACC	.....	>=25% fewer/RACC	"No added sugar", "Without added sugar", "No sugar added" if no amount of sugar, or ingredient that functionally substitutes for added sugars is added, the product does not contain ingredients containing added sugars, and the food declares (unless it meets definition that) it is not "low calorie" or "reduced calorie"

*RACC=Reference Amount Customarily Consumed

TABLE 8—NUTRIENT CLAIMS FOR MEALS

Nutrient	Free	Low	Reduced/less/fewer	Other
	Synonyms for "Free": "Free of", "No", "Zero", "Without", "Trivial source of", "Negligible source of", "Dietarily insignificant source of".	Synonyms for "Low": "Contains a small amount of", "Low source of", "Low in".	Synonyms for "Reduced/Less/Fewer".	
	Exception: "Sugarless", "Nonfat"	Exception: "Little sodium", "Few" for calories, "Little fat", "A little saturated fat", "Little cholesterol".		
Calories	Not defined	<=120/100g	>=25% fewer/100 grams.	
Sodium	<5mg/Labeled Serving	<=140mg/100g	>=25% fewer/100 grams	"Very Low Sodium" "Very Low in Sodium"
	"Salt Free" may be used if food is "Sodium Free".	.....	.....	<=35 mg/100 gram
Total Fat	<0.5g/Labeled Serving	<=3 g/100g and <30% cal from fat	>=25% fewer/100 grams	"____% Fat free" must meet "low fat" criteria.

TABLE 8—NUTRIENT CLAIMS FOR MEALS—Continued

Nutrient	Free	Low	Reduced/less/fewer	Other
Saturated Fat	<0.5g/Labeled Serving and Level of trans fatty acids. <1% Total Fat	<=1 g/100g <10% calories SFA	>=25% fewer/100 grams.	"___ % Lean" must meet "low fat" criteria.
Cholesterol	<2 mg/Labeled Serving	<20 mg/100 grams	>=25% fewer	
	<=2g SFA/Labeled Serving	<=2 g SFA/100g	<=2 g SFA/100g.	
Sugar	<0.5g/Labeled Serving		>=25% fewer/100 grams	"No added sugar", "Without added sugar", "No sugar added" if no amount of sugar, or ingredient that functionally substitutes for added sugars is added, the product does not contain ingredients containing added sugars, and the food declares (unless it meets definition that) it is not "low calorie" or "reduced".

7. *Petitions.* FSIS proposed to provide a petition process, consistent with FDA, to permit the use of nutrient content claims not included in the proposal, synonymous terms that are consistent with a regulatory term, and implied claims made as part of the brand name. The proposed rule would have required the petitions to be supported by detailed information, including:

(1) A description of the term and the nutrient that the term is intended to characterize;

(2) A detailed explanation of why use of the food component characterized by the claim is important to human nutrition;

(3) Analytical data that demonstrate the amount of the nutrient that is the subject of the claim; and

(4) A detailed analysis of the potential effect of the use of the proposed claim on food consumption.

The proposed rule would have required petitions for new nutrient content claims to be processed through rulemaking proceedings. Upon receipt and review of such petitions, FSIS would notify the applicant, in writing, that the petition was either being considered for further review or that the petition had been denied by the Administrator. If the Administrator denied the petition, he or she would notify the applicant, in writing, as to the reason(s) for the denial. If the claim were approved by the Administrator, the Agency would notify the applicant by letter and would also publish in the **Federal Register** a proposed rule to amend the regulations to authorize the use of the claim in the labeling of meat and poultry products.

FSIS also proposed petition processes for synonymous terms and implied claims that would not require processing through rulemaking proceedings. The petition process proposed for synonymous terms generally followed the same process as the process for new nutrient content claims, except, instead of publishing a proposed rule and seeking comment, the Agency would publish a notice in the **Federal Register** informing the public of the Administrator's decision to grant the approval of the synonymous term.

The petition process proposed for implied claims would have required FSIS, upon receipt and review of such petition, to notify the applicant, in writing, that the petition was either being considered for further review or that the petition had been denied. The Administrator would publish in the **Federal Register** a notice of the petition, announcing its availability to the public and seeking comment on the petition. If the Administrator denied the petition, he or she would notify the applicant, in writing, as to the reason(s) for the denial. If the claim were approved by the Administrator, the Agency would notify the applicant by letter and would also publish a notice in the **Federal Register** informing the public of such fact.

As discussed in FSIS's proposed rule on nutrition labeling, many comments responding to the ANPR on nutrition labeling recommended that FSIS not approve the use of claims on a case-by-case basis under the prior label approval process. Such commenters suggested that such uses be permitted through a petition and rulemaking process that would provide full opportunity for public comment. In response to those comments, FSIS proposed to establish such a petition process.

FSIS received a comment urging FSIS to simplify its request for information in the petitioning process. The commenter contended that such elaborate information would be unduly burdensome to industry and would serve as a disincentive for the development of healthful products.

In reevaluating this proposed process, FSIS determined that a process for approving new claims would best be conducted under the prior label approval system. The requesting establishment will be required to submit only one request to FSIS for approval on the use of a new claim. Rather than petitioning for the use of a certain claim and, after FSIS approval, submitting a labeling application for the use of that same claim, the requesting establishment would be, in effect, "petitioning" the Agency for use of a certain claim through its submittal of a labeling application. Thereafter, other manufacturers desiring to use such claims would simply submit their standard labeling applications to FSIS for approval. Under such a process, label approval for the use of such claims will be provided in a more timely fashion, and preparation and submittal of certain duplicative information would be eliminated. FSIS's petition process is still consistent with FDA's except for the mechanism used by manufacturers to request use of a new claim. FDA requires a "petition" whereas FSIS requires a "labeling application." All other aspects of the process are generally the same. The opportunity for public comment will still be available through the publication in the **Federal Register** of proposed rules or notices on the proposed claims, except synonymous claims, which will satisfy concerns discussed above regarding the need for public participation in the approval of new claims. (Labeling applications for the use of synonymous claims will not be issued for public comment prior to the Administrator's final determination, which is consistent with FDA).

In responding to the commenter of the proposed rule that the proposed information supporting a claim would be burdensome and discouraging to the industry, FSIS believes that determinations on the use of new nutrient content claims, synonymous claims, or implied claims must be validated by sound, reliable data. To assure the validity of any such claims, they must be supported by sound evidence on the potential effect of the proposed claim on food consumption and any corresponding changes in nutrient intake. The use of any such claims must also be proven to provide nutritional benefits to the public that are not already available through use of existing terms. Even more importantly, it must be demonstrated why the use of the proposed term would not be false or misleading.

FSIS maintains that responsibility for validating the use of a new claim rests with the manufacturer who desires to use the claim. Therefore, this final rule requires a manufacturer to request the use of a new claim by submitting a labeling application and the detailed proposed information which supports such use. Through review of the complete supporting information, FSIS can effectively determine the validity of such a proposed claim and, in the case of new nutrient claims and implied claims, provide the public with sufficient information upon which to base meaningful comment.

VIII. Compliance and Analytical Methods

As part of its prior label approval process, FSIS requires manufacturers to submit analytical data to support nutrient values and content claims on food labels. The Agency processed approximately 180,000 requests for label approvals in 1990, of which many contained nutrition information. FSIS conducts a nutrition labeling verification program to ensure the continued accuracy of label information after initial approval. Under the program, manufacturers periodically submit analytical data on their products for Agency review. FSIS nutrition labeling guidelines for meat and poultry products, which address requirements for initial label approval and continuing accuracy of labels, are contained in Policy Memoranda 85B and 86.

In the preamble to the proposed rule published in November 1991, FSIS maintained that each manufacturer is responsible for insuring the validity of nutrient declarations contained on product labels, and concluded that requirements for submission of laboratory data with requests for initial label approvals and nutrition labeling verification procedures are unnecessary. FSIS would require plant management to maintain records that support nutritional values and establish a partial quality control (PQC) program for nutrients that are subject of nutrient content claims. The Agency proposed to allow the most current representative data base values contained in USDA's National Nutrient Data Bank (NNDB) or its published form, the Agriculture Handbook No. 8 (AH–8) series, to be used for voluntary nutrition labeling of single-ingredient, raw meat and poultry products, without subjecting such labels or labeling to compliance review unless a nutrition claim was made.

On March 25, 1992, FSIS published a supplemental proposed rule in the **Federal Register** (57 FR 10298) to, in part, permit companies to base nutrient information on processed meat and poultry product labels on data bases, and on recipe analysis using data bases, as well as on laboratory analyses. The Agency proposed to adopt 80/120 tolerance levels in determining nutrition labeling compliance for naturally occurring nutrients and use samples consisting of a minimum of six units selected from within or across lots.

Commenters sought clarification about certain aspects of the compliance and analytical methods issues and suggested modification and revision of various provisions. A summary of these comments and the Agency's responses follow.

1. *Label approval and nutrition labeling verification.* All commenters addressing the current label approval requirements supported the termination of requirements relating to the submission of analytical data with initial requests for label approval, submission of periodic data to support the continuing accuracy of the label, and maintenance of FSIS-approved nutrition labeling verification procedures. Major reasons cited were associated burden, cost, and time consumption. Commenters supported Agency testing as the primary enforcement vehicle for the regulations. Trade associations and companies requested that current requirements be eliminated as soon as possible. Questions were raised as to whether a food may be labeled in compliance with the new nutrition labeling regulations, rather than existing policy memoranda, pending the implementation date of the nutrition labeling regulations.

FSIS believes that, in the best public interest, transition to nutrition labeling under the new regulations should begin immediately and that current testing requirements, as described in policy memoranda 85B and 86, be terminated upon publication of this final rule. This approach affords industry time to develop reliable data to meet the new labeling requirements and opportunity to develop or reformulate products to meet newly-defined nutrient content claims. During the 18-month interim period prior to implementation of these regulations, new labels bearing nutrition information that are not yet in compliance with these regulations will be accepted for initial prior label approval without previously required supporting laboratory data. Nutrition label panels will be validated as to conformance either with existing policy or the new regulations during initial approvals.

A number of commenters stated that firms with limited experience in nutrition and health-related labeling might need assistance in preparation and review of labels submitted for initial approval under the new regulations to ensure compliance and that manufacturers should be allowed to request such service. The Agency will provide such guidance in the form of instruction sheets for preparation of the nutrition panel and an FSIS manual on use of data bases. Copies of these materials may be obtained, without charge, from the Product Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. Copies are also available for public review in the FSIS Hearing Clerk's office.

Many industry groups, including large trade associations and small packers, requested FSIS to develop the nutrient data for food products via Agency analysis and to format the nutrition panel at no charge, and/or to pay for the compliance samples taken from within the establishment to alleviate financial impacts on small businesses.

FSIS recognizes the potential economic impact of the regulations on small businesses and industry at large. Accordingly, this final rule provides a small business exemption and permits the use of data bases and recipe analysis using data bases to alleviate costs. In its proposal, the Agency stated it would monitor a minimum of six units for compliance and, in most cases, the number of samples taken would be 12 whenever feasible and not too costly. It further stated that for various products, such as large samples of ham, a composite of six units will be taken for cost and logistical efficiency. FSIS concludes that these multiple cost-saving measures negate commenters' concerns.

Numerous commenters requested clarification as to the content of records supporting the validity of label declarations. FSIS believes that adequate records may consist of results of direct product analyses, data base values and/or recipe calculations, or a combination of direct analyses, data base values, and recipe calculations.

Regarding direct analyses, the Agency will not dictate the number of tests to be performed because the frequency needed for accuracy of label values will vary according to the nature of the product, the nutrient, the sample size, and a host of other product-specific variables. Many different sampling plans can produce equal assurance that label declarations reflect nutrient content. FSIS believes the manufacturer is in the best position to determine the most appropriate plan for its own products. FDA has prepared a comprehensive guide for developing data bases based on direct analyses for food labeling purposes. The guide covers sampling objectives, the target population, and the sampling frame. While a person may follow the manual or choose to use alternate procedures, FSIS believes the manual will be useful to manufacturers in developing nutrition labeling. Copies of the manual entitled "FDA Nutrition Labeling Manual: A Guide for Developing and Using Data Bases," 1992 edition, may be obtained from the Division of Nutrition, Office of Nutrition and Food Sciences, Center for Food Safety and Applied Nutrition, Food and Drug Administration, Washington, DC 20240. Use of data base values and/or recipe calculations to satisfy recordkeeping requirements is discussed under part 2b of this section.

Commenters asked if the Agency planned to require companies to use FSIS-accredited laboratories to generate their nutrient data, which might preclude use of company-generated data. Historically, the Agency has conducted accreditation of laboratories for its own use, as opposed to use by companies. FSIS does not plan to accredit laboratories or conduct an accredited laboratory program for nutrient analysis for food labeling. Companies may use any laboratory of their choice and are responsible for the accuracy of the analytical information.

Trade associations and large companies requested that the regulations make clear that supporting records for multi-plant firms can be maintained at corporate headquarters or a central location, as opposed to individual manufacturing establishments, because manufacturers with multiple production facilities typically generate all labels at a central location. The provisions of 9 CFR 320.2 and 381.176 indicate that, if a person conducts business at multiple locations, records may be maintained at the headquarters' office.

Almost without exception, commenters voiced strong opposition to the requirement that establishments must, as a prerequisite to the use of labels or labeling containing nutrient content claims, seek FSIS approval of a PQC program. While not objecting to the concept or value of such programs to assure product quality, industry representatives argued that PQC requirements: (a) Are redundant under these regulations because FSIS monitoring would be the primary compliance and enforcement vehicle, (b) are unnecessary since well-defined compliance criteria are contained in the rules, (c) imply the Agency places lower enforcement priority on other mandated information, (d) would delay the introduction of new and reformulated products, and (e) might undo the economic benefits gained by eliminating the current nutrition labeling verification procedures. Some suggested that PQC requirements not be mandated for claims but, instead, PQC programs be allowed on a voluntary basis for all nutrition label compliance measures on the condition that Agency compliance monitoring results not be given enforcement precedence over PQC records.

The Agency has carefully considered these comments and concludes that the PQC requirements are contradictory to its regulatory objectives to place responsibility for label accuracy on manufacturers and implement nutrition labeling in the most cost-effective manner possible. FSIS encourages the timely marketing of new and reformulated products of benefit to public health and use of nutrient content claims that will help consumers to select among foods to achieve a healthy diet The Agency is convinced that the compliance criteria contained in the rules, coupled with its approach to inspection, including the presence of inspectors to oversee processing controls and ensure good manufacturing practice in every federally inspected establishment, will provide a high degree of assurance that products meet compliance provisions for nutrient content claims. Accordingly, the proposed provisions requiring approved PQC programs for use of nutrient content claims (9 CFR 317.309(g)(8) and 381.409 (g)(8)) have been removed in this final rule.

2. *Use of data bases.* FSIS's proposal to permit the use of data bases and recipe analysis using data bases was supported by most commenters. FSIS continues to believe that the use of data bases, alone or in conjunction with analytical testing, can facilitate cost effective development of accurate nutrient declarations for meat and poultry products, which meet the requirements of these regulations and provide highly useful information to consumers. FSIS concludes that data bases, especially computerized systems, when effectively used, are powerful tools for developing nutrient declarations. Consequently, the final rule will allow nutrient declarations based on data base values, direct analysis, and/or combination approaches. The Agency encourages firms to fully exercise their prerogative to use data bases to construct labels reflecting the average nutrient levels in their products over time.

As previously discussed, the Agency has prepared a manual to provide guidance and practical information to meat and poultry product manufacturers who choose to use data base values or recipe analyses using such values to develop nutrition label declarations for all or selected nutrients in their products. The document will help establishments, especially those with limited experience in nutrition labeling or data base use, evaluate and use systems to insure compliance with USDA's nutrition labeling regulations. FSIS wants to stress that it is not its intent to proceed in a punitive manner against companies when problems surface during compliance monitoring. FSIS will expect the company to locate the source of the discrepancy and rectify any problem by such means as changing the label values and correcting the cause of the problem. If problems surface during Agency compliance sampling FSIS will review company records and work with the company to assure that label values reflect average nutrient levels in the food product. FSIS expects the focus of any compliance inquiry about labels based on data base values to be somewhat different from those based on direct analysis because variation can be introduced from multiple sources.

a. *Single-ingredient products.* Commenters generally supported the Agency's proposal to allow use of representative data base values from USDA's NNDB or the AH–8 series, without being subject to the compliance provisions of the regulations in the absence of claims, on point-of-purchase information and on labels for generic labeling of fresh meat and poultry products according to the guidelines for the voluntary program. Representatives

of the poultry industry requested FSIS to allow alternatively for the use of industry-prepared, separate data bases and other recognized data bases, such as "Nutri-Facts," to provide the information because AH–8 may not be representative of current poultry.

In its proposal, the Agency stated that it accepted the results of the research efforts to develop the nutrient profiles for meat and poultry as contained in the NNDB or AH–8 as adequately characterizing beef, pork, lamb, veal, chicken, and turkey. These data have been screened and accepted by USDA's Human Nutrition Information Service and, therefore, FSIS believes it is appropriate to exclude products using these data for labeling purposes from compliance review in the absence of claims. FSIS also stated that it did not discourage the use of private data base values but that products so labeled would be subject to compliance review. Products labeled with both USDA's public data base values and with private data base values will be included in measuring substantial participation in the voluntary program. FSIS will not approve, certify, or otherwise accept private data bases for single-ingredient, raw products for the purpose of exempting products labeled with such information from the compliance provisions of these regulations. FSIS holds that the accuracy of the data in these private systems is the responsibility of the developer.

Several commenters from foreign countries requested either to use their own national data or that FSIS allow use of U.S. data to label imported, single-ingredient, raw products without such labeling being subject to compliance review. FSIS considers foreign, nationally representative data bases to be private data bases that it will not accept for the purpose of exemption from the compliance provisions of these regulations. As with domestic private data bases, the accuracy of the data in these systems is the responsibility of the developer. FSIS cannot know in advance the scope of the research behind data in private systems as is possible with USDA's NNDB. The Agency notes that nutrient profiles for raw cuts of New Zealand lamb as contained in AH–8–17 are given the same status as NNDB or AH–8 data with regard to the labeling of imported product. Imported products bearing other U.S. data for labeling will be subject to compliance review because the Agency has no way to assess the applicability of data developed specifically for the U.S. food supply to foreign food sources.

A number of trade associations and companies contended the voluntary system should apply to all single-ingredient products whether or not they have been thermally processed. They argued that there is little difference between thermally processed and non-thermally processed single-ingredient products, particularly when the labeling options of "as packaged" and "as consumed" for voluntary goods is taken into account.

The Agency understands the argument about thermally processed products considering that information on single-ingredient, raw products may be presented on a cooked basis. In its discussion of alternatives considered in development of its proposed regulations, FSIS stated its belief that consumers should be provided with nutrition labeled products to the extent possible for all foods. Because nutrient values for single-ingredient, raw meat and poultry products are not modified through various stages of preparation, consumers have reasonable expectation as to their nutritional values such that a voluntary program for these products is suitable. The Agency cited referenced USDA sources which contain both raw and cooked nutritional data appropriate for these products. The cooked values in these sources were developed using protocols that reflected home preparation to every extent possible. The Agency has no information that industrial thermal processing procedures do not introduce different variables than considered in developing the USDA data. For these reasons, FSIS concludes that inclusion of thermally processed single-ingredient products in the voluntary program is not warranted.

Many trade associations and companies held the opinion that the voluntary program should include single-ingredient, raw products subjected to such mechanical activities as grinding, cubing, cutting, and pressing, and that there should be no distinction between fresh products packed in official establishments and at the retail level. FSIS notes that it has made no distinction between fresh products packaged in official establishments and those packaged at the retail level. The Agency does not believe that the site where a product is packaged has any relevance for its nutritional profile. The voluntary program includes retail cuts of meat and poultry (and ground beef), including those that have been previously frozen, because the nutrient values for these products are not modified through various stages of preparation, such as cooking and heat processing. Single-ingredient, raw products which are subjected to mechanical treatments, such as slicing, chopping, and shaping, would likewise meet the definition describing products considered to be suitable for inclusion under the voluntary nutrition labeling program. The nutrient contents of final products from mechanical treatments would be identical to those of their starting cuts and such products could be labeled appropriately using pertinent USDA data base information.

Commenters suggested that the definition of fresh product as "single-ingredient" was too strict and could greatly deter the introduction of new, minimally processed products such as low fat products containing binders. The Agency does not believe that multi-ingredient products are appropriate for the voluntary program because their nutrient content can vary significantly from single-ingredient, raw products, due to addition of ingredients and other steps during the manufacturing process.

FSIS proposed that appropriate nutritional values for labeling of single-ingredient, raw products are values for meat cuts with external cover fat at trim levels reflecting current market practices, and values for poultry cuts with skin on. The Agency also proposed to permit the additional listing of nutrients for the separable lean of meat cuts and skinless poultry cuts as an option. Consumer groups supported the Agency's position, but many commenters representing the red meat and food marketing industries objected to it. The industries cited several surveys of consumer trimming behavior suggesting many people trim fat from meat and, to a lesser extent, remove skin from poultry prior to cooking or eating.

The Agency recently received the preliminary results of a September 1992 study, sponsored by the National Live Stock and Meat Board, on consumer fat trimming behavior with regard to beef and pork cuts. A copy of the preliminary results of the work entitled "Determination of Consumer Behavior Regarding the Trimming of Fat from Selected Beef and Pork Cuts," October 1992, is available for public review in the FSIS Hearing Clerk's office. Actual trimming habits were measured through laboratory examination of meal preparation wastes and individual family member plate wastes.

The preliminary results show that 68 of 71 households participating in the study trimmed fat from beef ribeye steaks and 53 of 59 households trimmed fat from pork loin chops, either before or after cooking and before eating. Considering the margin of error in the study and sources of bias, the Agency accepts the results as conclusive of

consumer trimming behavior for beef and pork, and interprets them to show that many consumers do trim some fat from meat prior to eating. Preliminary calculations indicated that the amount of fat actually consumed equaled about 25 percent of the difference between the percent fat in the cooked total edible tissues (separable lean plus separable fat) and the percent fat in the cooked separable lean for the beef cut. Calculations also indicated that the amount of fat actually consumed equaled about 50 percent of the difference between the percent fat in the cooked total edible tissues and the percent fat in the cooked separable lean for the pork cut.

The Agency believes that these 25 and 50 percent differences can not be ignored, therefore, separable lean values would not be appropriate for beef and pork cuts. FSIS will not change its proposed position. The study indicated that not all consumers trim all fat and that there are some consumers who trim no fat from meat. Therefore, FSIS has not changed its proposed position on appropriate nutrient values for labeling of single-ingredient, raw meat products. Appropriate values for cuts of red meat are edible portions of meat cuts with external cover fat at trim levels reflecting current marketing practices. Additional nutritional data may be presented on an optional basis for the edible portions of the separable lean of meat cuts.

The broiler industry sought more flexible use of data base information because non-standardized multiple packs currently sold will create a great deal of variation in the nutrition profiles of raw poultry products. Other commenters questioned which specific cuts of meat and poultry from the NNDB or AH–8 referenced sources could be used for labeling. FSIS does not intend to limit the cuts to the 35 meat cuts listed in proposed 9 CFR 317.344 and 10 poultry cuts listed in proposed 9 CFR 381.444. The 45 cuts were identified only as major cuts for purposes of measuring significant participation in the voluntary program. FSIS believes data for any cut of beef, pork, lamb, veal, chicken, and turkey contained in the referenced USDA sources are appropriate for use for labeling purposes. The data for cuts may be used singly or in combination to accommodate multiple packs. Different tissues for cuts may be combined allowing for their proportions by weight, when such information is available, following calculation procedures described in the AH–8 publications. When data base values are not used directly and computations are applied, the Agency encourages manufacturers to keep track of the proportions of each AH–8 item combined so that the Agency can be satisfied that the values are actually derived from AH–8 data. Data for organ meats and data for species other than the six identified may also be used at the manufacturer's discretion although such data may not have as solid a research basis as noted for retail cuts of the major species.

Comments were received about the list of 45 major cuts of meat and poultry and the presentation of data on either a raw or cooked basis. These comments and the Agency's response are discussed under Part II, Mandatory Nutrition Labeling and Part VI, Serving Sizes, respectively.

b. *All other products.* Numerous trade associations and manufacturers requested explicit sanction of data base use to develop nutrition labels for processed or multi-component products to alleviate the cost of chemical analyses. Some firms supplied information and/or data attesting to the accuracy of the data base approach.

In response, FSIS proposed specifically to allow use of data base values and recipe analysis, and requested input on criteria for effective use of data bases, guidelines to provide producers who choose to use this approach, availability of data bases, and any changes that might be warranted in the compliance criteria if data bases are used. Many commenters provided such input to assist FSIS in development of a final rule which permits use of data base values and recipe analysis for nutrition labeling. Two consumer groups and one major company expressed concern that the data base approach would lead to less accurate nutrition information on labels and that the nutritional verification of such information would most likely cancel any savings. The Agency believes that effective use of data bases can reduce dramatically the overall cost for supporting nutrition labels and can provide consumers with high quality, useful nutrient information. Accordingly, FSIS will permit the use of data base values and recipe analysis using data bases to support nutrition labeling of processed and multi-component products. FSIS places responsibility for label accuracy on manufacturers. They may derive the nutritional values for product labels by any means to result in compliance with the provisions of these regulations. FSIS will accept introduction of the existence of a data base and supporting data, such as company ingredient analysis, USDA or supplier data for ingredients, formulas, and calculations applied, as appropriate records supporting nutrition label declarations.

FSIS believes the use of nutrient data bases, especially computerized systems, offers a very powerful tool for the development of nutrition labels. However, their effective use is a complex issue involving considerations about completeness, accuracy, precision, and support. Many commenters asked the Agency to provide guidelines for data base use that are simple and concise. As previously discussed, FSIS has compiled relevant suggestions by experienced data base users into a manual to assist those meat and poultry processors who elect to employ this approach, copies of which are available from the Product Assessment Division.

Many small companies requested FSIS to provide the data base values or systems for computerized calculation and not hold users liable for any faulty data in such systems. FSIS does not believe that it is practical for it to provide data bases or computer systems to industry for use in calculating nutrient values. FSIS will provide guidance for effective use of data bases and computer systems in the manual, as well as information about appropriate composite species data and computations it believes applicable to products that are not highly formulated, and references to commercial sources of computer data base systems. However, use of the guidelines in the manual does not negate a manufacturer's responsibility for the accuracy of the nutrient information on its labels.

A number of commenters asked FSIS to evaluate and certify data bases and/or computerized recipe systems for acceptability either as a prerequisite to use or on a voluntary basis. The Agency does not believe it is either practical or warranted that it perform such a function. Available data bases and/or systems include publicly available material, such as USDA's Nutrient Data Base for Standard Reference, commercial systems, and companies' proprietary data bases. FSIS believes manufacturers should evaluate and select a system best suited to meet their own needs, taking into account their type of product, its ingredient formulation, and the processing procedures employed. General factors to consider in a data base selection process are provided in the FSIS manual to help guide potential users.

Most commenters responding to the question in the supplementary proposed rule about compliance parameters (57 FR 10298, March 25, 1992) expressed the opinion that compliance criteria in

nutrition labeling should be the same for all processed and multi-component products regardless of the data source. One trade association stated that products which are supported by data base values should be in a fundamentally different compliance category, whereby reference to the data base would essentially curtail a compliance inquiry in most cases. The suggestion was also made that USDA adopt compliance parameters that reflect product characteristics so that commodity-type products, when labeled according to an accepted national data base, should not be subject to compliance checks.

The Agency believes that compliance criteria that allow variation based on data sources, i.e., direct analysis, data base values, recipe calculations using data base values, and combinations of these approaches, would be inconsistent with the intent of nutrition labeling. It will hold manufacturers of all products not exempted from compliance review under provisions of these regulations to identical compliance parameters. FSIS expects the focus of any compliance inquiry about labels of products based on data base values and/or recipe analysis to be somewhat different from products based on direct analysis because variation can be introduced from multiple sources. Nonetheless, the Agency expects companies to locate the source of a discrepancy and take appropriate steps to correct errors.

A number of commenters said FSIS should not allow manufacturers of products bearing nutrient content claims to base the claims on data base values or recipe analysis and that FSIS should require chemical analysis to justify the validity of claims. The Agency maintains that the manufacturer is responsible for the accuracy of the claims and will not dictate that direct analysis must be conducted on nutrients which are the subject of claims. Because of the high visibility of claims and their use as marketing tools, manufacturers would place themselves at risk if claims cannot be adequately substantiated.

3. *Compliance parameters.* Many commenters addressed the 80/120 tolerance levels, commonly referred to as the 80/120 rule, for naturally occurring nutrients and the Agency's proposed sampling scheme. Approximately half were supportive of the proposed requirements as written. A number of large trade associations and companies offered alternative enforcement schemes or sought modifications of the tolerance levels to accommodate specific nutrients or single versus multi-lot sampling. Many requested FSIS to discuss the considerations it would make during a compliance inquiry and before it would deem a product to be misbranded because nutrients did not meet compliance provisions. Commenters cited situations where variations in processed products might cause compliance parameters to be exceeded unavoidably as follows: (a) Wide natural variation of nutrients in an ingredient; (b) decreases in nutrients during shelf life of a product; (c) variability of methods at low levels of nutrients; (d) adjustments for container fill; and (e) processing methods, such as retorting, which degrade certain nutrients. A few commenters held misconceptions that the 80 and 120 percent values represented the upper and lower bounds of an acceptable range for every nutrient and/or that products must be labeled at lot averages without allowance for safety factors.

The Agency shares the concerns that wide variation can be introduced due to natural variability of nutrients in foods and that some nutrients do change over the course of product shelf life. Examples of such cases are variable contents of fat in hams and sides of bacon from relatively uniform groups of market hogs and decreases over time in sodium ascorbate (vitamin C sodium) levels in fermented sausage, respectively. Therefore, the Agency is outlining its interpretation of the 80/120 rule, which it will adopt, and how it intends to determine a misbranding status. It is the Agency's position that declared nutrient values on food labels preferably should reflect average nutrient levels in the product produced or manufactured by a company or establishment within the company. The provisions of these regulations and other policies in regard to implementing these regulations are consistent with this position. The allowance in the 80/120 rule for nutrition labeling, developed by FDA and first implemented by that agency in 1974, is meant to take into account inherent manufacturing and product variation. The FDA approach was concentrated on single lot sampling. Under this scheme of sampling, lot-to-lot variation is not taken into account. However, compliance sampling of 12 subsamples within a lot does not imply that such a sample is adequate to develop the nutrition label.

FSIS compliance procedures will involve collecting samples from within a lot and use of results on samples that are collected from different lots, either at the establishment or at the wholesale/retail level. The sampling of product from different lots has the effect of decreasing the producer's risk that test results will not be in compliance compared to sampling of product from a single lot, provided that the product is produced under similar conditions. This type of sampling is consistent with the Agency's position that the nutrition label reflect the average level of nutrients in the product over time. FSIS has also adopted a strategy for some products of collecting six units instead of 12. The primary reason for this change is that the size of some products makes it difficult to mail, store, cook in some instances, and prepare homogeneous composites within the laboratory. Use of six units, instead of 12, will also reduce cost to the establishment when the samples are drawn at that site. The Agency believes that results based on six samples will provide reasonable assurance of accuracy, while offering considerable benefits. The Agency does not believe that this decrease in sample size warrants a statistical adjustment to the rule as it is being applied.

The Agency's experience with the 80/120 rule shows that it works well to ensure reliable label values for the majority of processed products, and is not overly burdensome. FSIS believes that the labeling strategy suggested by FDA in development of the 80/120 rule was based on using statistical procedures for guiding a producer in selecting a label value in order to be highly confident that sample results would satisfy the rule. FDA outlined a procedure which suggested that the nutrients in a food in a package must be within the 80/120 percent tolerances with high probability (95 percent) regardless of the average amounts of the food's nutrients in packages over time. If, in fact, nutrient variability were high, the manufacturer would be forced, under this procedure, to label above or below the average, depending on the nutrient, in order to satisfy the procedure. Also, in the case where variability was small, the label value could be below the average for so-called negative nutrients like calories, sodium, and fat and above the average for so-called positive nutrients like vitamins, minerals and protein. In either case, the average nutrient level in a food in a package would not agree with the label value.

FSIS, as mentioned previously, has adopted the policy that values on food labels preferably should reflect average nutrient levels in the food product. If this is achieved, it would enable consumers to have more accurate information over time than is possible with the FDA approach described above. The Agency recognizes that, for some nutrients in foods, natural

variability will be large, thereby increasing the probability of noncompliance under the 80/120 rule when the label value reflects average nutrient content. Consequently, the Agency will provide exemptions if it can be demonstrated that variability is unavoidably high due to inherent nutrient variation in a product or product ingredient, which cannot be controlled under normal processing. This type of variation is shown with carrots, an ingredient in some meat and poultry products. The vitamin A activity of carrots varies extensively and increases with maturity at harvest. However, variation caused by changes in proportions of ingredients, such as beef and pork in a frankfurter, would not qualify a product for an exemption.

The Agency will use the FDA procedure as a guideline to determine high variability. If a manufacturer labels at the average, and if the standard deviation of values within a lot is 42 percent of the mean, i.e., the coefficient of variation (CV) equals 42 percent, then there is a 95 percent probability that analytical results on 12 samples will satisfy the 80 or 120 percent criteria when analytical variability is ignored. This 42 percent value can be used as a guideline for exemptions based on inherent nutrient variability. When six samples are taken, 95 percent probability of satisfying the criteria is achieved when the CV equals 30 percent. This 30 percent value will be used as a guideline for providing exemptions for those products on which only six samples will be drawn.

When Agency test sample results are not in compliance with the 80/120 rule, FSIS will expect the company to indicate how it will rectify the problem. Actions may include changing the label values or identifying and correcting the cause of the problem. Alternatively, the company could notify the Agency that it is going to present data or information to support the label. The company could either present data that shows to the Agency's satisfaction that the sample result found not in compliance is not representative or likely to reoccur under the establishment's normal processing. Alternatively, the company could present evidence to relax the 80/120 tolerance because of unavoidable variability, either because of large within lot variability as described above, or because of large processing variability caused by product variation over the year.

In order for the Agency to accept the label value as stated, information presented during a compliance inquiry should demonstrate that the company satisfies the Agency's goal to have the label value reflect the average. Such effort could be demonstrated by data showing, with 80 percent statistical confidence, that the label value is equal to or less than the process mean value for nutrients where the 80 percent tolerance applies. In addition, the company must show consistent processing to ensure that only low percentages of future samples would not be in compliance. Such consistency could be shown by data demonstrating process control to the extent that there is expected to be less than a 10 percent probability that the mean result from a composite of six or 12 units within a lot, as appropriate, would not be in compliance. Similarly, for nutrients where the 120 percent tolerance applies, the Agency would be satisfied and accept the label value if the company can show that there is 80 percent statistical confidence that the process mean value for the product is equal to or less than the label value, and also that there is expected to be less than a 10 percent probability that the mean result from a composite of six or 12 units within a lot, as appropriate, would not be in compliance. The results used in these statistical computations should be rounded to one additional significant digit beyond the prescribed label increment for the nutrient. This rounding requirement will increase the accuracy of the evaluation.

If the company wishes to relax the 80/120 rule, then it should provide FSIS records of data collected under good manufacturing practice that would provide evidence to relax the 80/120 rule based on unavoidable variability with the intent of judging a product on its time weighted average nutritional profile over a year. The company has to present information which will explain and document the unavoidable variability. This would include amounts of raw materials that are generally used in processing, together with nutrient information on these materials, as well as data showing process variability under good manufacturing practices. For example, variation in fat content of bacon might be due to variation in fat content of the pork source material from different suppliers producing carcasses of different yield grades. Relaxation of the 80/120 rule will be made when it can be shown that nutrient levels in raw products are of high variability over time, or that there is a high amount of within lot variability as described above.

The Agency concludes that it is not necessary to alter the provisions of proposed 9 CFR 317.309(g)(4)(ii) and (5) or 381.409(g)(4)(ii) and (5) to incorporate the above stated policies to implementing the compliance provisions of these regulations. However, FSIS has modified proposed 9 CFR 317.309(g)(2) and 381.409(g)(2) to allow individual samples to be analyzed and the results averaged by adding a third sentence to read "In each case, the units may be individually analyzed and the results of these analyses averaged." The Agency has also corrected errors at proposed 9 CFR 317.309(g)(6) and 318.409(g)(6), the meaning of which was questioned by two trade associations. These provisions are changed to read "The amount of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium may vary over the labeled amounts within good manufacturing practice. The amount of calories, sugars, total fat, saturated fat, cholesterol, or sodium may vary under the labeled amounts within good manufacturing practice." The purpose of these provisions is to prevent large understatements of vitamins, etc., and overstatements of calories, etc., on labels as compared to amounts actually present in analyzed composites. For example, if a product is labeled at 100 calories, an analyzed composite's caloric value may be no higher than 120 calories for the sample to be found in compliance. However, if the analyzed sample is found to contain only 20 calories, the product may be misbranded, because the Agency would consider the value to be outside the levels generally expected during good manufacturing practices. The Agency could ascertain this either by data collected from the manufacturers or data collected through its own monitoring program. While the Agency does not preclude adjustments in label declarations to minimize risk of noncompliance, it encourages manufacturers to label close to average values and, as discussed above, will take into consideration inherent nutrient variability and shelf stability factors when nutrients in products fall outside the 80/120 tolerance levels.

Some commenters contended that nutrients present at low concentrations are particularly susceptible to compliance problems due to method variability and rounding procedures. They argued that if a process mean value of 1.3 units were rounded for label declarations to one unit, then the acceptable range would be 0.8 to 1.2 units when applying the 80/120 rule. The range would be below the true mean value which could result in many products being found not in compliance. Furthermore, these small differences of 0.2 units may not be

within the accuracy of many methods so that the analytical variance could be greater than the allowed regulatory variance.

FSIS points out that the 20-percent tolerance does not represent a range but rather a discrepancy of an analytical result on a sample from a label value. FSIS believes that the point that the commenters wish to make is that, for class II nutrients such as fat and sugars, the upper bound for a label claim of 1 would be 1.2, which, in the example presented, is below the mean. In response, FSIS believes it is the manufacturer's responsibility to target values to correspond to an appropriate label declaration so products will meet compliance requirements. This includes taking into consideration the effects of rounding. In this example, FSIS would expect the label to indicate 1.5 units for fat and 2 units for sugars.

The Agency also recognizes that analytical variability may be larger at low nutrient levels. For this reason, FSIS proposed at 9 CFR 317.309(g)(4)(ii) and 381.409(g)(4)(ii) for vitamins, minerals, protein, total carbohydrate, dietary fiber, etc., that no regulatory action will be taken unless the nutrient level found in the product exceeds both the 20-percent tolerance and whatever variability is recognized for the particular method being used at the nutrient level involved. FSIS believes this same provision should apply to all nutrients. The Agency has added the provision for allowance for method variability at proposed 9 CFR 317.309(g)(5) and 381.409(g)(5) to cover calories, sugars, total fat, saturated fat, cholesterol, and sodium. FSIS does not believe that incorporation into the regulations of any other explicit provision or compliance position for low level nutrients or small labeling increments, such as 2 percent, would provide added protection for manufacturers.

Several commenters stated that container fill, specifically over fill to assure compliance with declared quantity of contents, will contribute errors under the proposed definition for single-serving containers, which will use the entire contents of the container in determining compliance. FSIS does not consider this issue to be a valid concern. While the entire contents of a container will be used to prepare the sample for analysis, the Agency will not use the actual weight of the contents in determining compliance. FSIS will use the precise metric weight equivalent of the serving or portion size, fluids in milliliters and all other foods in grams, which is required to be included on the label, for compliance purposes. For purposes of clarity, the Agency is adding a provision at proposed 9 CFR 317.309(g) and 381.409(g) to state specifically that this metric measure will be used for compliance purposes.

While discussing nutrient variability, some trade associations and companies said manufacturing processes, such as heat treatments, alter nutrients. The Agency holds that such losses must be accounted for either by finished product testing or by use of yield and retention factors, as appropriate, during recipe analysis. The latter considerations are discussed in the FSIS manual on use of data bases.

Industry groups said decision criteria for compliance should be based on actual, unrounded values used in compiling the label information. If FSIS unrounded compliance sample data were compared to rounded label declarations, whether the industry source data came from direct analyses or data bases, errors in data interpretation might result. Because the Agency has dropped the requirement for submission of company data with initial label approvals, FSIS must make initial comparisons with label declarations. However, in the event of a compliance inquiry, FSIS will examine the company's records and make decisions using the company's original, unrounded values.

A few large companies sought clarification as to why FSIS defined and established tolerances for class I nutrients; i.e., those added in fortified and fabricated foods, noting that FSIS has not allowed fortification of meat and poultry products. In the preamble to the proposed rule, FSIS stated that it had little experience with added nutrients unless specific regulations permit their addition, e.g., vitamin A to margarine (9 CFR 319.700). The Agency proposed to define class I nutrients in these regulations to cover this situation. The use of nutrients solely for technological purposes, e.g., in curing meats to use L-ascorbic acid (vitamin C) or its sodium salt (sodium ascorbate) to accelerate color fixing or preserve color during storage, would not subject the added nutrient in the product to the class I compliance criteria shown at proposed 9 CFR 317.309(g)(4)(i) and 381.409(g)(4)(i). Similarly, the use of ingredients such as "textured vegetable protein" or enriched flour in a product would not subject the product to any class I criteria simply because the word "protein" is in an ingredient name or nutrients had been added to an ingredient of the product. The Agency also notes that if voluntary vitamins and minerals are required to be added or permitted in a standardized food (e.g., thiamin in enriched flour), which is used as an ingredient in a meat or poultry product, or if they are included solely for technological purposes and declared only in the ingredient statement, they need not be declared on the label if not otherwise referred to on the label or in labeling or advertising. The Agency believes that further discussion of its fortification policy is beyond the scope of this rulemaking.

A number of commenters expressed concerns about the need to analyze for nutrients which are not indigenous to meat or poultry products, e.g., dietary fiber in muscle meat tissue, stating that to analyze for "zero" level nutrients would be costly and a waste of time. FSIS does not expect manufacturers to conduct analyses for nutrients that are not present in a food or even to run tests to establish that fact unless there is reasonable doubt about the nutrient's presence or as to whether the level would round to "zero" for the label declaration. Knowledge of the food and information on its ingredient formulation and processing, review of food composition tables, consultation with nutritionists, food scientists, and others can all show that only certain nutrients should be targeted for analysis in specific foods or products. To undertake analyses for all mandatory nutrients in such situations would be a waste of resources.

Regarding analytical methodology, commenters stressed the importance that methods used for regulatory compliance by FSIS and FDA be the same except to the extent where the unique characteristics of meat and poultry products dictate a different method. Both the FSIS "Chemistry Laboratory Guidebook" and the "Official Methods of Analysis" of the AOAC International, formerly Association of Official Analytical Chemists, were recognized as appropriate sources of chemical methodology. Commenters said the "Guidebook" must be updated and include references for all required nutrients and that specific reference to the 15th edition, 1990, of the AOAC should not be made because, when subsequent editions are printed, the regulations will reference obsolete material. It was also noted that some AOAC methods are not current with contemporary analytical procedures and that there is a need to develop better, more reliable analytical methods subject to collaborative studies. The AOAC International Board of Directors established a Task Force on Nutrient Labeling Methods charged with identifying deficiencies in current methods and expediting key

collaborative studies. Many commenters also requested specific guidance as to the analytical procedures the Agency will use to enforce these regulations at the time the final rule is published.

The Agency agrees with the majority of these comments concerning analytical methodology and the goals of the AOAC Task Force on Nutrient Labeling Methods. USDA's Agricultural Research Service, FSIS and FDA are actively participating in the AOAC deliberations, as well as in development of appropriate standard reference materials for chemical analyses. FSIS recognizes that some of the methods now in use may be changed in the next several years in order to better meet nutrition labeling needs. Such changes, when accepted by the Agency, will be incorporated into the "Chemistry Laboratory Guidebook," which will be updated on an ongoing basis. In regard to the suggestion to delete the reference to the 15th edition of the AOAC, FSIS does not have the authority to delete such reference. The Office of the Federal Register requires that each statement of incorporation by reference into the Code of Federal Regulations contain specific information, including the date and edition of the publication. This is required because all incorporated material, like any other properly issued regulation, has the force and effect of law.

Accordingly, FSIS has modified the proposed 9 CFR 317.309(g)(2) and 381.409(g)(2) to change the cross reference to 21 CFR 101.9(c) to 9 CFR 317.309(b) for meat and 9 CFR 381.409(b) for poultry. The Agency also notes that the provisions at 317.309(h)(2) and 381.409(h)(2) state that, if no USDA, AOAC, or specified method is available or appropriate, that other reliable and appropriate analytical procedures should be used. Other reliable and appropriate procedures may not have been collaboratively tested, but rather include validated methods, published peer-reviewed methods and correlated methods. Because they are not necessarily fully characterized, like official methods, they are not specified. In the preamble to the proposed rule, FSIS said that if use of a method will result in a significant (10 percent or greater) under-representation of a caloric value or misrepresentation of an available nutrient such that the nutrients whose intakes should be limited appear to be present at lower levels than is actually the case, then a more appropriate method of analysis should be used. These provisions have relevance, for example, to products containing a large proportion of fat as phospholipid, which is not quantitatively extracted with ether.

The "Chemistry Laboratory Guidebook" is now in the process of being updated but is not yet available. For this reason and to provide commenters with specific guidance as to the methods for required nutrients, moisture, and ash that it will use for compliance purposes, FSIS has listed below the method citations with brief clarifying descriptions and/or additional considerations. A full description of the procedures, including measures of analytical variability, as well as any changes made for considerations outlined below or in response to Federal or AOAC deliberations prior to publication of the updated guidebook, will appear in the revised version. Further information about analytical methods may be obtained from the Chemistry Division, Science and Technology, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

FSIS Methods for Nutritional Analysis

- Calories—At 317.309(b) and 381.409(b). Calculated using specific Atwater factors; general factors of 4, 4, 9; general factors of 4, 4, 9 after subtracting insoluble dietary fiber from total carbohydrate, if desired; or, specific food factors approved by FDA.
- Moisture—AOAC, 15th ed., 1990, 950.46B. Air Drying; or AOAC, 15th ed., 1990, 950.46. Vacuum Oven.
- Total Fat—FSIS has tested several procedures to measure fat on various meat and poultry products, including AOAC, 15th ed., 1990, 960.39 using petroleum ether as solvent. The Agency is currently testing methods to measure only the total lipid fatty acids to be expressed as triglycerides, which constitute total dietary fat as defined in this final rule. More information will be provided as soon as it is available.
- Saturated Fat—Lipid Manual, "Methodology Appropriate for Fatty Acid-Cholesterol Analysis," 1992. U.S. Food and Drug Administration. Wm. C. Brown Publishers, Dubuque, IA, 109 pp. FSIS will use capillary columns, and the shortest chain fatty acid to be measured will be butyric acid.
- Cholesterol—Lipid Manual, "Methodology Appropriate for Fatty Acid-Cholesterol Analysis," 1992. U.S. Food and Drug Administration. Wm. C. Brown Publishers, Dubuque, IA, 109 pp. FSIS will use capillary columns.
- Total Carbohydrate—At § 317.309(b) and § 381.409(b). Determined by difference.
- Sugars—Chemistry Laboratory Guidebook, Revised Basic, 1987, 3.022. Dextrose, Sucrose, Maltose, and Lactose by HPLC.
- Dietary Fiber—AOAC, 15th ed., 1990, 985.29. Enzymatic Gravimetric Method; or AOAC, 15th ed., 1990: 3rd Supplement, 1992, 991.43. Enzymatic Gravimetric Method, MES-TRIS Buffer. Special precautions are needed to ensure that meat and poultry product samples are thoroughly defatted prior to analysis.
- Other Carbohydrate—At § 317.309(b) and § 381.409(b). Determined by difference.
- Protein—Chemistry Laboratory Guidebook, Revised Basic, 1987, 3.002. Kjeldahl.
- Ash—AOAC, 15th ed., 1990, 920.153.
- Vitamin A—High Pressure Liquid Chromatography. In-house FDA procedure. FSIS will measure preformed retinol and beta-carotene separated from other vitamin A precursors. The Agency will not make a noncompliance finding for this nutrient when a company includes other vitamin A active carotenoids in compiling the label declaration where data for such carotenoids have been determined using appropriate methods and the activity has been calculated using the factor of one retinol equivalent equal to 12 micrograms of these other carotenoids.
- Vitamin C—FSIS is studying the procedure of Vanderslice, J.T. and Higgs, D.J. 1990. "Separation of ascorbic acid, isoascorbic acid, dehydroascorbic acid and dehydroisoascorbic acid in food and animal tissue". J. Micronutrient Anal. 7, 67–70. This HPLC procedure can distinguish between L-ascorbic acid (and sodium ascorbate) and isoascorbic; i.e., erythorbic acid (and its sodium salt, sodium erythorbate), which is commonly used in meat and poultry products but has little or no vitamin C activity. FSIS has not yet determined whether this method is reliable. The Agency will use this procedure if reliability is established. FSIS is also studying the procedure of the International Organization of Standardization (ISO), 1990–09. "Meat and Meat Products—determination of L(+)—ascorbic acid—HPLC method", Document 34–SC6N337.
- Sodium—Chemistry Laboratory Guidebook, Revised Basic, 1987, 4.010. Using Inductively Coupled Plasma Optical Emission Spectrometry.
- Iron and Calcium—Analytical Chemistry Laboratory Guidebook, Residue Chemistry, Winter 1991. MTL. Inductively Coupled Plasma Optical Emission Spectrometry.

FSIS is extending this procedure to include calcium. FSIS notes that it does

not prescribe methods which must be used by manufacturers to support label values. The methods listed above are those the Agency will use to analyze samples for enforcement purposes. The Chemistry Division will make copies of single nutrient analyses available at interim periods between publications of the Chemistry Laboratory Guidebook.

IX. Health Claims

FSIS does not currently permit health claims explicitly linking food attributes to diet-related disease or health-related conditions. FSIS does permit statements informing consumers that a food can be part of a specific dietary pattern to meet an organization's dietary guidelines or that a food was developed to help follow a specific dietary pattern.

The rationale adopted by FSIS for approving health claims on labeling is to encourage labeling which supplements the information contained in the nutrition label with information that provides truthful data about a product's nutritional characteristics, and provides generally accepted information about how a product satisfies consumers' total dietary requirements. By contrast, labeling is not approved by FSIS under the FMIA or PPIA if the Secretary of Agriculture has reason to believe that the claim is false or misleading in any particular.

To implement the use of health claims on labeling, FSIS provides general guidelines and objectives which permit claims if they are based on a consensus of medical and scientific information, emphasize that good nutrition is a function of the total diet, and are reasonably uniform from product to product.

The following is an example of a health-related claim that would currently be permitted: "This food was specifically developed to help you follow the current U.S. Dietary Guidelines for sodium, fat and cholesterol. For further information on the U.S. Dietary Guidelines call * * *"

In its proposed rule on nutrition labeling, FSIS stated its intent to publish a proposed rule on health claims in line with FDA's proposal. At the time the FSIS proposal was published, the health claims issue was still under study by FDA and FSIS. FSIS is continuing its study of this issue and plans to publish a proposed rule in the near future.

X. Food Ingredients and Standards of Identity

FSIS requires full ingredient labeling on all meat and poultry products, including standardized products.

The Agency believes that concerns about disjunctive labeling of fats and oils can be resolved by proper labeling of saturated fat. Because USDA standards of identity and composition do not require minimum fat contents, development of products with desirable characteristics is not hampered by minimum fat criteria. However, levels for minimum amounts of meat and poultry are a part of most standards. These criteria protect consumers against economic fraud and dilution of beneficial micronutrients and protein expected in certain products. Due to the shift of concern from problems connected to underconsumption to those associated with overconsumption of certain food components such as fat, FSIS plans to reassess this matter after completing its rulemaking on nutrition labeling.

XI. Prior Label Approval

FSIS is considering changes to its current label approval process for labeling of meat and poultry products. At this time, two options are being considered: (1) Revising the current system by significantly reducing the scope of review, through expanding the categories of labeling that would be generically approved, and replacing the current general requirement of FSIS approval of final labeling with one for sketch labeling only; and (2) replacing the current system with a system in which all labeling would be generically approved and used without prior submission to FSIS. FSIS published an ANPR in the **Federal Register** on March 25, 1992 (57 FR 10300), requesting comments from interested parties on these two options. FSIS plans to issue a proposed rule based on comments received on the ANPR.

List of Subjects

9 CFR Part 317

Food labeling, Food packaging, Incorporation by reference, Meat inspection.

9 CFR Part 320

Meat inspection, Reporting and recordkeeping requirements.

9 CFR Part 381

Food labeling, Incorporation by reference, Poultry and poultry products, Reporting and recordkeeping requirements.

Final Rule

For the reasons discussed in the preamble, FSIS is amending 9 CFR parts 317, 320, and 381 of the Federal meat and poultry products inspection regulations as follows:

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

1. The authority citation for part 317 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

2. Part 317 is amended by designating the current sections 317.1 through 317.24 as subpart A—General, and by adding a new subpart B—Nutrition Labeling to read as follows:

Subpart B—Nutrition Labeling

Sec.
317.300 Nutrition labeling of meat products.
317.301 [Reserved]
317.302 Location of nutrition information.
317.303–317.307 [Reserved]
317.308 Labeling of meat products with number of servings.
317.309 Nutrition label content.
317.310 [Reserved]
317.311 [Reserved]
317.312 Reference amounts customarily consumed per eating occasion.
317.313 Nutrient content claims; general principles.
317.314–317.342 [Reserved]
317.343 Significant participation for voluntary nutrition labeling.
317.344 Identification of major cuts of meat products.
317.345 Guidelines for voluntary nutrition labeling of single-ingredient, raw products.
317.346–317.353 [Reserved]
317.354 Nutrient content claims for "good source" and "high".
317.355 [Reserved]
317.356 Nutrient content claims for "light" or "lite".
317.357–317.359 [Reserved]
317.360 Nutrient content claims for calorie content.
317.361 Nutrient content claims for sodium content.
317.362 Nutrient content claims for fat, fatty acids, and cholesterol content of meat products.
317.363–317.368 [Reserved]
317.369 Labeling applications for nutrient content claims.
317.370–317.379 [Reserved]
317.380 Label statements relating to usefulness in reducing or maintaining body weight.
317.381–317.399 [Reserved]
317.400 Exemption from nutrition labeling.

Subpart B—Nutrition Labeling

§ 317.300 Nutrition labeling of meat products.

(a) Nutrition labeling shall be provided for all meat products, except single-ingredient, raw products, in accordance with the requirements of § 317.309; except as exempted under § 317.400 of this Subpart.

(b) Nutrition labeling may be provided for single-ingredient, raw meat products in accordance with the

requirements of §§ 317.309 and 317.345. Significant participation in voluntary nutrition labeling shall be measured by the Agency in accordance with §§ 317.343 and 317.344 of this Subpart.

§ 317.301 [Reserved]

§ 317.302 Location of nutrition information.

(a) Nutrition information on a label of packaged meat products shall appear on the label's principal display panel or on the information panel, except as provided in paragraph (b) of this section.

(b) Nutrition information for gift packs may be shown at a location other than on the product label, provided that the labels for these products bear no nutrition claim. In lieu of on the product label, nutrition information may be provided by alternate means such as product label inserts.

§§ 317.303–317.307 [Reserved]

§ 317.308 Labeling of meat products with number of servings.

The label of any package of a meat product that bears a representation as to the number of servings contained in such package shall meet the requirements of § 317.2(h)(10).

§ 317.309 Nutrition label content.

(a)(1) All nutrient and product component quantities shall be declared in relation to a serving or to a portion, as defined in 21 CFR 101.9(b) (1) and (2) except (b)(2)(i), and 21 CFR 101.9(b) (5) through (9) except (b)(5)(iii).

(2) The declaration of nutrient and product component content shall be on the basis of the product "as packaged" for all products, except that single-ingredient, raw products may be declared on the basis of the product "as consumed" as set forth in § 317.345(a)(1). In addition to the required declaration on the basis of "as packaged" for products other than single-ingredient, raw products, the declaration may also be made on the basis of "as consumed," provided that preparation and cooking instructions are clearly stated.

(3) For products in discrete units (e.g., hotdogs, and individually packaged products within a multi-serving package), serving size shall be the number of whole units that most closely approximates the Reference Amount for the Product Category. If a unit weighs 67 percent or more, but less than 200 percent of the Reference Amount, serving size shall be one unit. If a unit weighs more than 50 percent but less than 67 percent of the Reference Amount, the manufacturer may decide whether one unit is one serving. If a unit weighs 200 percent or more of the Reference Amount, the manufacturer may declare the whole unit as one serving if the whole unit can reasonably be consumed at a single-eating occasion.

(4) Serving size for meal-type products as defined in § 317.313(l) shall be the entire content (edible portion only) of the package.

(5) Another column of figures may be used to declare the nutrient and food component information in the same format as required by § 317.309(e),

(i) Per 100 grams, 100 milliliters, or 1 ounce of the food as packaged or purchased.

(ii) Per one unit if the serving size of a product in discrete units in a multi-serving container is more than one unit.

(6) If cups, tablespoons and teaspoons, or units such as piece, slice, tray, jar, or fraction are not applicable, ounces may be used. Ounce measurements shall be expressed in 0.5 ounce increments most closely approximating the Reference Amount, with rounding indicated by use of the term "about" (e.g., about 2.5 ounces).

(b) The declaration of nutrition information on the label shall contain the following information, except for that which is identified as "VOLUNTARY" or for those meat products where a simplified format may be used as provided for in paragraph (g) of this section or as in § 317.400(b). No nutrients or food components, other than those listed in 21 CFR 101.9(c) as either voluntary or mandatory, except for stearic acid, may be included within the nutrition label. Information shall be presented using the nutrient names specified and in the formats specified in paragraph (e) of this section. Definitions, units of measure, increments for declaring values, and methods of calculation shall be in accordance with 21 CFR 101.9 (c)(1) through (c)(9), except 21 CFR 101.9(c)(1)(i)(E), bomb calorimetry, and in 21 CFR 101.9(c)(7)(ii), use of nitrogen conversion factors, other than 6.25.

(c)(1) If a product consists of assortments of meat products (e.g., variety packs) in the same package, nutrient content shall be expressed on the entire package contents or on each individual product.

(2) If a product is commonly combined with other ingredients or is cooked or otherwise prepared before eating, and directions for such combination or preparations are provided, another column of figures may be used to declare the nutrient contents on the basis of the product as consumed for the product alone (e.g., a cream soup mix may be labeled with one set of Daily Values for the dry mix (per serving), and another set for the serving of the final soup when prepared (e.g., per serving of cream soup mix and 1 cup of vitamin D fortified whole milk)): *Provided*, That the type and quantity of the other ingredients to be added to the product by the user and the specific method of cooking and other preparation shall be specified prominently on the label.

(d) "Stearic acid" may be declared "VOLUNTARY." If stearic acid is declared "VOLUNTARY" a statement of the number of grams of stearic acid shall be included under saturated fat content and expressed to the nearest 0.5 (1/2) gram increment below 3 grams and to the nearest gram increment above 3 grams.

(e) Formats for nutrition labeling shall be in accordance with 21 CFR 101.9 (d) and (e) except for references to (f), (j)(5), and (j)(13), or in accordance with paragraph (g)(1) of this section.

(f) Foods in packages that have a total surface area available to bear labeling of 40 or less square inches may modify the requirements of paragraphs (b), (e), and (g) of this section and § 317.302(a) by one or more of the following means:

(1) Presenting the required nutrition information in a tabular or linear (i.e., string) fashion, rather than in vertical columns, if the package shape or size cannot accommodate a column display on any label panel. Nutrition information may be given in a linear fashion only if the label will not accommodate a tabular display and, in that case, subcomponents (e.g., saturated fat shall be declared in parentheses after total fat).

(2) Using any of the following abbreviations:

Serving size—Serv. size
Servings per container—Servings
Calories from fat—Fat cal
Saturated fat—Sat fat
Cholesterol—Cholest
Total carbohydrate—Total carb
Dietary fiber—Fiber

(3) Omitting the footnote and caloric conversion information required in paragraphs (d)(9) and (d)(10) of 21 CFR 101.9 and placing another asterisk at the bottom of the label followed by the statement "Percent Daily Values are based on a 2,000 calorie diet" and, if the term "Daily Value" is not spelled out in the heading, a statement that "DV" represents "Daily Value," and

(4) Presenting the required nutrition information on any other label panel.

(g)(1) Nutrition information may be presented in a simplified format as set forth herein when any required nutrients, other than the core nutrients,

are present in insignificant amounts. An insignificant amount shall be defined as that amount that may be rounded to zero in nutrition labeling, except that for total carbohydrate, dietary fiber, and protein, it shall be an amount less than 1 gram.

(2) The simplified format shall include: Serving size, number of servings per container, calories, total fat (grams), total carbohydrate (grams), protein (grams), and sodium (milligrams).

(3) Any nutrient, other than a core nutrient, that is present in an insignificant amount may be omitted from the tabular listing, provided that the following statement is included within the nutrition label, "Not a significant source of _____." The blank shall be filled in with the appropriate nutrient or food component.

(4) The omission of the listing of daily values and the caloric conversion information, and the expression of the percent of daily value in the simplified format shall be in accordance with 21 CFR 101.9(f)(5) except for references to (j)(5) and (j)(13).

(h) Compliance with this section shall be determined as follows:

(1) A production lot is a set of food production consumer units that are from one production shift. Alternatively, a collection of consumer units of the same size, type, and style produced under conditions as nearly uniform as possible, designated by a common container code or marking, constitutes a production lot.

(2) The sample for nutrient analysis shall consist of a composite of a minimum of six consumer units, each from a production lot. Alternatively, the sample for nutrient analysis shall consist of a composite of a minimum of six consumer units, each randomly chosen to be representative of a production lot. In each case, the units may be individually analyzed and the results of the analyses averaged, or the units would be composited and the composite analyzed. In both cases, the results, whether an average or a single result from a composite, will be considered by the Agency to be the nutrient content of a composite. All analyses shall be performed by appropriate methods and procedures used by the Department for each nutrient in accordance with the "Chemistry Laboratory Guidebook," or, if no USDA method is available and appropriate for the nutrient, by appropriate methods for the nutrient in accordance with the 1990 edition of the "Official Methods of Analysis" of the AOAC International, formerly Association of Official Analytical Chemists, 15th ed., which is incorporated by reference, unless a particular method of analysis is specified in § 317.309(b), or, if no USDA, AOAC, or specified method is available and appropriate, by other reliable and appropriate analytical procedures as so determined by the Agency. The "Official Methods of Analysis" is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be purchased from the AOAC International, 2200 Wilson Blvd., suite 400, Arlington, VA 22201. It is also available for inspection at the Office of the Federal Register Information Center, suite 700, 800 North Capitol Street, NW., Washington, DC.

(3) Two classes of nutrients are defined for purposes of compliance:

(i) Class I. Added nutrients in fortified or fabricated foods; and

(ii) Class II. Naturally occurring (indigenous) nutrients. If any ingredient which contains a naturally occurring (indigenous) nutrient is added to a food, the total amount of such nutrient in the final food product is subject to Class II requirements unless the same nutrient is also added, which would make the total amount of such nutrient subject to Class I requirements.

(4) A product with a label declaration of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium shall be deemed to be misbranded under section 1(n) of the Federal Meat Inspection Act (21 U.S.C. 601(n)(1)) unless it meets the following requirements:

(i) Class I vitamin, mineral, protein, dietary fiber, or potassium. The nutrient content of the composite is at least equal to the value for that nutrient declared on the label.

(ii) Class II vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium. The nutrient content of the composite is at least equal to 80 percent of the value for that nutrient declared on the label; *Provided,* That no regulatory action will be based on a determination of a nutrient value which falls below this level by an amount less than the variability generally recognized for the analytical method used in that product at the level involved, and inherent nutrient variation in a product.

(5) A product with a label declaration of calories, sugars, total fat, saturated fat, cholesterol, or sodium shall be deemed to be misbranded under section 1(n) of the Federal Meat Inspection Act (21 U.S.C. 601(n)(1)) if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label; *Provided,* That no regulatory action will be based on a determination of a nutrient value which falls below this level by an amount less than the variability generally recognized for the analytical method used in that product at the level involved, and inherent nutrient variation in a product.

(6) The amount of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium may vary over labeled amounts within good manufacturing practice. The amount of calories, sugars, total fat, saturated fat, cholesterol, or sodium may vary under labeled amounts within good manufacturing practice.

(7) Compliance will be based on the metric measure specified in the label statement of serving size.

(8) The management of the establishment must maintain records to support the validity of nutrient declarations contained on product labels. Such records shall be made available to the inspector or any duly authorized representative of the Agency upon request.

(9) The compliance provisions set forth in paragraph (h) (1) through (8) of this section shall not apply to single-ingredient, raw meat (including ground beef) products, including those that have been previously frozen, when nutrition labeling is based on the most current representative data base values contained in USDA's National Nutrient Data Bank or its published form, the Agriculture Handbook No. 8 series available from the Government Printing Office.

§ 317.310 [Reserved]

§ 317.311 [Reserved]

§ 317.312 Reference amounts customarily consumed per eating occasion.

(a) The general principles followed in arriving at the Reference Amounts for serving (portion) sizes set forth in paragraph (b) of this section are found in 21 CFR 101.12(a), (c), (d) and (g).

(b) The following Product Categories and Reference Amounts shall be used as the basis for determining serving sizes for specific products:

TABLE 1.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION—INFANT AND TODDLER FOODS [1,2,3]

Product category	Reference amount
Infant & Toddler Foods:	
Dinner Dry Mix	15 g
Dinner, ready-to-serve, strained type	60 g
Dinner, soups, ready-to-serve junior type	110 g
Dinner, stew or soup ready-to-serve toddlers	170 g

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–1978 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

[2] Unless otherwise noted in the Reference Amount column, the Reference Amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e., heat and serve). If not listed separately, the Reference Amount for the unprepared form (e.g., dehydrated cereal) is the amount required to make one Reference Amount of the prepared form.

[3] Manufacturers are required to convert the Reference Amount to the label serving size in a household measure most appropriate to their specific product using the procedures established by regulation.

TABLE 2.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION—GENERAL FOOD SUPPLY [1,2,3,4,5]

Product category	Reference amount	Reference amount
	Ready-to-serve	Ready-to-cook
Egg mixtures, (western style omelet, souffle, egg foo young	110 g	n/a.
Lard, margarine, shortening	1 tbsp	n/a.
Salad and potato toppers; e.g., bacon bits	7 g	n/a.
Bacon (bacon, beef breakfast strips, pork breakfast strips, pork rinds)	15 g	54 g=bacon. 30 g = breakfast strips.
Dried; e.g., jerky, dried beef, Parma ham sausage products with a moisture/protein ratio of less than 2:1; e.g., pepperoni	30 g	n/a.
Snacks; e.g., meat snack food sticks	30 g	n/a.
Luncheon meat, bologna, Canadian style bacon, pork pattie crumbles, beef pattie crumbles, blood pudding, luncheon loaf, old fashioned loaf, berlinger, bangers, minced luncheon roll, thuringer, liver sausage, mortadella, uncured sausage (franks), ham and cheese loaf, P&P loaf, scrapple souse, head cheese, pizza loaf, olive loaf, pate, deviled ham, sandwich spread, teawurst, cervelet, Lebanon bologna, potted meat food product, taco fillings, meat pie fillings.	55 g	n/a.
Linked meat sausage products, Vienna sausage, frankfurters, pork sausage, imitation frankfurters, bratwurst, kielbasa, Polish sausage, summer sausage, mettwurst, smoked country sausage, smoked sausage, smoked or pickled meat, pickled pigs feet.	55 g	n/a. 75 g=uncooked sausage.
Entrees without sauce, cuts of meat including marinated, tenderized, injected cuts of meat, beef patty, corn dog, bagel dog, croquettes, fritters, cured ham, dry cured ham, dry cured cappicola, corned beef, pastrami, country ham, pork shoulder picnic, meatballs, pureed adult foods.	85 g	106 g.
Canned meats, canned beef, canned pork. [4]	55 g	n/a.
Entrees with sauce, barbecued meats in sauce	140 g	n/a.
Mixed dishes NOT measurable with a cup; [6] e.g., burrito, egg roll, enchilada, pizza, pizza roll, quiche, all types of sandwiches, cracker and meat lunch type packages, gyro, stromboli, burger on a bun, frank on a bun, calzone, taco, pockets stuffed with meat, foldovers, meat lasagna, stuffed vegetables with meat, shish kabobs, empanada.	140 g (plus 55 g for products with sauce toppings)	n/a.
Mixed dishes measurable with a cup; e.g., meat casserole, macaroni and cheese with meat, pot pie, spaghetti with sauce, meat chili, chili with beans, meat hash, creamed chipped beef, beef ravioli in sauce, beef stroganoff, Brunswick stew, goulash, meat stew, ragout.	1 cup	n/a.
Salads—pasta or potato, potato salad with bacon, macaroni and meat salad	140 g	n/a.
Salads—all other meat, salads, ham salad	100 g	n/a.
Soups—all varieties	245 g	n/a.
Major main entree type sauce; e.g., spaghetti sauce with meat, spaghetti sauce with meatballs	125 g	n/a.
Minor main entree sauce; e.g., pizza sauce with meat, gravy	¼ cup	n/a.
Seasoning mixes dry, freeze dry, dehydrated, concentrated soup mixes, bases, extracts, dried broths and stock/juice, freeze dry trail mix products with meat.		
As reconstituted:		
Amount to make one Reference Amount of the final dish; e.g.,		
Gravy	¼ cup	n/a.
Major main entree type sauce	125 g	n/a.
Soup	245 g	n/a.
Entree measurable with a cup	1 cup	n/a.

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–78 and the 1987–88 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

[2] Manufacturers are required to convert the Reference Amounts to the label serving size in a household measure most appropriate to their specific product using the procedures established by regulation.

[3] Examples listed under Product Category are not all inclusive or exclusive. Examples are provided to assist manufacturers in identifying appropriate product Reference Amount.

[4] If packed or canned in liquid, the Reference Amount is for the drained solids.

[5] Pizza sauce is part of the pizza and is not considered to be sauce topping.

(c) The Reference Amount for products that represent two or more foods packaged and presented to be consumed together (e.g., lunch meat, cheese, and crackers) shall be the sum of the Reference Amounts for individual foods in the package if the Reference Amount is not listed in paragraph (b) of this section and the product is not a meal-type product.

(d) The Administrator, on his or her own initiative or on behalf of any interested person who has submitted a labeling application, may issue a proposal to establish or amend a Product Category or Reference Amount identified in paragraph (b) of this section.

(1) Labeling applications and supporting documentation to be filed under this section shall be submitted in quadruplicate, except that the supporting documentation may be submitted on a computer disc copy. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The labeling application shall state the applicant's post office address.

(2) Pertinent information will be considered as part of an application on the basis of specific reference to such information submitted to and retained in the files of the Food Safety and Inspection Service. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(3) The availability for public disclosure of labeling applications, along with supporting documentation, submitted to the Agency under this section will be governed by the rules specified in subchapter D, title 9.

(4) Data accompanying the labeling application, such as food consumption data, shall be submitted on separate sheets, suitably identified. If such data has already been submitted with an earlier labeling application from the applicant, the present labeling application must provide the data.

(5) The labeling application must be signed by the applicant or by his or her attorney or agent, or (if a corporation) by an authorized official.

(6) The labeling application shall include a statement signed by the person responsible for the labeling application, that to the best of his or her knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him or her pertinent to the evaluation of the labeling application.

(7) Labeling applications for a new Reference Amount and/or Product Category shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 317.312 with respect to Reference Amount and/or Product Category.

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement of the objective of the labeling application;

(ii) A description of the product;

(iii) A complete sample product label including nutrition label, using the format established by regulation;

(iv) A description of the form in which the product will be marketed;

(v) The intended dietary uses of the product with the major use identified (e.g., ham as a luncheon meat);

(vi) If the intended use is primarily as an ingredient in other foods, list of foods or food categories in which the product will be used as an ingredient with information on the prioritization of the use;

(vii) The population group for which the product will be offered for use (e.g., infants, children under 4 years of age);

(viii) The names of the most closely-related products (or in the case of foods for special dietary use and imitation or substitute foods, the names of the products for which they are offered as substitutes);

(ix) The suggested Reference Amount (the amount of edible portion of food as consumed, excluding bone, skin or other inedible components) for the population group for which the product is intended with full description of the methodology and procedures that were used to determine the suggested Reference Amount. In determining the Reference Amount, general principles and factors in paragraph (a) of this section should be followed.

(x) The suggested Reference Amount shall be expressed in metric units. Reference Amounts for foods shall be expressed in grams except when common household units such as cups, tablespoons, and teaspoons are more appropriate or are more likely to promote uniformity in serving sizes declared on product labels. For example, common household measures would be more appropriate if products within the same category differ substantially in density such as mixed dishes measurable with a cup.

(A) In expressing the Reference Amount in grams, the following general rules shall be followed:

(*1*) For quantities greater than 10 grams, the quantity shall be expressed in nearest 5 grams increment.

(*2*) For quantities less than 10 grams, exact gram weights shall be used.

(B) [Reserved]

(xi) A labeling application for a new subcategory of food with its own Reference Amount shall include the following additional information:

(A) Data that demonstrate that the new subcategory of food will be consumed in amounts that differ enough from the Reference Amount for the parent category to warrant a separate Reference Amount. Data must include sample size, and the mean, standard deviation, median, and modal consumed amount per eating occasion for the product identified in the labeling application and for other products in the category. All data must be derived from the same survey data.

(B) Documentation supporting the difference in dietary usage and product characteristics that affect the consumption size that distinguishes the product identified in the labeling application from the rest of the products in the category.

(xii) In conducting research to collect or process food consumption data in support of the labeling application, the following general guidelines should be followed.

(A) Sampled population selected should be representative of the demographic and socioeconomic characteristics of the target population group for which the food is intended.

(B) Sample size (i.e., number of eaters) should be large enough to give reliable estimates for customarily consumed amounts.

(C) The study protocol should identify potential biases and describe how potential biases are controlled for or, if not possible to control, how they affect interpretation of results.

(D) The methodology used to collect or process data including study design, sampling procedures, materials used (e.g., questionnaire, interviewer's manual), procedures used to collect or process data, methods or procedures used to control for unbiased estimates, and procedures used to correct for nonresponse, should be fully documented.

(xiii) A statement concerning the feasibility of convening associations, corporations, consumers, and other interested parties to engage in negotiated rulemaking to develop a proposed rule.

Yours very truly,

Applicant _____

By _____

(Indicate authority)

(8) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(9) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(10) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed Reference Amount and/or Product Category is false or misleading.

The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed Reference Amount and/or Product Category.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(11) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish in the **Federal Register** a proposed rule to amend the regulations to authorize the use of the Reference Amount and/or Product Category. The proposal shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's proposed rule shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the proposed Reference Amount and/or Product Category. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the proposed Reference Amount and/or Product Category shall be approved for use on the labeling of meat food products.

(i) If the Reference Amount and/or Product Category is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the Reference Amount and/or Product Category on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed Reference Amount and/or Product Category.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of an answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of the notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(ii) If the Reference Amount and/or Product Category is approved, the Agency shall notify the applicant, in writing, and shall also publish in the **Federal Register** a final rule amending the regulations to authorize the use of the Reference Amount and/or Product Category.

§ 317.313 Nutrient content claims; general principles.

(a) This section applies to meat products that are intended for human consumption and that are offered for sale, except that nutrient content claims may not be made on products intended specifically for use by infants and toddlers less than 2 years of age.

(b) A claim which, expressly or by implication, characterizes the level of a nutrient (nutrient content claim) of the type required in nutrition labeling pursuant to § 317.309, may not be made on a label or in labeling of that product unless the claim is made in accordance with 21 CFR 101.13 (b) through (f).

(c) through (h) [Reserved]

(i) The labeling of a product may contain a statement about the amount or percentage of a nutrient in accordance with 21 CFR 101.13(i) (1) through (3).

(j) Products may bear a statement that compares the level of a nutrient in the product with the level of a nutrient in a reference food in accordance with 21 CFR 101.13(j), except comparison to product of another manufacturer at 21 CFR 101.13(j)(1)(ii)(B).

(k) The term "modified" may be used in the statement of identity of a product in accordance with 21 CFR 101.13(k).

(l) For purposes of making a claim, a "meal-type product" shall be defined as a product that:

(1) Makes a significant contribution to the diet by weighing at least 6 ounces, but no more than 12 ounces per serving (container), and

(2) Contains ingredients from two or more of the following four food groups:

(i) Bread, cereal, rice and pasta group,

(ii) Fruits and vegetables group,

(iii) Milk, yogurt, and cheese group, and

(iv) Meat, poultry, fish, dry beans, eggs, and nuts group, and

(3) Is represented as, or is in a form commonly understood to be a breakfast, lunch, dinner, meal, main dish, entree, or pizza. Such representations may be made either by statements, photographs, or vignettes.

(m) [Reserved]

(n) Nutrition labeling in accordance with § 317.309, shall be provided for any food for which a nutrient content claim is made.

(o) Compliance with requirements for nutrient content claims shall be in accordance with § 317.309(h).

(p) The Reference Amount shall be used to determine whether a product meets the criteria for a nutrient content claim as discussed in 21 CFR 101.13(p)(1).

(q) The following exemptions apply:

(1) Nutrient content claims that have not been defined by regulation and that appear as part of a brand name that was in use prior to November 27, 1991, may continue to be used as part of that brand name, provided they are not false or misleading under section 1(n) of the Act (21 U.S.C. 601(n)(1)).

(2) [Reserved]

(3) A statement that describes the percentage of a vitamin or mineral in the food in relation to a reference daily intake (RDI) as defined in 21 CFR 101.9(c) may be made on the label.

(4) The requirements of this section do not apply to products for special dietary use as described in § 317.2(j)(2).

(5) [Reserved]

(6) Nutrient content claims that were part of the name of a product that was subject to a standard of identity as of November 27, 1991, are not subject to

the requirements of paragraph (b) of this section whether or not they meet the definition of the descriptive term.

(7) Implied nutrient content claims may be used as part of a brand name, provided that the use of the claim has been authorized by FSIS. Labeling applications requesting approval of such a claim may be submitted pursuant to § 317.369.

§§ 317.314–317.342 [Reserved]

§ 317.343 Significant participation for voluntary nutrition labeling.

(a) In evaluating significant participation for voluntary nutrition labeling, FSIS will consider only the major cuts of single-ingredient, raw meat products, as identified in § 317.344, including those that have been previously frozen.

(b) FSIS will judge a food retailer to be participating at a significant level if the retailer provides nutrition labeling information for at least 90 percent of the major cuts of single-ingredient, raw meat products, listed in § 317.344, that it sells, and if the nutrition label is consistent in content and format with the mandatory program, or nutrition information is displayed at point-of-purchase in an approriate manner.

(c) To determine whether there is significant participation by retailers under the voluntary nutrition labeling guidelines, FSIS will select a representative sample of companies allocated by type and size.

(d) FSIS will find that significant participation by food retailers exists if at least 60 percent of all companies that are evaluated are participating in accordance with the guidelines.

(e) FSIS will evaluate significant participation of the voluntary program every 2 years beginning in May 1995.

(1) If significant participation is found, the voluntary nutrition labeling guidelines shall remain in effect.

(2) If significant participation is not found, FSIS shall initiate rulemaking to require nutrition labeling on those products under the voluntary program.

§ 317.344 Identification of major cuts of meat products.

The major cuts of single-ingredient, raw meat products are: Beef chuck blade roast, beef loin top loin steak, beef rib roast large end, beef round eye round steak, beef round top round steak, beef round tip roast, beef chuck arm pot roast, beef loin sirloin steak, beef round bottom round steak, beef brisket (whole, flat half, or point half), beef rib steak small end, beef loin tenderloin steak, ground beef regular without added seasonings, ground beef extra lean without added seasoning, pork loin chop, pork loin country style ribs, pork loin top loin chop boneless, pork loin rib chop, pork spareribs, pork loin tenderloin, pork loin sirloin roast, pork shoulder blade steak, pork loin top roast boneless, ground pork, lamb shank, lamb shoulder arm chop, lamb shoulder blade chop, lamb rib roast, lamb loin chop, lamb leg (whole, sirloin half, or shank half), veal shoulder arm steak, veal shoulder blade steak, veal rib roast, veal loin chop, and veal cutlets.

§ 317.345 Guidelines for voluntary nutrition labeling of single-ingredient, raw products.

(a) Nutrition information on the cuts of single-ingredient, raw meat products, including those that have been previously frozen, shall be provided in the following manner:

(1) If a retailer chooses to provide nutrition information on the label of these products, these products shall be subject to all requirements of the mandatory nutrition labeling program, except that nutrition labeling may be declared on the basis of either "as consumed" or "as packaged." In addition, the declaration of the number of servings per container need not be included in nutrition labeling of single-ingredient, raw meat products (including ground beef), including those that have been previously frozen.

(2) If a retailer chooses to provide nutrition information at the point-of-purchase, such as by posting a sign, or by making the information readily available in brochures, notebooks, or leaflet form in close proximity to the food. If a nutrition claim is made on point-of-purchase materials all of the requirements of the mandatory nutrition labeling program apply. However, if only nutrition information—and not a nutrition claim—is supplied on point-of-purchase materials:

(i) The requirements of the mandatory nutrition labeling program apply, but the nutrition information may be supplied on an "as packaged" or "as consumed," basis;

(ii) The listing of DRV's may be voluntary; and

(iii) The point-of-purchase materials are not subject to any of the format requirements. The nutrition labeling information may also be supplemented by a video, live demonstration, or other media.

(b) [Reserved]

(c) The declaration of nutrition information may be presented in a simplified format as specified in § 317.309(g) for the mandatory nutrition labeling program.

(d) The nutrition label data should be based on either the raw or cooked edible portions of meat cuts with external cover fat at trim levels reflecting current marketing practices. If data are based on cooked portions, the methods used to cook the products must be specified and should be those which do not add nutrients from other ingredients such as flour, breading, and salt. Additional nutritional data may be presented on an optional basis for the raw or cooked edible portions of the separable lean of meat cuts.

(e) Nutrient data that are the most current representative data base values contained in USDA's National Nutrient Data Bank or its published form, the Agriculture Handbook No. 8 series, may be used for nutrition labeling of single-ingredient, raw meat products (including ground beef), including those that have been previously frozen. These data may be composite data that reflect different quality grades of beef or other variables affecting nutrient content. Alternatively, data that reflect specific grades or other variables may be used, except that if data are used on labels attached to a product which is labeled as to grade of meat or other variables, the data must represent the product in the package when such data are contained in the representative data base. When data are used on labels attached to a product, the data must represent the edible meat tissues present in the package.

(f) If the nutrition information is in accordance with paragraph (e) of this section, a nutrition label or labeling will not be subject to the Agency compliance review under § 317.309(h), unless a nutrition claim is made on the basis of the representative data base values.

(g) Retailers may use data bases that they believe reflect the nutrient content of single-ingredient, raw meat products (including ground beef), including those that have been previously frozen; however, such labeling shall be subject to the compliance procedures of paragraph (e) of this section and the requirements specified in this subpart for the mandatory nutrition labeling program.

§ 317.346–317.353 [Reserved]

§ 317.354 Nutrient content claims for "good source" and "high".

Nutrient content claims about a nutrient in a product in relation to the Reference Daily Intake (RDI) established for that nutrient in 21 CFR 101.9(c)(11)(iv) or Daily Reference Value (DRV) established for that nutrient in 21 CFR 101.9(c)(12)(i), excluding total carbohydrate and unsaturated fatty acids, may be used on the label or in

labeling, in accordance with 21 CFR 101.54 (a) through (d).

§ 317.355 [Reserved]

§ 317.356 Nutrient content claims for "light" or "lite".

(a) *General requirements.* The following nutrient content claims using the term "light" or "lite" to describe a product may be used on the label and in labeling, provided that the product is labeled in compliance with 21 CFR 101.56.

(b) The terms "light" or "lite" may be used in the brand name of foods to describe the sodium content, provided that:

(1) The product meets the sodium criteria provided in paragraph (a) of this section, and

(2) A statement specifically stating that the product is "light in sodium" or "lite in sodium" appears:

(i) Contiguous to the brand name;

(ii) In uniform type size, style, color, and prominence as the product name; and

(iii) The "light in sodium" or "lite in sodium" statement complies with paragraph (a) of this section.

§§ 317.357–317.359 [Reserved]

§ 317.360 Nutrient content claims for calorie content.

Nutrient content claims about the calorie content of a product may be used on the label or in labeling in accordance with 21 CFR 101.60(a) through (c).

§ 317.361 Nutrient content claims for sodium content.

Nutrient content claims about the sodium content of a product may be used on the label and in labeling in accordance with 21 CFR 101.61 (a) and (b).

§ 317.362 Nutrient content claims for fat, fatty acids, and cholesterol content of meat products.

(a) A claim about the level of fat, fatty acid, and cholesterol in a meat product may only be made on the label and in the labeling of the product in accordance with 21 CFR 101.62 (a) through (d), except, 21 CFR 101.62(c), (d)(1)(i), (d)(1)(ii) (A) through (D), (d)(2)(i), (d)(2)(ii) (A) through (D), (d)(4)(i), (d)(4)(ii) (A) through (D), (d)(5)(i), and (d)(5)(ii) (A) through (D).

(b) The terms "low in cholesterol" or "low cholesterol" may be used on the label or in labeling of a meal-type product as defined in § 317.313, provided that the product meets the requirements of 21 CFR 101.62(d)(2), except that requirements of 21 CFR 101.62(d)(2) (i)(A) and (ii)(A) shall be limited to 20 milligrams of cholesterol per 100 grams, and the requirements of 21 CFR 101.62(d)(2) (i)(B) and (ii)(B) shall be modified to require that the product contain 2 grams or less of saturated fat per 100 grams.

(c) *"Lean" and "Extra Lean" Claims.* The following nutrient content claims may be used on the label or in labeling, provided that the product is labeled in accordance with § 317.309, and the nutrient content claim complies with § 317.313:

(1) The term "lean" may be used on the label or in labeling of a meat product, provided that the product contains less than 10 grams fat, less than 4 grams saturated fat, and less than 95 milligrams cholesterol per 100 grams and Reference Amount Customarily Consumed (RACC) for individual foods, and per 100 grams and labeled serving size for meal-type products.

(2) The term "extra lean" may be used on the label or in labeling of a meat product, provided that the product contains less than 5 grams fat, less than 2 grams saturated fat, and less than 95 milligrams cholesterol per 100 grams and Reference Amount Customarily Consumed (RACC) for individual foods, and per 100 grams and per labeled serving size for meal-type products.

§§ 317.363–317.368 [Reserved]

§ 317.369 Labeling applications for nutrient content claims.

(a) This section pertains to labeling applications for claims, express or implied, that characterize the level of any nutrient required to be on the label or in labeling of product by this subpart.

(b) Labeling applications included in this section are:

(1) Labeling applications for a new (heretofore unauthorized) nutrient content claim,

(2) Labeling applications for a synonymous term (i.e., one that is consistent with a term defined by regulation) for characterizing the level of a nutrient, and

(3) Labeling applications for the use of an implied claim in a brand name.

(c) Labeling applications and supporting documentation to be filed under this section shall be submitted in quadruplicate, except that the supporting documentation may be submitted on a computer disc copy. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The labeling application shall state the applicant's post office address.

(d) Pertinent information will be considered as part of an application on the basis of specific reference to such information submitted to and retained in the files of the Food Safety and Inspection Service. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(e) If nonclinical laboratory studies accompany a labeling application, the applicant shall include, with respect to each nonclinical study included with the application, either a statement that the study has been, or will be, conducted in compliance with the good laboratory practice regulations as set forth in part 58 of chapter 1, title 21, or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(f) If clinical investigations accompany a labeling application, the applicant shall include, with respect to each clinical investigation included with the application, either a statement that the investigation was conducted in compliance with the requirements for institutional review set forth in part 56 of chapter 1, title 21, or was not subject to such requirements in accordance with § 56.194 or § 56.105, and that it was conducted in compliance with the requirements for informed consents set forth in part 50 of chapter 1, title 21.

(g) The availability for public disclosure of labeling applications, along with supporting documentation, submitted to the Agency under this section will be governed by the rules specified in subchapter D, title 9.

(h) The data specified under this section to accompany a labeling application shall be submitted on separate sheets, suitably identified. If such data has already been submitted with an earlier labeling application from the applicant, the present labeling application must provide the data.

(i) The labeling application must be signed by the applicant or by his or her attorney or agent, or (if a corporation) by an authorized official.

(j) The labeling application shall include a statement signed by the person responsible for the labeling application, that to the best of his or her knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him or

her pertinent to the evaluation of the labeling application.

(k)(1) Labeling applications for a new nutrient content claim shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250.

(Date)

The undersigned, _____, submits this labeling application pursuant to 9 CFR 317.369 with respect to (statement of the claim and its proposed use).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the nutrient content claim and the nutrient that the term is intended to characterize with respect to the level of such nutrient. The statement shall address why the use of the term as proposed will not be misleading. The statement shall provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of products on which the claim will be used. The statement shall also specify the level at which the nutrient must be present or what other conditions concerning the product must be met for the appropriate use of the term in labels or labeling, as well as any factors that would make the use of the term inappropriate.

(ii) A detailed explanation supported by any necessary data of why use of the food component characterized by the claim is of importance in human nutrition by virtue of its presence or absence at the levels that such claim would describe. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed and why such benefit is not available through the use of existing terms defined by regulation. If the claim is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group, and scientific data sufficient for such purpose, and data and information to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

(iii) Analytical data that demonstrates the amount of the nutrient that is present in the products for which the claim is intended. The assays should be performed on representative samples in accordance with 317.309(h). If no USDA or AOAC methods are available, the applicant shall submit the assay method used, and data establishing the validity of the method for assaying the nutrient in the particular food. The validation data shall include a statistical analysis of the analytical and product variability.

(iv) A detailed analysis of the potential effect of the use of the proposed claim on food consumption, and any corresponding changes in nutrient intake. The analysis shall specifically address the intake of nutrients that have beneficial and negative consequences in the total diet. If the claim is intended for a specific group within the population, the analysis shall specifically address the dietary practices of such group, and shall include data sufficient to demonstrate that the dietary analysis is representative of such group.

Yours very truly,

Applicant _____

By _____

(Indicate authority)

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed nutrient content claim is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed nutrient content claim.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish in the **Federal Register** a proposed rule to amend the regulations to authorize the use of the nutrient content claim. The proposal shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's proposed rule shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the proposed nutrient content claim. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the proposed nutrient content claim shall be approved for use on the labeling of meat and food products.

(i) If the claim is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the claim on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed nutrient content claim.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the preceding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of the notice of such final determination, the application appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States

Court of Appeals for the District of Columbia Circuit.

(ii) If the claim is approved, the Agency shall notify the applicant, in writing, and shall also publish in the **Federal Register** a final rule amending the regulations to authorize the use of the claim.

(l) (1) Labeling applications for a synonymous term shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 317:369 with respect to (statement of the synonymous term and its proposed use in a nutrient content claim that is consistent with an existing term that has been defined under subpart B of part 317).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the synonymous term, the existing term defined by a regulation with which the synonymous term is claimed to be consistent, and the nutrient that the term is intended to characterize the level of. The statement shall address why the use of the synonymous term as proposed will not be misleading. The statement shall provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of products on which the claim will be used. The statement shall also specify whether any limitations not applicable to the use of the defined term are intended to apply to the use of the synonymous term.

(ii) A detailed explanation supported by any necessary data of why use of the proposed term is requested, including whether the existing defined term is inadequate for the purpose of effectively characterizing the level of a nutrient. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed, and why such benefit is not available through the use of existing terms defined by regulation. If the claim is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group, scientific data sufficient for such purpose, and data and information to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

Yours very truly,

Applicant _____

By _____

(Indicate authority)

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed synonymous term is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed synonymous term.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the claim is approved, the Agency shall notify the applicant, in writing, and shall publish in the **Federal Register** a notice informing the public that the synonymous term has been approved for use.

(m) (1) Labeling applications for the use of an implied nutrient content claim in a brand name shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 317.369 with respect to (statement of the implied nutrient content claim and its proposed use in a brand name).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the implied nutrient content claim, the nutrient the claim is intended to characterize, the corresponding term for characterizing the level of such nutrient as defined by a regulation, and the brand name of which the implied claim is intended to be a part. The statement shall address why the use of the brand-name as proposed will not be misleading. The statement shall provide examples of the types of products on which the brand name will appear. It shall also include data showing that the actual level of the nutrient in the food would qualify the label of the product to bear the corresponding term defined by regulation. Assay methods used to determine the level of a nutrient shall meet the requirements stated under labeling application format in paragraph (k)(1)(iii) of this section.

(ii) A detailed explanation supported by any necessary data of why use of the proposed brand name is requested. This explanation shall also state what nutritional benefit to the public will derive from use of the brand name as proposed. If the branded product is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group and scientific data sufficient for such purpose.

Yours very truly,

Applicant _____

By _____

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the

reasons therefor, including why the Agency has determined that the proposed implied nutrient content claim is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed implied nutrient content claim.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish a notice of the labeling application in the Federal Register seeking comment on the use of the implied nutrient content claim. The notice shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's notice shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the implied nutrient content claim. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the implied nutrient content claim shall be approved for use on the labeling of meat food products.

(i) If the claim is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the claim on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed implied nutrient content claim.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of the notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(ii) If the claim is approved, the Agency shall notify the applicant, in writing, and shall also publish in the Federal Register a notice informing the public that the implied nutrient content claim has been approved for use.

§§ 317.370–317.379 [Reserved]

§ 317.380 Label statements relating to usefulness in reducing or maintaining body weight.

(a) *General requirements.* Any product that purports to be or is represented for special dietary use because of usefulness in reducing body weight shall bear:

(1) Nutrition labeling in conformity with § 317.309 of this subpart, unless exempt under that section, and

(2) A conspicuous statement of the basis upon which the product claims to be of special dietary usefulness.

(b) *Nonnutritive ingredients.* (1) Any product subject to paragraph (a) of this section that achieves its special dietary usefulness by use of a nonnutritive ingredient (i.e., one not utilized in normal metabolism) shall bear on its label a statement that it contains a nonnutritive ingredient and the percentage by weight of the nonnutritive ingredient.

(2) A special dietary product may contain a nonnutritive sweetener or other ingredient only if the ingredient is safe for use in the product under the applicable law and regulations of this chapter. Any product that achieves its special dietary usefulness in reducing or maintaining body weight through the use of a nonnutritive sweetener shall bear on its label the statement required by paragraph (b)(1) of this section, but need not state the percentage by weight of the nonnutritive sweetener. If a nutritive sweetener(s) as well as nonnutritive sweetener(s) is added, the statement shall indicate the presence of both types of sweetener; e.g., "Sweetened with nutritive sweetener(s) and nonnutritive sweetener(s)."

(c) *"Low calorie" foods.* A product purporting to be "low calorie" must comply with the criteria set forth for such foods in § 317.360(b) (2) and (3).

(d) *"Reduced calorie" foods and other comparative claims.* A product purporting to be "reduced calorie" or otherwise containing fewer calories than a reference food must comply with the criteria set forth for such foods in § 317.360(b) (4) and (5).

§§ 317.381–317.399 [Reserved]

§ 317.400 Exemption from nutrition labeling.

(a) The following meat food products are exempt from nutrition labeling:

(1) Food products produced by small businesses provided that the labels for these products bear no nutrition claims or nutrition information,

(i) A food product, for the purposes of the small business exemption, is defined as a formulation, not including distinct flavors which do not significantly alter the nutritional profile, sold in any size package in commerce.

(ii) For purposes of this paragraph, a small business is any single-plant facility or multi-plant company/firm that employs 500 or fewer people and produces no more than the following amounts of pounds of the product qualifying the firm for exemption from this subpart:

(A) During the first year of implementation of nutrition labeling, from July 1994 to July 1995, 250,000 pounds or less,

(B) During the second year of implementation of nutrition labeling, from July 1995 to July 1996, 175,000 pounds or less, and

(C) During the third year of implementation and subsequent years thereafter, 100,000 pounds or less.

(2) Products intended for further processing, provided that the labels for these products bear no nutrition claim or nutrition information,

(3) Products that are not for sale to consumers, provided that the labels for these products bear no nutrition claims or nutrition information,

(4) Products in small packages that are individually wrapped packages of less than ½ ounce net weight, provided that the labels for these products bear no nutrition claims or nutrition information,

(5) Products custom slaughtered or prepared,

(6) Products intended for export, and

(7) The following products prepared and served or sold at retail provided that the labels or the labeling of these products bear no nutrition claims or nutrition information:

(i) Ready-to-eat products that are packaged or portioned at a retail store or similar retail-type establishment; and

(ii) Multi-ingredient products (e.g., sausage) processed at a retail store or similar retail-type establishment.

(b) Restaurant menus generally do not constitute labeling or fall within the scope of these regulations.

(c) Foods represented to be specifically for infants and children less than 2 years of age shall bear nutrition labeling, except such labeling shall not include calories from fat, calories from saturated fat, saturated fat, polyunsaturated fat, monounsaturated fat, and cholesterol. Foods represented to be specifically for infants and children less than 4 years of age shall bear nutrition labeling, except that such labeling shall not include listings of percent of daily value and the daily value list. Nutrient names and quantitative amounts by weight shall be presented in two separate columns.

PART 320—RECORDS, REGISTRATION, AND REPORTS

3. The authority citation for part 320 continues to read follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

4. Section 320.1 is amended by adding a new paragraph (b)(8) to read as follows:

§ 320.1 Records required to be kept.

* * * * *

(b) * * *

(8) Records of nutrition labeling as required by subpart B, part 317, of this subchapter.

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

5. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 450, 21 U.S.C. 451–470, 7 CFR 2.17, 2.55.

6. Section 381.175 is amended by adding a new paragraph (b)(5) to read as follows:

§ 381.175 Records required to be kept.

* * * * *

(b) * * *

(5) Records of nutrition labeling as required by subpart Y of this part.

7. Part 381 is amended by adding a new subpart Y to read as follows:

Subpart Y—Nutrition Labeling

Sec.
381.400 Nutrition labeling of poultry products.
381.401 [Reserved]
381.402 Location of nutrition information.
381.403–381.407 [Reserved]
381.408 Labeling of poultry products with number of servings.
381.409 Nutrition label content.
381.410 [Reserved]
381.411 [Reserved]
381.412 Reference amounts customarily consumed per eating occasion.
381.413 Nutrient content claims; general principles.
381.414–381.442 [Reserved]
381.443 Significant participation for voluntary nutrition labeling.
381.444 Identification of major cuts of poultry products.
381.445 Guidelines for voluntary nutrition labeling of single-ingredient, raw products.
381.446–381.453 [Reserved]
381.454 Nutrient content claims for "good source" and "high".
381.455 [Reserved]
381.456 Nutrient content claims for "light" or "lite".
381.457–381.459 [Reserved]
381.460 Nutrient content claims for calorie content.
381.461 Nutrient content claims for sodium content.
381.462 Nutrient content claims for fat, fatty acids, and cholesterol content of poultry products.
381.463–381.468 [Reserved]
381.469 Labeling applications for nutrient content claims.
381.470–381.479 [Reserved]
381.480 Label statements relating to usefulness in reducing or maintaining body weight.
381.481–381.499 [Reserved]
381.500 Exemption from nutrition labeling.

Subpart Y—Nutrition Labeling

§ 381.400 Nutrition labeling of poultry products.

(a) Nutrition labeling shall be provided for all poultry products, except single-ingredient, raw products, in accordance with the requirements of § 381.409, except as exempted under § 381.500 of this subpart.

(b) Nutrition labeling may be provided for single-ingredient, raw poultry products in accordance with the requirements of §§ 381.409 and 381.445. Significant participation in voluntary nutrition labeling shall be measured by the Agency in accordance with §§ 381.443 and 381.444 of this subpart.

§ 381.401 [Reserved]

§ 381.402 Location of nutrition information.

(a) Nutrition information on a label of packaged poultry products shall appear on the label's principal display panel or on the information panel, except as provided in paragraph (b) of this section.

(b) Nutrition information for gift packs may be shown at a location other than on the product label, provided that the labels for these products bear no nutrition claim. In lieu of on the product label, nutrition information may be provided by alternate means such as product label inserts.

§§ 381.403–381.407 [Reserved]

§ 381.408 Labeling of poultry products with number of servings.

The label of any package of a poultry product that bears a representation as to the number of servings contained in such package shall meet the requirements of § 381.121(c)(7).

§ 381.409 Nutrition label content.

(a)(1) All nutrient and product component quantities shall be declared in relation to a serving or to a portion, as defined in 21 CFR 101.9(b) (1) and (2) except (b)(2)(i), and 21 CFR 101.9(b) (5) through (9) except (b)(5)(iii).

(2) The declaration of nutrient and product component content shall be on the basis of the product "as packaged" for all products, except that single-ingredient, raw products may be declared on the basis of the product "as consumed" as set forth in § 381.445(a)(1). In addition to the required declaration on the basis of "as packaged" for products other than single-ingredient, raw products, the declaration may also be made on the basis of "as consumed," provided that preparation and cooking instructions are clearly stated.

(3) For products in discrete units (e.g., chicken wings, chicken breasts, and individually packaged products within a multi-serving package), serving size shall be the number of whole units that most closely approximates the Reference Amount for the Product Category. If a unit weighs 67 percent or more, but less than 200 percent of the Reference Amount, serving size shall be one unit. If a unit weighs more than 50 percent but less than 67 percent of the Reference Amount, the manufacturer may decide whether one unit is one

serving. If a unit weighs 200 percent or more of the Reference Amount, the manufacturer may declare the whole unit as one serving if the whole unit can reasonably be consumed at a single-eating occasion.

(4) Serving size for meal-type products as defined in § 381.413(l) shall be the entire content (edible portion only) of the package.

(5) Another column of figures may be used to declare the nutrient and food component information, in the same format as required by § 381.408(e),

(i) Per 100 grams, 100 milliliters, or 1 ounce of the food as packaged or purchased.

(ii) Per one unit if the serving size of a product in discrete units in a multi-serving container is more than one unit.

(6) If cups, tablespoons and teaspoons, or units such as piece, slice, tray, jar, or fraction are not applicable, ounces may be used. Ounce measurements shall be expressed in 0.5 ounce increments most closely approximating the Reference Amount, with rounding indicated by use of the term "about" (e.g., about 2.5 ounces).

(b) The declaration of nutrition information on the label shall contain the following information, except for that which is identified as "VOLUNTARY" or for those poultry products where a simplified format may be used as provided for in paragraph (g) of this section or as in § 381.500(b). No nutrients or food components, other than those listed in 21 CFR 101.9(c) as either voluntary or mandatory, except for stearic acid, may be included within the nutrition label. Information shall be presented using the nutrient names specified and in the formats specified in paragraph (e) of this section. Definitions, units of measure, increments for declaring values, and methods of calculation shall be in accordance with 21 CFR 101.9 (c)(1) through (c)(9), except 21 CFR 101.9(c)(1)(i)(E), bomb calorimetry, and 21 CFR 101.9(c)(7)(ii) use of nitrogen conversion factors, other than 6.25.

(c)(1) If a product consists of assortments of poultry products (e.g., variety packs) in the same package, nutrient content shall be expressed on the entire package contents or on each individual product.

(2) If a product is commonly combined with other ingredients or is cooked or otherwise prepared before eating, and directions for such combination or preparations are provided, another column of figures may be used to declare the nutrient contents on the basis of the product as consumed for the product alone (e.g., a cream soup mix may be labeled with one set of Daily Values for the dry mix (per serving), and another set for the serving of the final soup when prepared (e.g., per serving of cream soup mix and 1 cup of vitamin D fortified whole milk)): *Provided*, that the type and quantity of the other ingredients to be added to the product by the user and the specific method of cooking and other preparation shall be specified prominently on the label.

(d) "Stearic acid" may be declared "VOLUNTARY." If stearic acid is declared "VOLUNTARY" a statement of the number of grams of stearic acid shall be included under saturated fat content and expressed to the nearest 0.5 (½) gram incremented below 3 grams and to the nearest gram increment above 3 grams.

(e) Formats for nutrition labeling shall be in accordance with 21 CFR 101.9 (d) and (e) except for references to (f), (j)(5), and (j)(13), or in accordance with paragraph (g)(1) of this section.

(f) Foods in packages that have a total surface area available to bear labeling of 40 or less square inches may modify the requirements of paragraphs (b), (e), and (g) of this section and 381.402(a) by one or more of the following means:

(1) Presenting the required nutrition information in a tabular or linear (i.e., string) fashion, rather than in vertical columns, if the package shape or size cannot accommodate a column display on any label panel. Nutrition information may be given in a linear fashion only if the label will not accommodate a *tabular display and, in that case, subcomponents (e.g., saturated fat shall be declared in parentheses after total fat).*

(2) Using any of the following abbreviations:

Serving size—Serv. size
Servings per container—Servings
Calories from fat—Fat cal
Saturated fat—Sat fat
Cholesterol—Cholest
Total carbohydrate—Total carb
Dietary fiber—Fiber

(3) Omitting the footnote and caloric conversion information required in paragraphs (d)(9) and (d)(10) of 21 CFR 101.9 and placing another asterisk at the bottom of the label followed by the statement "Percent Daily Values are based on a 2,000 calorie diet" and, if the term "Daily Value" is not spelled out in the heading, a statement that "DV" represents "Daily Value," and

(4) Presenting the required nutrition information on any other label panel.

(g)(1) Nutrition information may be presented in a simplified format as set forth herein when any required nutrients, other than the core nutrients, are present in insignificant amounts. An insignificant amount shall be defined as that amount that may be rounded to zero in nutrition labeling, except that for total carbohydrate, dietary fiber, and protein, it shall be an amount less than 1 gram.

(2) The simplified format shall include: Serving size, number of servings per container, calories, total fat (grams), total carbohydrate (grams), protein (grams), and sodium (milligrams).

(3) Any nutrient, other than a core nutrient, that is present in an insignificant amount may be omitted from the tabular listing, provided that the following statement is included within the nutrition label, "Not a significant source of _____." The blank shall be filled in with the appropriate nutrient or food component.

(4) The omission of the listing of daily values and the caloric conversion information, and the expression of the percent of daily value in the simplified format shall be in accordance with 21 CFR 101.9(f)(5), except for references to (j)(5) and (j)(13).

(h) Compliance with this section shall be determined as follows:

(1) A production lot is a set of food production consumer units that are from one production shift. Alternatively, a collection of consumer units of the same size, type, and style produced under conditions as nearly uniform as possible, designated by a common container code or marking, constitutes a production lot.

(2) The sample for nutrient analysis shall consist of a composite of a minimum of six consumer units, each from a production lot. Alternatively, the sample for nutrient analysis shall consist of a composite of a minimum of six consumer units, each randomly chosen to be representative of a production lot. In each case, the units may be individually analyzed and the results of the analyses averaged, or the units would be composited and the composite analyzed. In both cases, the results, whether an average or a single result from a composite, will be considered by the Agency to be the nutrient content of a composite. All analyses shall be performed by appropriate methods and procedures used by the Department for each nutrient in accordance with the "Chemistry Laboratory Guidebook," or, if no USDA method is available and appropriate for the nutrient, by appropriate methods for the nutrient in accordance with the 1990 edition of the "Official Methods of Analysis" of the AOAC International, formerly Association of Official Analytical

Chemists, 15th ed., which is incorporated by reference, unless a particular method of analysis is specified in § 381.409(b), or, if no USDA, AOAC, or specified method is available and appropriate, by other reliable and appropriate analytical procedures as so determined by the Agency. The "Official Methods of Analysis" is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the **Federal Register** in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be purchased from the AOAC International, 2200 Wilson Blvd., Suite 400, Arlington, VA 22201. It is also available for inspection at the Office of the Federal Register Information Center, suite 700, 800 North Capitol Street, NW., Washington, DC.

(3) Two classes of nutrients are defined for purposes of compliance:

(i) Class I. Added nutrients in fortified or fabricated foods; and

(ii) Class II. Naturally occurring (indigenous) nutrients. If any ingredient which contains a naturally occurring (indigenous) nutrient is added to a food, the total amount of such nutrient in the final food product is subject to Class II requirements unless the same nutrient is also added, which would make the total amount of such nutrient subject to Class I requirements.

(4) A product with a label declaration of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium shall be deemed to be misbranded under section 4(h) of the Poultry Products Inspection Act (21 U.S.C. 453(h)(4)) unless it meets the following requirements:

(i) Class I vitamin, mineral, protein, dietary fiber, or potassium. The nutrient content of the composite is at least equal to the value for that nutrient declared on the label.

(ii) Class II vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium. The nutrient content of the composite is at least equal to 80 percent of the value for that nutrient declared on the label; *Provided,* That no regulatory action will be based on a determination of a nutrient value which falls below this level by an amount less than the variability generally recognized for the analytical method used in that product at the level involved, and inherent nutrient variation in a product.

(5) A product with a label declaration of calories, sugars, total fat, saturated fat, cholesterol, or sodium shall be deemed to be misbranded under section 4(h) of the Poultry Products Inspection Act (21 U.S.C. 453(h)(4)) if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label; *Provided,* That no regulatory action will be based on a determination of a nutrient value which falls below this level by an amount less than the variability generally recognized for the analytical method used in that product at the level involved, and inherent nutrient variation in a product.

(6) The amount of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium may vary over labeled amounts within good manufacturing practice. The amount of calories, sugars, total fat, saturated fat, cholesterol, or sodium may vary under labeled amounts within good manufacturing practice.

(7) Compliance will be based on the metric measure specified in the label statement of serving size.

(8) The management of the establishment must maintain records to support the validity of nutrient declarations contained on product labels. Such records shall be made available to the inspector or any duly authorized representative of the Agency upon request.

(9) The compliance provisions set forth in paragraph (h)(1) through (8) of this section shall not apply to single-ingredient, raw poultry products, including those that have been previously frozen, when nutrition labeling is based on the most current representative data base values contained in USDA's National Nutrient Data Bank or its published form, the Agriculture Handbook No. 8 series.

§ 381.410 [Reserved]

§ 381.411 [Reserved]

§ 381.412 Reference amounts customarily consumed per eating occasion.

(a) The general principles followed in arriving at the Reference Amounts for serving (portion) sizes set forth in paragraph (b) of this section are found in 21 CFR 101.12(a), (c), (d) and (g).

(b) The following Product Categories and Reference Amounts shall be used as the basis for determining serving sizes for specific products:

TABLE 1.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION—INFANT AND TODDLER FOODS [1,2,3]

Product category	Reference amount
Infant & Toddler Foods:	
Dinner Dry Mix	15 g
Dinner, ready-to-serve, strained type	60 g
Dinner, soups, ready-to-serve junior type	110 g
Dinner, stew or soup ready-to-serve toddlers	170 g

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–1978 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

[2] Unless otherwise noted in the Reference Amount column, the Reference Amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e., heat and serve). If not listed separately, the Reference Amount for the unprepared form (e.g., dehydrated cereal) is the amount required to make one Reference Amount of the prepared form.

[3] Manufacturers are required to convert the Reference Amount to the label serving size in a household measure most appropriate to their specific product using the procedures established by the regulation.

TABLE 2.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION—GENERAL FOOD SUPPLY [1,2,3,4,5]

Product category	Reference	Reference
	Ready-to-serve	Ready-to-cook
Egg mixtures, (western style omelet, souffle, egg foo young with poultry)	110 g	n/a
Salad and potato toppers; e.g., poultry bacon bits	7 g	n/a
Bacon; e.g., poultry breakfast strips	15 g	26 g = bacon. 18 g = breakfast strips
Dried; e.g., poultry jerky, dried poultry, poultry sausage products with a moisture/protein ratio of less than 2:1	30 g	n/a
Snacks; e.g., poultry snack food sticks	30 g	n/a
Luncheon products, poultry bologna, poultry Canadian style bacon, poultry crumbles, poultry luncheon loaf, potted poultry products, poultry taco fillings.	55 g	n/a
Linked poultry sausage products, poultry franks, poultry Polish sausage, smoked or pickled poultry meat, poultry smoked sausage.	55 g	n/a 69 g = uncooked sausage.

TABLE 2.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION—GENERAL FOOD SUPPLY [1,2,3,4,5]—Continued.

Product category	Reference	Reference
	Ready-to-serve	Ready-to-cook
Entrees without sauce, poultry cuts, ready to cook poultry cuts, including marinated, tenderized, injected cuts of poultry, poultry corn dogs, poultry bagel dogs, poultry croquettes, poultry fritters, cured poultry ham products, adult pureed poultry.	85 g	106 g
Canned poultry, canned chicken, canned[4] turkey	55 g	n/a
Entrees with sauce, turkey and gravy	140 g	n/a
Mixed dishes NOT measurable with a cup;[5] e.g., poultry burrito, poultry enchiladas, poultry pizza, poultry quiche, all types of poultry sandwiches, cracker and poultry lunch-type packages, poultry gyro, poultry stromboli, poultry frank on a bun, poultry burger on a bun, poultry taco, chicken cordon bleu, poultry calzone, poultry lasagna, stuffed vegetables with poultry, poultry kabobs.	140 g (plus 55 g for products toppings)	n/a
Mixed dishes, measurables with a cup; e.g., poultry casserole, macaroni and cheese with poultry, poultry pot pie, poultry spaghetti with sauce, poultry chili, poultry chili with beans, poultry hash, creamed dried poultry, poultry ravioli in sauce, poultry a la king, poultry stew, poultry goulash.	1 cup	n/a
Salads—pasta or potato, potato salad with poultry, macaroni and poultry salad	140 g	n/a
Salads—all other, poultry salads, chicken salad, turkey salad	100 g	n/a
Soups—all varieties	245 g	n/a
Major main entree type sauce; e.g., spaghetti sauce with poultry	125 g	n/a
Minor main entree sauce; e.g., pizza sauce with poultry, gravy	¼ cup	n/a
Seasoning mixes dry, freeze dry, dehydrated, concentrated soup mixes, bases, extracts, dried broths and stock/juice, freeze dry trail mix products with poultry.		
As reconstituted: Amount to make one Reference Amount of the final dish; e.g.—		
Gravy	¼ cup	n/a
Major main entree type sauce	125 g	n/a
Soup	245 g	n/a
Entree measurable with a cup	1 cup	n/a

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–78 and the 1987–88 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.
[2] Manufacturers are required to convert the Reference Amounts to the label serving size in a household measure most appropriate to their specific product using the procedures established by regulation.
[3] Examples listed under Product Category are not all inclusive or exclusive. Examples are provided to assist manufacturers in identifying appropriate product Reference Amount.
[4] If packed or canned in liquid, the Reference Amount is for the drained solids.
[5] Pizza sauce is part of the pizza and is not considered to be a sauce topping.

(c) The Reference Amount for products that represent two or more foods packaged and presented to be consumed together (e.g., lunch meat, cheese, and crackers) shall be the sum of the Reference Amounts for individual foods in the package if the Reference Amount is not listed in section (b) of this section and the product is not a meal-type product.

(d) The Administrator, on his or her own initiative or on behalf of any interested person who has submitted a labeling application, may issue a proposal to establish or amend a Product Category or Reference Amount identified in paragraph (b) of this section.

(1) Labeling applications and supporting documentation to be filed under this section shall be submitted in quadruplicate, except that the supporting documentation may be submitted on a computer disc copy. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The labeling application shall state the applicant's post office address.

(2) Pertinent information will be considered as part of an application on the basis of specific reference to such information submitted to and retained in the files of the Food Safety and Inspection Service. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(3) The availability for public disclosure of labeling applications, along with supporting documentation, submitted to the Agency under this section will be governed by the rules specified in subchapter D, title 9.

(4) Data accompanying the labeling application, such as food consumption data, shall be submitted on separate sheets, suitably identified. If such data has already been submitted with an earlier labeling application from the applicant, the present labeling application must provide the data.

(5) The labeling application must be signed by the applicant or by his or her attorney or agent, or (if a corporation) by an authorized official.

(6) The labeling application shall include a statement signed by the person responsible for the labeling application, that to the best of his or her knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him or her pertinent to the evaluation of the labeling application.

(7) Labeling applications for a new Reference Amount and/or Product Category shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 381.412 with respect to Reference Amount and/or Product Category.

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement of the objective of the labeling application;

(ii) A description of the product;

(iii) A complete sample product label including nutrition label, using the format established by regulation;

(iv) A description of the form in which the product will be marketed;

(v) The intended dietary uses of the product with the major use identified (e.g., turkey as a luncheon meat);

(vi) If the intended use is primarily as an ingredient in other foods, list of foods or food categories in which the product will be used as an ingredient with information on the prioritization of the use;

(vii) The population group for which the product will be offered for use (e.g., infants, children under 4 years of age);

(viii) The names of the most closely-related products (or in the case of foods for special

dietary use and imitation or substitute foods, the names of the products for which they are offered as substitutes);

(ix) The suggested Reference Amount (the amount of edible portion of food as consumed, excluding bone, skin or other inedible components) for the population group for which the product is intended with full description of the methodology and procedures that were used to determine the suggested Reference Amount. In determining the Reference Amount, general principles and factors in paragraph (a) of this section should be followed.

(x) The suggested Reference Amount shall be expressed in metric units. Reference Amounts for foods shall be expressed in grams except when common household units such as cups, tablespoons, and teaspoons are more appropriate or are more likely to promote uniformity in serving sizes declared on product labels. For example, common household measures would be more appropriate if products within the same category differ substantially in density such as mixed dishes measurable with a cup.

(A) In expressing the Reference Amount in grams, the following general rules shall be followed:

(1) For quantities greater than 10 grams, the quantity shall be expressed in nearest 5 grams increment.

(2) For quantities less than 10 grams, exact gram weights shall be used.

(B) [Reserved]

(xi) A labeling application for a new subcategory of food with its own Reference Amount shall include the following additional information:

(A) Data that demonstrate that the new subcategory of food will be consumed in amounts that differ enough from the Reference Amount for the parent category to warrant a separate Reference Amount. Data must include sample size, and the mean, standard deviation, median, and modal consumed amount per eating occasion for the product identified in the labeling application and for other products in the category. All data must be derived from the same survey data.

(B) Documentation supporting the difference in dietary usage and product characteristics that affect the consumption size that distinguishes the product identified in the labeling application from the rest of the products in the category.

(xii) In conducting research to collect or process food consumption data in support of the labeling application, the following general guidelines should be followed.

(A) Sampled population selected should be representative of the demographic and socioeconomic characteristics of the target population group for which the food is intended.

(B) Sample size (i.e., number of eaters) should be large enough to give reliable estimates for customarily consumed amounts.

(C) The study protocol should identify potential biases and describe how potential biases are controlled for or, if not possible to control, how they affect interpretation of results.

(D) The methodology used to collect or process data including study design, sampling procedures, materials used (e.g., questionnaire, interviewer's manual), procedures used to collect or process data, methods or procedures used to control for unbiased estimates, and procedures used to correct for nonresponse, should be fully documented.

(xiii) A statement concerning the feasibility of convening associations, corporations, consumers, and other interested parties to engage in negotiated rulemaking to develop a proposed rule.

Yours very truly,

Applicant _____

By _____

(Indicate authority)

(8) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(9) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(10) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed Reference Amount and/or Product Category is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed Reference Amount and/or Product Category.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(11) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish in the **Federal Register** a proposed rule to amend the regulations to authorize the use of the Reference Amount and/or Product Category. The proposal shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's proposed rule shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the proposed Reference Amount and/or Product Category. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the proposed Reference Amount and/or Product Category shall be approved for use on the labeling of poultry products.

(i) If the Reference Amount and/or Product Category is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the Reference Amount and/or Product Category on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed Reference Amount and/or Product Category.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with

the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia.

(ii) If the Reference Amount and/or Product Category is approved, the Agency shall notify the applicant, in writing, and shall also publish in the Federal Register a final rule amending the regulations to authorize the use of the Reference Amount and/or Product Category.

§ 381.413 Nutrient content claims; general principles.

(a) This section applies to poultry products that are intended for human consumption and that are offered for sale, except that nutrient content claims may not be made on products intended specifically for use by infants and toddlers less than 2 years of age.

(b) A claim, which expressly or by implication, characterizes the level of a nutrient (nutrient content claim) of the type required in nutrition labeling pursuant to § 381.409, may not be made on a label or in labeling of that product unless the claim is made in accordance with 21 CFR 101.13(b) through (f).

(c) through (h) [Reserved]

(i) The labeling of a product may contain a statement about the amount or percentage of a nutrient in accordance with 21 CFR 101.13(i) (1) through (3).

(j) Products may bear a statement that compares the level of a nutrient in the product with the level of a nutrient in a reference food in accordance with 21 CFR 101.13(j), except comparison to another manufacturer at 21 CFR 101.13(j)(1)(ii)(B).

(k) The term "modified" may be used in the statement of identity of a product in accordance with 21 CFR 101.13(k).

(l) For purposes of making a claim, a "meal-type product" shall be defined as a product that:

(1) Makes a significant contribution to the diet by weighing at least 6 ounces, but no more than 12 ounces per serving (container), and

(2) Contains ingredients from two or more of the following four food groups:

(i) Bread, cereal, rice and pasta group,

(ii) Fruits and vegetables group,

(iii) Milk, yogurt, and cheese group, and

(iv) Meat, poultry, fish, dry beans, eggs, and nuts group, and

(3) Is represented as, or is in a form commonly understood to be a breakfast, lunch, dinner, meal, main dish, entree, or pizza. Such representations may be made either by statements, photographs, or vignettes.

(m) [Reserved]

(n) Nutrition labeling in accordance with § 381.409 shall be provided for any food for which a nutrient content claim is made.

(o) Compliance with requirements for nutrient content claims shall be in accordance with § 381.409(h).

(p) The Reference Amount shall be used to determine whether a product meets the criteria for a nutrient content claim as discussed in 21 CFR 101.13(p)(1).

(q) The following exemptions apply:

(1) Nutrient content claims that have not been defined by regulation and that appear as part of a brand name that was in use prior to November 27, 1991, may continue to be used as part of that brand name, provided they are not false or misleading under section 4(h) of the Act (21 U.S.C. 453(h)(4)).

(2) [Reserved]

(3) A statement that describes the percentage of a vitamin or mineral in the food in relation to a reference daily intake (RDI) as defined in 21 CFR 101.9(c) may be made on the label.

(4) The requirements of this section do not apply to products for special dietary use as described in § 381.124.

(5) [Reserved]

(6) Nutrient content claims that were part of the name of a product that was subject to a standard of identity as of November 27, 1991, are not subject to the requirements of paragraph (b) of this section whether or not they meet the definition of the descriptive term.

(7) Implied nutrient content claims may be used as part of a brand name, provided that the use of the claim has been authorized by FSIS. Labeling applications requesting approval of such a claim may be submitted pursuant to § 381.469.

§ 381.414–381.442 [Reserved]

§ 381.443 Significant participation for voluntary nutrition labeling.

(a) In evaluating significant participation for voluntary nutrition labeling, FSIS will consider only the major cuts of single-ingredient, raw poultry products, as identified in § 381.444, including those that have been previously frozen.

(b) FSIS will judge a food retailer to be participating at a significant level if the retailer provides nutrition labeling information for at least 90 percent of the major cuts of single-ingredient, raw poultry products, listed in § 381.444, that it sells, and if the nutrition label is consistent in content and format with the mandatory program, or nutrition information is displayed at point-of-purchase in an appropriate manner.

(c) To determine whether there is significant participation by retailers under the voluntary nutrition labeling guidelines, FSIS will select a representative sample of companies allocated by type and size.

(d) FSIS will find that significant participation by food retailers exists if at least 60 percent of all companies that are evaluated are participating in accordance with the guidelines.

(e) FSIS will evaluate significant participation of the voluntary program every 2 years beginning in May 1995.

(1) If significant participation is found, the voluntary nutrition labeling guidelines shall remain in effect.

(2) If significant participation is not found, FSIS shall initiate rulemaking to require nutrition labeling on those products under the voluntary program.

§ 381.444 Identification of major cuts of poultry products.

The major cuts of single-ingredient, raw poultry products are: Whole chicken (without neck and giblets), chicken breast, chicken wing, chicken drumstick, chicken thigh, whole turkey (without necks and giblets; separate nutrient panels for white and dark meat permitted as an option), turkey breast, turkey wing, turkey drumstick, and turkey thigh.

§ 381.445 Guidelines for voluntary nutrition labeling of single-ingredient, raw products.

(a) Nutrition information on the cuts of single-ingredient, raw poultry products, including those that have been previously frozen, shall be provided in the following manner:

(1) If a retailer chooses to provide nutrition information on the label of these products, these products shall be subject to all requirements of the mandatory nutrition labeling program, except that nutrition labeling may be declared on the basis of either "as consumed" or "as packaged." In addition, the declaration of the number of servings per container need not be included in nutrition labeling of single-ingredient, raw poultry products, including those that have been previously frozen.

(2) If a retailer chooses to provide nutrition information at the point-of-purchase by an appropriate means, such as by posting a sign, or by making the information readily available in brochures, notebooks, or leaflet form in close proximity to the food. If a nutrition claim is made on point-of-

purchase materials all of the requirements of the mandatory nutrition labeling program apply. However, if only nutrition information—and not a nutrition claim—is supplied on point-of-purchase materials:

(i) The requirements of the mandatory nutrition labeling program apply, but the nutrition information may be supplied on an "as packaged" or "as consumed," basis;

(ii) The listing of DRV's may be voluntary; and

(iii) The point-of-purchase materials are not subject to any of the format requirements. The nutrition labeling information may also be supplemented by a video, live demonstration, or other media.

(b) [Reserved]

(c) The declaration of nutrition information may be presented in a simplified format as specified in § 381.409(g) for the mandatory nutrition labeling program.

(d) The nutrition label data should be based on either raw or cooked edible portions of poultry cuts with skin. If data are based on cooked portions, the methods used to cook the products must be specified and should be those which do not add nutrients from other ingredients such as flour, breading, and salt. Additional nutritional data may be presented on an optional basis for the raw or cooked edible portions of the skinless poultry meat.

(e) Nutrient data that are the most current representative data base values contained in USDA's National Nutrient Data Bank or its published form, the Agriculture Handbook No. 8 series, may be used for nutrition labeling of single-ingredient, raw poultry products, including those that have been previously frozen. These data may be composite data that reflect different classes of turkey or other variables affecting nutrient content. Alternatively, data that reflect specific classes or other variables may be used, except that if data are used on labels attached to a product which is labeled as to class of poultry or other variables, the data must represent the product in the package when such data are contained in the representative data base. When data are used on labels attached to a product, the data must represent the edible poultry tissues present in the package.

(f) If the nutrition information is in accordance with paragraph (e) of this section, a nutrition label or labeling will not be subject to the Agency compliance review under § 381.409(h), unless a nutrition claim is made on the basis of the representative data base values.

(g) Retailers may use data bases that they believe reflect the nutrient content of single-ingredient, raw poultry products, including those that have been previously frozen; however, such labeling shall be subject to the compliance procedures of paragraph (e) of this section and the requirements specified in this Subpart for the mandatory nutrition labeling program.

§§ 381.446–381.453 [Reserved]

§ 381.454 Nutrient content claims for "good source" and "high".

Nutrient content claims about a nutrient in a product in relation to the Reference Daily Intake (RDI) established for that nutrient in 21 CFR 101.9(c)(11)(iv) or Daily Reference Value (DRV) established for that nutrient in 21 CFR 101.9(c)(12)(i), excluding total carbohydrate and unsaturated fatty acids, may be used on the label or in labeling, in accordance with 21 CFR 101.54(a) through (d).

§ 381.455 [Reserved]

§ 381.456 Nutrient content claims for "light" or "lite".

(a) *General requirements.* The following nutrient content claims using the term "light" or "lite" to describe a product may be used on the label and in labeling, provided that the product is labeled in compliance with 21 CFR 101.56.

(b) The term "light" or "lite" may be used in the brand name of foods to describe the sodium content, provided that:

(1) The product meets the sodium criteria provided in paragraph (a) of this section, and

(2) A statement specifically stating that the product is "light in sodium" or "lite in sodium" appears:

(i) Contiguous to the brand name;

(ii) In uniform type size, style, color, and prominence as the product name; and

(iii) The "light in sodium" or "lite in sodium" statement complies with paragraph (a) of this section.

§§ 381.457–381.459 [Reserved]

§ 381.460 Nutrient content claims for calorie content.

Nutrient content claims about the calorie content of a product may be used on the label or in labeling in accordance with 21 CFR 101.60 (a) through (c).

§ 381.461 Nutrient content claims for sodium content.

Nutrient content claims about the sodium content of a product may be used on the label and in labeling in accordance with 21 CFR 101.61 (a) and (b).

§ 381.462 Nutrient content claims for fat, fatty acids, and cholesterol content of poultry products.

(a) A claim about the level of fat, fatty acid, and cholesterol in a poultry product may only be made on the label and in the labeling of the product in accordance with 21 CFR 101.62 (a) through (d), except 21 CFR 101.62 (c), (d)(1)(i), (d)(1)(ii) (A) through (D), (d)(2)(i), (d)(2)(ii) (A) through (D), (d)(4)(i), (d)(4)(ii) (A) through (D), (d)(5)(i), and (d)(5)(ii) (A) through (D).

(b) The term "low in cholesterol" or "low cholesterol" may be used on the label or in labeling of a meal-type product as defined in § 381.413, provided that the product meets the requirements of 21 CFR 101.62(d)(2), except that requirements of 21 CFR 101.62 (d)(2) (i)(A) and (ii)(A) shall be limited to 20 milligrams of cholesterol per 100 grams, and the requirements of 21 CFR 101.62(d)(2) (i)(B) and (ii)(B) shall be modified to require that the product contain 2 grams or less of saturated fat per 100 grams.

(c) "Lean" and "Extra Lean" Claims. The following nutrient content claims may be used on the label or in labeling, provided that the product is labeled in accordance with § 381.409, and the nutrient content claim complies with § 381.413:

(1) The term "lean" may be used on the label or in labeling of a poultry product, provided that the product contains less than 10 grams fat, less than 4 grams saturated fat, and less than 95 milligrams cholesterol per 100 grams and Reference Amount Customarily Consumed (RACC) for individual foods, and per 100 grams and labeled serving size for meal-type products.

(2) The term "extra lean" may be used on the label or in labeling of a poultry product, provided that the product contains less than 5 grams fat, less than 2 grams saturated fat, and less than 95 milligrams cholesterol per 100 grams and Reference Amount Customarily Consumed (RACC) for individual foods, and per 100 grams and per labeled serving size for meal-type products.

§§ 381.463–381.468 [Reserved]

§ 381.469 Labeling applications for nutrient content claims.

(a) This section pertains to labeling applications for claims, express or implied, that characterize the level of any nutrient required to be on the label or in labeling of product by this subpart.

(b) Labeling applications included in this section are:

(1) Labeling applications for a new (heretofore unauthorized) nutrient content claim.

(2) Labeling applications for a synonymous term (i.e., one that is consistent with a term defined by regulation) for characterizing the level of a nutrient, and

(3) Labeling applications for the use of an implied claim in a brand name.

(c) Labeling applications and supporting documentation to be filed under this section shall be submitted in quadruplicate, except that the supporting documentation may be submitted on a computer disc copy. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The labeling application shall state the applicant's post office address.

(d) Pertinent information will be considered as part of an application on the basis of specific reference to such information submitted to and retained in the files of the Food Safety and Inspection Service. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(e) If nonclinical laboratory studies accompany a labeling application, the applicant shall include, with respect to each nonclinical study included with the application, either a statement that the study has been, or will be, conducted in compliance with the good laboratory practice regulations as set forth in Part 58 of Chapter 1, Title 21, or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(f) If clinical investigations accompany a labeling application, the applicant shall include, with respect to each clinical investigation included with the application, either a statement that the investigation was conducted in compliance with the requirements for institutional review set forth in Part 56 of Chapter 1, Title 21, or was not subject to such requirements in accordance with § 56.194 or § 56.105, and that it was conducted in compliance with the requirements for informed consents set forth in Part 50 of Chapter 1, Title 21.

(g) The availability for public disclosure of labeling applications, along with supporting documentation, submitted to the Agency under this section will be governed by the rules specified in Subchapter D, Title 9.

(h) The data specified under this section to accompany a labeling application shall be submitted on separate sheets, suitably identified. If such data has already been submitted with an earlier labeling application from the applicant, the present labeling application must provide the data.

(i) The labeling application must be signed by the applicant or by his or her attorney or agent, or (if a corporation) by an authorized official.

(j) The labeling application shall include a statement signed by the person responsible for the labeling application, that to the best of his or her knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him or her pertinent to the evaluation of the labeling application.

(k)(1) Labeling applications for a new nutrient content claim shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 381.469 with respect to (statement of the claim and its proposed use).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the nutrient content claim and the nutrient that the term is intended to characterize with respect to the level of such nutrient. The statement shall address why the use of the term as proposed will not be misleading. The statement shall provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of products on which the claim will be used. The statement shall also specify the level at which the nutrient must be present or what other conditions concerning the product must be met for the appropriate use of the term in labels or labeling, as well as any factors that would make the use of the term inappropriate.

(ii) A detailed explanation supported by any necessary data of why use of the food component characterized by the claim is of importance in human nutrition by virtue of its presence or absence at the levels that such claim would describe. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed and why such benefit is not available through the use of existing terms defined by regulation. If the claim is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group, and scientific data sufficient for such purpose, and data and information to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

(iii) Analytical data that demonstrates the amount of the nutrient that is present in the products for which the claim is intended. The assays should be performed on representative samples in accordance with 381.409(h). If no USDA or AOAC methods are available, the applicant shall submit the assay method used, and data establishing the validity of the method for assaying the nutrient in the particular food. The validation data shall include a statistical analysis of the analytical and product variability.

(iv) A detailed analysis of the potential effect of the use of the proposed claim on food consumption, and any corresponding changes in nutrient intake. The analysis shall specifically address the intake of nutrients that have beneficial and negative consequences in the total diet. If the claim is intended for a specific group within the population, the above analysis shall specifically address the dietary practices of such group, and shall include data sufficient to demonstrate that the dietary analysis is representative of such group.

Yours very truly,

Applicant _____

By _____

(Indicate authority)

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed nutrient content claim is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed nutrient content claim.

(i) If the applicant fails to accept the determination of the Administrator and

files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish in the **Federal Register** a proposed rule to amend the regulations to authorize the use of the nutrient content claim. The proposal shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's proposed rule shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the proposed nutrient content claim. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the proposed nutrient content claim shall be approved for use on the labeling of poultry products.

(i) If the claim is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the claim on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed nutrient content claim.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of the notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(ii) If the claim is approved, the Agency shall notify the applicant, in writing, and shall also publish in the **Federal Register** a final rule amending the regulations to authorize the use of the claim.

(l)(1) Labeling applications for a synonymous term shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 381.469 with respect to (statement of the synonymous term and its proposed use in a nutrient content claim that is consistent with an existing term that has been defined under subpart Y of part 381).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the synonymous term, the existing term defined by a regulation with which the synonymous term is claimed to be consistent, and the nutrient that the term is intended to characterize the level of. The statement shall address why the use of the synonymous term as proposed will not be misleading. The statement shall provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of products on which the claim will be used. The statement shall also specify whether any limitations not applicable to the use of the defined term are intended to apply to the use of the synonymous term.

(ii) A detailed explanation supported by any necessary data of why use of the proposed term is requested, including whether the existing defined term is inadequate for the purpose of effectively characterizing the level of a nutrient. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed, and why such benefit is not available through use of existing terms defined by regulation. If the claim is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group, scientific data sufficient for such purpose, and data and information to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

Yours very truly,

Applicant _____

By _____

(Indicate authority)

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed synonymous term is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed synonymous term.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the

Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the claim is approved, the Agency shall notify the applicant, in writing, and shall publish in the **Federal Register** a notice informing the public that the synonymous term has been approved for use.

(m)(1) Labeling applications for the use of an implied nutrient content claim in a brand name shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 381.469 with respect to (statement of the implied nutrient content claim and its proposed use in a brand name).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the implied nutrient content claim, the nutrient the claim is intended to characterize, the corresponding term for characterizing the level of such nutrient as defined by a regulation, and the brand name of which the implied claim is intended to be a part. The statement shall address why the use of the brand-name as proposed will not be misleading. The statement shall provide examples of the types of products on which the brand name will appear. It shall also include data showing that the actual level of the nutrient in the food would qualify the label of the product to bear the corresponding term defined by regulation. Assay methods used to determine the level of a nutrient shall meet the requirements stated under labeling application format in paragraph (k)(1)(iii) of this section.

(ii) A detailed explanation supported by any necessary data of why use of the proposed brand name is requested. This explanation shall also state what nutritional benefit to the public will derive from use of the brand name as proposed. If the branded product is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group and scientific data sufficient for such purpose.

Yours very truly,

Applicant _____

By _____

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed implied nutrient content claim is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed implied nutrient content claim.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish a notice of the labeling application in the **Federal Register** seeking a comment on the use of the implied nutrient content claim. The notice shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's notice rule shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the implied nutrient content claim. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the implied nutrient content claim shall be approved for use on the labeling of poultry products.

(i) If the claim is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the claim on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed implied nutrient content claim.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of the notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(ii) If the claim is approved, the Agency shall notify the applicant, in writing, and shall also publish in the **Federal Register** a notice informing the public that the implied nutrient content claim has been approved for use.

§ 381.470–381.479 [Reserved]

§ 381.480 Label statements relating to usefulness in reducing or maintaining body weight.

(a) *General requirements.* Any product that purports to be or is represented for special dietary use because of usefulness in reducing body weight shall bear:

(1) Nutrition labeling in conformity with § 381.409 of this subpart, unless exempt under that section, and

(2) A conspicuous statement of the basis upon which the product claims to be of special dietary usefulness.

(b) *Nonnutritive ingredients.* (1) Any product subject to paragraph (a) of this section that achieves its special dietary usefulness by use of a nonnutritive ingredient (i.e., one not utilized in normal metabolism) shall bear on its label a statement that it contains a nonnutritive ingredient and the percentage by weight of the nonnutritive ingredient.

(2) A special dietary product may contain a nonnutritive sweetener or other ingredient only if the ingredient is safe for use in the product under the applicable law and regulations of this chapter. Any product that achieves its special dietary usefulness in reducing or maintaining body weight through the use of a nonnutritive sweetener shall bear on its label the statement required by paragraph (b)(1) of this section, but need not state the percentage by weight of the nonnutritive sweetener. If a nutritive sweetener(s) as well as nonnutritive sweetener(s) is added, the statement shall indicate the presence of both types of sweetener; e.g., "Sweetened with nutritive sweetener(s) and nonnutritive sweetener(s)."

(c) *"Low calorie" foods.* A product purporting to be "low calorie" must comply with the criteria set forth for such foods in § 381.460(b) (2) and (3).

(d) *"Reduced calorie" foods and other comparative claims.* A product purporting to be "reduced calorie" or otherwise containing fewer calories than a reference food must comply with the criteria set forth for such foods in § 387.460(b) (4) and (5).

§§ 381.481–381.499 [Reserved]

§ 381.500 Exemption from nutrition labeling.

(a) The following poultry food products are exempt from nutrition labeling:

(1) Products produced by small businesses, provided that the labels for these products bear no nutrition claims or nutrition information,

(i) A food product, for purposes of the small business exemption, is defined as a formulation, not including distinct flavors which do not significantly alter the nutritional profile, sold in any size package in commerce.

(ii) For purposes of this paragraph, a small business is any single-plant facility or multi-plant company/firm that employs 500 or fewer people and produces no more than the following amounts of pounds of the product qualifying the firm for exemption from this subpart:

(A) During the first year of implementation of nutrition labeling, from July 1994 to July 1995, 250,000 pounds or less,

(B) During the second year of implementation of nutrition labeling, from July 1995 to July 1996, 175,000 pounds or less, and

(C) During the third year of implementation and subsequent years thereafter, 100,000 pounds or less.

(2) Products intended for further processing, provided that the labels for these products bear no nutrition claims or nutrition information,

(3) Products that are not for sale to consumers, provided that the labels for these products bear no nutrition claims or nutrition information,

(4) Products in small packages that are individually wrapped packages of less than ½ ounce net weight, provided that the labels for these products bear no nutrition claims or nutrition information,

(5) Products custom slaughtered or prepared,

(6) Products intended for export, and

(7) The following products prepared and served or sold at retail provided that the labels or the labeling of these products bear no nutrition claims or nutrition information:

(i) Ready-to-eat products that are packaged or portioned at a retail store or similar retail-type establishment; and

(ii) Multi-ingredient products (e.g. sausage) processed at a retail store or similar retail-type establishment.

(b) Restaurant menus generally do not constitute labeling or fall within the scope of these regulations.

(c) Foods represented to be specifically for infants and children less than 2 years of age shall bear nutrition labeling, except such labeling shall not include calories from fat, calories from saturated fat, saturated fat, polyunsaturated fat, monounsaturated fat, and cholesterol. Foods represented to be specifically for infants and children less than 4 years of age shall bear nutrition labeling, except that such labeling shall not include listings of percent of daily value and the daily value list. Nutrient names and quantitative amounts by weight shall be presented in two separate columns.

Done at Washington, DC, on: December 24, 1992.

H. Russell Cross,

Administrator, Food Safety and Inspection Service.

[FR Doc. 93–29 Filed 1–5–93; 8:45 am]

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federal register

Wednesday
January 6, 1993

Part III

Department of Agriculture

Food Safety and Inspection Service

9 CFR Parts 317 and 381

Nutrition Labeling: Use of "Healthy" and Similar Terms on Meat and Poultry Product Labeling; Proposed Rule

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317 and 381

[Docket No. 91-006P-HLTH]

RIN 0583-AB34

Nutrition Labeling: Use of "Healthy" and Similar Terms on Meat and Poultry Product Labeling

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service is proposing to amend the Federal meat and poultry products inspection regulations to permit the use of the term "healthy" or any other derivative of the term "healthy," such as "healthful" or "healthier," on the labeling of meat and poultry products. FSIS is engaging in rulemaking proceedings to establish nutrition labeling regulations for meat and poultry products. This action is intended to provide consumers with accurate, informative labeling on meat and poultry products.

DATES: Comments must be received on or before February 5, 1993.

ADDRESSES: Written comments to: Policy Office, ATTN: Linda Carey, FSIS Hearing Clerk, Room 3171, South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. Oral comments as provided by the Poultry Products Inspection Act should be directed to: Mr. Charles R. Edwards at (202) 205-0080. (See also "Comments" under "SUPPLEMENTARY INFORMATION.")

FOR FURTHER INFORMATION CONTACT: Charles R. Edwards, Director, Product Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, (202) 205-0080.

SUPPLEMENTARY INFORMATION: The Agency advises that it intends to make any final rule that derives from this rulemaking effective the same effective date as the final rule titled, "Nutrition Labeling of Meat and Poultry Products" (published elsewhere in this issue of the **Federal Register**). If, for some reason, a final rule on "healthy" and similar terms is not issued in time to meet the same effective date as FSIS's final rule on nutrition labeling, the use of "healthy" and similar terms would be subject to the nutrient content claim provisions set forth in the final rule on nutrition labeling.

Executive Order 12291 and Effect on Small Entities

FSIS is publishing elsewhere in this issue of the **Federal Register** a final rule on nutrition labeling of meat and poultry products. The rule was reviewed under USDA procedures established to implement Executive Order 12291 and was classified as a major rule pursuant to section 1(b)(1) of that order because it is likely to result in an annual effect on the economy of $100 million or more. The review is reported in a Final Regulatory Impact Analysis (FRIA) which is available for review in the FSIS Hearing Clerk's office. The FRIA also satisfies the analysis requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 5 U.S.C. 601 *et seq.*) which deals with the effect on small entities.

This proposed rule is one element of the overall nutrition labeling rulemaking which was considered in the FRIA. A summary of the FRIA can be found in the Agency's final rule on nutrition labeling published elsewhere in this issue of the **Federal Register**.

Executive Order 12778

This proposed rule has been reviewed pursuant to Executive Order 12778, Civil Justice Reform. This proposed rule seeks comments on provisions for permitting the use of the term "healthy" or any other derivative of the term "health" on the labeling of meat and poultry products.

This proposed rule concerns labeling of meat and poultry products. States and local jurisdictions are preempted under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) from imposing any marking, labeling, packaging, or ingredient requirements on federally inspected meat or poultry products that are in addition to, or different than, those imposed under the FMIA or the PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat and poultry products that are outside official establishments for the purpose of preventing the distribution of meat and poultry products that are misbranded or adulterated under the FMIA or PPIA, or, in the case of imported articles, which are not at such an establishment, after their entry into the United States. Under the FMIA and the PPIA, States that maintain meat and poultry inspection programs must impose requirements on State inspected products and establishments that are at least equal to those imposed on federally inspected products and establishments under the FMIA or PPIA. These States may, however, impose more stringent requirements on such State inspected products and establishments.

If adopted, no retroactive effect would be given to this proposed rule, and applicable administrative procedures must be exhausted before any judicial challenge to its provisions or their application. Those administrative procedures are set forth in the rules of practice governing proceedings for labeling determinations at 9 CFR parts 335 and 381, subpart W.

Paperwork Requirements

This proposed rule specifies the regulations permitting the use of the term "healthy," or any other derivative of the term "health" on the labeling of meat and poultry products.

The paperwork requirements contained in this proposed rule were incorporated into the Information Collection Request on Nutrition Labeling of Meat and Poultry Products which has been submitted to the Office of Management and Budget.

Regulatory Reform

Less Burdensome or More Efficient Alternatives

The Department of Agriculture is committed to carrying out its statutory and regulatory mandates in a manner that best serves the public interest. Therefore, where legal discretion permits, the Department actively seeks to promulgate regulations that promote economic growth, create jobs, are minimally burdensome, and are easy for the public to understand, use or comply with. In short, the Department is committed to issuing regulations that maximize net benefits to society and minimize costs imposed by those regulations. This principle is articulated in President's Bush's January 28, 1992, memorandum to agency heads, and in Executive Orders 12291 and 12498. The Department applies this principle to the fullest extent possible, consistent with law.

The Department has developed and reviewed this regulatory proposal in accordance with these principles. Nonetheless, the Department believes that public input from all interested persons can be invaluable to ensuring that the final regulatory product is minimally burdensome and maximally efficient. Therefore, the Department specifically seeks comments and suggestions from the public regarding any less burdensome or more efficient alternative that would accomplish the purposes described in the proposal. Such comments should be addressed to

the Agency as provided in the "Comments" section below.

Comments

Interested persons are invited to submit comments concerning this proposed rule. Written comments should be sent to the Policy Office and refer to Docket No. 91–006P–HLTH. Any person desiring an opportunity for an oral presentation of views as provided by the Poultry Products Inspection Act should make such request to Charles R. Edwards so that arrangements can be made for such views to be presented. A record will be made of all views orally presented. All comments submitted in response to this proposed rule will be available for public inspection in the Policy Office from 9 a.m. to 12:30 p.m. and from 1:30 p.m. to 4 p.m., Monday through Friday.

Background

On November 27, 1991, FSIS published in the **Federal Register** a proposed rule entitled "Nutrition Labeling of Meat and Poultry Products" (56 FR 60302). In addition to proposing specific regulations for nutrition labeling, the Agency solicited comments on the appropriateness and usefulness of the term "healthy" on the labeling of meal-type products, and requested specific information on the criteria for the use of such term. The proposed rule would permit voluntary nutrition labeling on single-ingredient, raw meat and poultry products, and would establish mandatory nutrition labeling for most processed meat and poultry products.

Published elsewhere in this issue of the **Federal Register** is FSIS's final rule on nutrition labeling, which does not contain regulatory provisions covering the use of the term "healthy." Because the public has not been afforded the opportunity to comment on the regulatory provisions proposed herein, FSIS is issuing this proposed rule to allow public comment prior to issuing a final rule. The following discussion addresses the use of the term "healthy" on meat and poultry products, the comments received in response to the proposal relevant to this issue, and the regulatory provisions established to respond to the concerns of the issue.

As previously mentioned, FSIS solicited comments, in its November 1991 proposal, on the use of the term "healthy" on labeling of meal-type products. FSIS stated in the proposal that nutrient content claims not defined by regulation that appear as part of the brand name may be used on the label or in labeling if they are not false or misleading and only if the brand name was in use prior to November 27, 1991 (publication date of the proposal). The term "healthy" was not defined. The Agency specifically solicited comments on how best to determine when a term incorporated into a brand name should be regulated as a nutrient content claim.

FSIS included, in the proposal, examples of products with brand names, trade names, and product lines, that contain nutrient content claims, which may be affected by the proposed rule. The list of examples, which was not all inconclusive, contained 19 such products that include the term "healthy" or a derivative of the term "health," including "Light & Healthy," "Healthy Choice," "LeMenu Healthy," "HealthCheck," "Healthy Deli," and "Lean & Healthy."

The majority of the responses received from FSIS's solicitation for comments on the criteria for the term "healthy" suggested that the term be defined by meeting several criteria. Some comments suggested that the products should qualify if they meet several of the "low" criteria for certain nutrients. Others recommended that the term be equated with controlled amounts of fat, saturated fatty acids, cholesterol, and sodium. A few comments stated that, not only should the term equate controlled amounts of fat, saturated fatty acids, cholesterol, and sodium, use of the term should meet the "high" definition for a certain number of micronutrients.

In its final rule on nutrition labeling, FSIS discusses the rationale and basis for defining the terms "lean" and "extra lean." The primary focus of the Agency's decision to define these terms was to provide meat and poultry products with nutrient content claims that could be used to distinguish between products in that category that contained less fat, saturated fatty acids, and cholesterol. "Lean" is defined for a product that contains less than 10 grams of fat, less than 4 grams of saturated fatty acids, and less than 95 milligrams of cholesterol. The Agency believes that these levels are appropriate "disqualifying" levels (i.e., levels above which would disqualify the food from making a health claim) to apply to the term "healthy" because they are based on dietary recommendations for Americans. Therefore, this proposed rule would permit the term "healthy" to be used on the label of meat and poultry products, provided the product contains less than 10 grams of fat, less than 4 grams of saturated fatty acids, less than 95 milligrams of cholesterol, and less than 480 milligrams of sodium per 100 grams and Reference Amount Customarily Consumed for individual foods, and per 100 grams and labeled serving for meal-type products. In addition, products bearing the term "healthy" must comply with the nutrition label contents prescribed in 9 CFR 317.309 and 381.409, and the labeling of such products must comply with nutrient content claims provisions, prescribed in 9 CFR 317.313 and 381.413 (see FSIS's final rule on nutrition labeling).

On November 27, 1991, the Food and Drug Administration (FDA) also proposed regulations to require nutrition labeling on most foods that are meaningful sources of nutrients, to revise the list of required nutrients and food components and the conditions for declaring them in nutrition labeling, and to establish up-to-date reference standards for those nutrients and food components.

In response to comments received on its general principles proposal, FDA is proposing a definition of the term "healthy," published elsewhere in this issue of the **Federal Register**. As proposed by FDA, uses of the term "healthy" that refer only to general dietary guidance, such as "eat lots of fruits and vegetables for a healthy diet," would not be implied nutrient content claims and would not be subject to any requirements. FDA believes that the term "healthy" constitutes an implied nutrient content claim only when it appears in a nutritional context, such as when the term is associated with an explicit or implicit claim or statement about a nutrient. An example of "healthy" used as an implied claim would be "Healthy, contains 5 grams of fat." The term "healthy," when used in this context, would be subject to a definition under FDA's proposal.

Both FSIS and FDA received comments suggesting that the definition for "healthy" should focus on restrictions for fat, saturated fat, sodium, and cholesterol, because these nutrients are of particular significance to public health. The agencies are tentatively in agreement with these comments and, accordingly, both FSIS and FDA have incorporated these four nutrients into their proposed definitions of "healthy."

Many recommendations for healthy diets from professional health organizations and the U.S. Dietary Guidelines for Americans advise choosing lean meat and poultry as a means of achieving a healthy diet. Food consumption data indicates that 89 percent of Americans eat meat and poultry on a daily basis. In its final rule on nutrition labeling, FSIS provides guidelines for the term "lean" that include restricted levels of fat, saturated fat, and cholesterol. FSIS believes it is

important to convey to consumers consistent dietary messages. Likewise, from a consumer education standpoint, it is essential to communicate analogous messages concerning healthy diets and the role meat and poultry products can play in achieving balanced, healthy diets.

FDA's definition for "healthy" applies to products that do not exceed the disqualifying level for sodium or cholesterol and are low in fat and saturated fat. Many cuts of meat and poultry would not meet such a definition. In order to maintain a consistent dietary message, FSIS believes that linking the definition of "lean" to the definition of "healthy" is an appropriate connection. Therefore, the Agency is proposing to define the term "healthy" with parallel levels for fat, saturated fat, and cholesterol as "lean," above which products would not be eligible for use of the term. In addition, the Agency believes a sodium requirement should be a criterion for eligibility because FSIS agrees with comments received suggesting that sodium be considered in defining "healthy." For the sodium requirement, FSIS is proposing that 480 milligrams would be the limit, parallelling FDA's sodium requirement for individual foods. The levels for the term "healthy" would be applied to both individual foods and meal-type products, with the criterion for individual foods per 100 grams and Reference Amount Customarily Consumed, and per 100 grams and labeled serving for meal-type products. The Agency also believes that any use of the term "healthy," whether in a brand name or used in conjunction with a nutrient, must meet this requirement. The Agency will refer to these levels as "disqualifying" levels.

In comparing the FSIS and FDA disqualifying levels for cholesterol and sodium for individual foods, the sodium levels are the same (480 milligrams); however, the FSIS cholesterol level of 95 milligrams is slightly higher than that of FDA's level of 60 milligrams. The higher cholesterol level is expected for meat and poultry products since these products contain inherent cholesterol, while products regulated by FDA typically contain no cholesterol.

In comparing the FSIS and FDA disqualifying levels for cholesterol and sodium for main dishes, FDA's proposed sodium level of 720 milligrams is one and a half times higher than the level proposed by FSIS, and FDA's cholesterol level (90 milligrams) is similar. FDA's proposed sodium level of 960 milligrams and cholesterol level of 120 milligrams are higher than FSIS's proposed levels for meal-type products. FSIS specifically requests comments on its proposed sodium and cholesterol levels.

Americans are interested in lowering their sodium intake because they are increasingly aware of the role sodium plays in hypertension. Two major public health reports, the Surgeon General's report on "Nutrition and Health" and the National Research Council report "Diet and Health: Implications for Reducing Chronic Disease Risk" identify high blood pressure as one of America's ten major chronic diseases that are affected by daily dietary patterns.

Hypertension is a major risk factor for heart disease, which is the leading cause of death in the U.S., and for stroke, the third most frequent cause of death. In addition, hypertension is also a problem in renal failure. Prevalence of hypertension increases with age in the U.S. population and is higher for black Americans (38 percent) than for white Americans.

Although the link between sodium intake and high blood pressure is not completely understood, a committee of the National Institute of Health's National Heart, Lung and Blood Institute recently issued new recommendations to lower Americans' blood pressure, including drastically reducing daily intake of salt.

The food industry has responded to this consumer interest by the development of a variety of products with lower sodium levels. Since as much as 80 percent of the salt consumed each day by the average American comes from processed foods, it is important to continue to provide incentives to the food industry to develop and market reduced sodium foods.

Although FDA and FSIS define "healthy" differently, FSIS believes this is one area where it is appropriate. Meat and poultry products are different from other foods in that all meat and poultry products contain fat, saturated fat, and cholesterol. In addition, cholesterol is not ubiquitous in the food supply but only found in foods of animal origin.

This proposed rule would apply the criteria for "healthy" to any term used anywhere on the label that includes the term "health." This includes, but is not limited to, the following terms:

Health
Healthy
Healthful
Healthfully
Healthfulness
Healthier
Healthiest
Healthily
Healthiness

Thus, this proposed rule would permit the use of the term "healthy' or any other derivative of the term "health" under the conditions described above.

List of Subjects

9 CFR Part 317

Food labeling, Meat inspection.

9 CFR Part 381

Food labeling, Poultry and poultry products.

The Proposed Rule

For the reasons discussed in the preamble, FSIS is proposing to amend 9 CFR parts 317 and 381 of the Federal meat and poultry products inspection regulations to read as follows:

Note: The following proposed amendments are based on the final rule published elsewhere in this issue which becomes effective July 6, 1994.

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

1. The authority citation for part 317 would continue to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

2. Section 317.309 would be amended by adding a new paragraph (j) to read as follows:

§ 317.309 Nutrition label content.

* * * * *

(j) The term "healthy" or any other derivative of the term "health" may be used on the label or in labeling of a meat product, provided that:

(1) The product contains less than 10 grams of fat, less than 4 grams of saturated fatty acids, less than 95 milligrams of cholesterol, and less than 480 milligrams of sodium per 100 grams and Reference Amount Customarily Consumed for individual foods, and per 100 grams and labeled serving for meal-type products, as defined in § 317.313(1),

(2) The product is labeled in compliance with this section, and

(3) The term complies with the requirements of § 317.313.

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

3. The authority citation for part 381 would continue to read as follows:

Authority: 7 U.S.C. 450, 21 U.S.C. 451–470, 7 CFR 2.17, 2.55.

4. Section 381.409 would be amended by adding a new paragraph (j) to read as follows:

§ 381.409 Nutrition label content.

* * * * *

(j) The term "healthy" or any other derivative of the term "health" may be used on the label or in labeling of a poultry product, provided that:

(1) The product contains less than 10 grams of fat, less than 4 grams of saturated fatty acids, less than 95 milligrams of cholesterol, and less than 480 milligrams of sodium per 100 grams and Reference Amount Customarily Consumed for individual foods, and per 100 grams and labeled serving for meal-type products, as defined in § 381.413(l),

(2) The product is labeled in compliance with this section, and

(3) The term complies with the requirement of § 381.413.

Done at Washington, DC, on: December 24, 1992.

H. Russell Cross,

Administrator, Food Safety and Inspection Service.

[FR Doc. 93–28 Filed 1–5–93; 8:45 am]

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federal register

Wednesday
January 6, 1993

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 1, et al.

Food Labeling; General Provisions; Nutrition Labeling; Label Format; Nutrient content Claims; Health Claims; Ingredient Labeling; State and Local Requirements; and Exemptions; Final Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 5, 20, 100, 101, 105, and 130

[Docket No. 92N-0440]

Food Labeling Regulations Implementing the Nutrition Labeling and Education Act of 1990; Opportunity for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; opportunity for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is revoking the regulations implementing section 403(q) and (r) of the Federal Food, Drug, and Cosmetic Act (the act), and the lists implementing section 6 of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), that were considered final by operation of law as of November 8, 1992 (hereinafter referred to as the November 8 regulations). Elsewhere in this issue of the **Federal Register**, FDA is adopting final rules based on public comment to replace the November 8 regulations. FDA is taking this action to ensure that the final regulations that implement the 1990 amendments are those based on full public comment, and that those regulations are put in place without delay.

DATES: Effective January 6, 1993. Comments by February 5, 1993.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Frank E. Scarbrough, Center for Food Safety and Applied Nutrition (HFS-150), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4561.

SUPPLEMENTARY INFORMATION:

I. Background

On November 8, 1990, President Bush signed the 1990 amendments into law. Sections 2, 3, and 6 of the 1990 amendments gave FDA 24 months from the date of their enactment to promulgate final rules implementing those sections. In response, FDA published proposals on November 27, 1991 (56 FR 60366 through 60878) and July 28, 1992 (57 FR 33283).

Sections 2(b)(2) and 3(b)(2) of the 1990 amendments provided that, if final rules to implement section 403(q) and (r) of the act, respectively, were not promulgated by November 8, 1992, then the regulations proposed to implement these sections of the act were to be considered as final regulations. There are similar provisions in section 6(b)(3)(D) of the 1990 amendments.

The 24-month period established by the 1990 amendments expired on Sunday, November 8, 1992, without the issuance of final rules implementing section 403(q) and (r) of the act or section 6 of the 1990 amendments. Thus, on November 8, 1992, the proposed regulations implementing those sections of the act and section 6 of the 1990 amendments were considered final regulations by operation of law. Under sections 2(b)(2) and 3(b)(2) of the 1990 amendments, FDA was directed to promptly publish in the **Federal Register** notice of the new status of the proposed regulations. FDA published that notice on November 27, 1992 (57 FR 56347).

II. The Revocation

The triggering of the mechanism established in sections 2(b)(2), 3(b)(2), and 6(b)(3) of the 1990 amendments did not toll the rulemakings instituted on November 27, 1991, and July 28, 1992, in response to sections 2, 3, and 6 of the 1990 amendments. Elsewhere in this issue of the **Federal Register**, FDA is publishing the final rules that are the culmination of those rulemakings. FDA has concluded that the final rules based on public comment should replace the November 8 regulations.

Because the agency is completing the rulemaking process begun in 1991, it is necessary to revoke the November 8 regulations so that only the rules that have had the benefit of full notice-and-comment procedures are in effect and provide a basis on which industry can begin to conform its food labels to the new requirements. This revocation does not constitute a reversal of the agency's former views as expressed in the November 27, 1991, and July 28, 1992, proposals and in the November 8 regulations, except to the extent that any changes, in accordance with the Administrative Procedure Act (5 U.S.C. 553(b)), are a logical outgrowth of the proposals. To the extent that differences exist between the November 8 regulations and the new final rules, a reasoned analysis for the changes is supplied in the preambles to the final rules published elsewhere in this issue of the **Federal Register**.

The legislative history of the 1990 amendments states that, if the deadline for publishing final rules based on public comment was not met, there would be good cause to consider the proposed regulations as final regulations because of the importance of mandatory nutrition labeling, rules on claims, and a unified system of regulations on misbranding. The legislative history also pointed to the fact that Congress expected the agency to have received public input prior to issuing the proposed regulations (H. Rept. 101-538, 101st Cong., 2d sess. 18-19 (1990)). The November 8 regulations were to be considered final rules to ensure that some rules would be in place without undue delay to implement the statutory requirements of the 1990 amendments.

Congress contemplated that, if the agency did not issue final rules based on public comment by the specified date (H. Rept. 101-538, supra, 18), and the provisions of sections 2(b)(2), 3(b)(2), and 6(b)(3)(D) of the 1990 amendments were triggered, then the consideration of the proposed rules as final rules without notice and comment should occur and would be justified. This so-called "hammer" provision had an overriding purpose: to motivate FDA and all parties involved in these rules to resolve expeditiously the many issues raised in them, rather than become mired indefinitely in their complexity. FDA believes the hammer has fully achieved its important purpose. It has encouraged prompt resolution of outstanding issues and led to agreement on final rules that represent substantial improvement over the proposed rules and that will be in place sufficiently before the date the statute must be applied to allow full industry compliance.

There is no indication in the legislative history of the 1990 amendments that Congress intended FDA to disregard the comments that it had received on the November 27, 1991, and July 28, 1992, proposals once the "hammer" had fallen and the November 8 regulations were considered final, or that Congress intended the triggering of the mechanism in sections 2(b)(2), 3(b)(2), and 6(b)(3)(D) of the 1990 amendments to prevent FDA from putting in place final regulations based on public comments as quickly as possible. While the proposals to implement the 1990 amendments may have had the benefit of general public comment on food labeling issues, they are no substitute for final rules based on the extensive rulemaking record developed in response to those proposals. In response to the public comments on the proposals, FDA has improved the regulations in numerous respects, better achieving the goals of the 1990 amendments, to the benefit of both industry and consumers.

Revocation of the November 8 regulations will eliminate any ambiguity as to which final regulations are controlling. Thus, for the reasons set forth above, FDA believes that this revocation is fully consistent with the 1990 amendments.

This revocation is also fully consistent with the requirements of the Administrative Procedure Act. The Administrative Procedure Act provides that the agency may revoke a regulation without notice-and-comment procedures "when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." FDA finds that there is good cause for dispensing with notice-and-comment procedures in revoking the November 8 regulations.

First, notice-and-comment rulemaking on the revocation of the November 8 regulations is impracticable. Very little time remains before the provisions added by the 1990 amendments and implemented by the November 8 regulations go into effect. The new provisions of the act on health claims are effective on May 8, 1993, without any possibility of extension. Under those provisions, foods are automatically misbranded if health claims are made on their labels that do not meet the requirements of FDA's regulations.

In the final rules published elsewhere in this issue of the **Federal Register**, FDA is exercising the statutory flexibility granted in section 10(a)(3)(B) of the 1990 amendments to extend the date on which it will apply the new provisions on nutrition labeling and nutrient content claims to May 8, 1994. Comments have shown that this additional time for compliance with the final regulations is necessary to prevent undue economic hardship to industry. Even a minimal prior notice-and-comment period on this revocation would be likely to delay issuance of any final rules for at least several months. This delay would reduce significantly the amount of time industry is permitted under the statute to come into compliance with the nutrition labeling and nutrient content claims rules. That compliance cannot begin until the final rules on which the agency intends to rely in enforcing the amendments are in place. Use of notice-and-comment procedures to revoke the November 8 regulations and to replace them with new final rules would thus risk causing the very harm Congress attempted to prevent in permitting this extension.

Secondly, engaging in notice-and-comment rulemaking on the revocation of the November 8 regulations would be contrary to the public interest. The delay caused by receiving and responding to comments on the revocation would increase confusion and could lead to substantial hardship and expense to industry, which would face the possibility of having to label its products to comply with the November 8 regulations and then having to relabel them to comply with any new final rules that the agency eventually issued after the comment period. Revoking the November 8 regulations without notice and comment allows the agency to replace them immediately with final rules based on extensive public comment and thus to provide certainty to industry as to the regulatory requirements with which it must comply.

There is a strong interest in ensuring continuity of regulation, particularly where the purpose of the regulations is to provide information to consumers that they can understand and on which they can rely. A situation in which labels appear that comply with the November 8 regulations, only to be replaced by labels that comply with any final rules that the agency might ultimately issue, would be inconsistent with this goal. Rather, it would contribute to consumer confusion, which is precisely what Congress was trying to prevent in enacting the 1990 amendments to reform the food label.

The agency's final rules implementing the 1990 amendments need to be the gold standard for the food marketplace. Based as they are on public comment, scientific evidence, and sound public policy, the final rules issued today are the culmination of the Department of Health and Human Services' efforts, begun in August 1989, and reinforced in 1990 by the Administration and Congress, to reform the food label.

Finally, it is in the public interest and consistent with the purposes of the Administrative Procedure Act to have in place as quickly as possible final rules that are the product of a full rulemaking procedure. As stated above, Congress included sections 2(b)(2), 3(b)(2), and 6(b)(3) in the 1990 amendments because of the importance of having final regulations in place implementing the 1990 amendments without undue delay. H. Rept. 101–538, supra, 18. Today's action is consistent with that goal, because final rules implementing section 403(q) and (r) will be in place. By revoking the November 8 regulations in a manner consistent with the Administrative Procedure Act, FDA is giving full recognition to the effect of sections 2(b)(2), 3(b)(2), and 6(b)(3) of the 1990 amendments. The rules that will be in place as a result of today's action have had the benefit of full public comment. Those comments established the existence of problems with the proposals, and FDA has fully addressed those problems in the final rules. (See the final rules published elsewhere in this issue of the **Federal Register**.)

Considering the factual situation as a whole, there is good cause for waiving notice and comment. FDA has been diligent in arriving at final rules. In the past year, FDA has reviewed over 40,000 comments, held three public hearings, and produced final rules in more than 20 separate proceedings. There has been full notice-and-comment rulemaking on the final rules that FDA is issuing today, and interested persons have had ample opportunity to comment on all substantive issues addressed in those rules. However, circumstances outside FDA's control prevented it from issuing those final rules by the statutory deadline. In light of this, the agency is acting responsibly and reasonably in dealing with the unique situation it faces. The agency's prompt action to withdraw the November 8 regulations is necessary to facilitate the enormous transformation of the food label that will occur over the coming months. Moreover, no hardship will result from replacing the November 8 regulations now, because not enough time has passed since November 8 to permit significant action in reliance on the November 8 regulations.

Therefore, FDA concludes that there is good cause for withdrawing the November 8 regulations without notice and comment.

Consistent with its own procedural regulations, however, FDA is providing an opportunity for comment on its decision to revoke the November 8 regulations. Under § 10.40(e)(1) (21 CFR 10.40(e)(1)), FDA may issue a regulation without notice and public procedures when the agency determines for good cause that they are impracticable, unnecessary, or contrary to the public interest. In such a situation, the FDA procedural regulations require that the notice promulgating the regulation state the reasons for the determination, and provide an opportunity for comment to determine whether the regulation should subsequently be modified or revoked. This notice complies with these procedural requirements. Given the present unique circumstances, however, FDA finds under § 10.40(b)(2) that there is good cause to limit the comment period to 30 days.

FDA also finds, based on the reasons discussed above, that there is good cause to issue this revocation effective immediately (5 U.S.C. 553(d)(3)). A delayed effective date would be contrary to the public interest in minimizing regulatory uncertainty: it would create unnecessary confusion if these rules remained in effect for 30 days after the issuance of the final rules based on notice and comment. Moreover, this revocation of regulations that are not yet effective will not impose any behavioral changes on regulated industry, unlike the promulgation of a normative rule. Thus, a delayed effective date for this final rule would be unnecessary, impracticable, and contrary to the public interest.

After carefully considering the provisions of the 1990 amendments and their legislative history, FDA believes that, in this final rule and in the other final rules published today, it has taken the appropriate steps to resolve any questions created by the hammer. FDA is taking a course that recognizes Congress' desire to have final regulations in place by November 8, 1992, but that also recognizes, as discussed above, that Congress ultimately would not want to undercut the benefits of notice-and-comment rulemaking. The agency considered various alternate courses of action but rejected them because they were inconsistent with the 1990 amendments, the amendments' legislative history, the relevant facts, or the urgency of the current situation.

One alternative would have been to propose to revoke the November 8 regulations and to propose rules to replace them. This course was rejected because it would create too much uncertainty for industry, which would then have been compelled to begin complying with section 403(r)(1)(B) of the act on May 8, 1993, and with requirements on nutrition labeling and nutrient content claims by May 8, 1994, and because this course of action gives no effect to the extensive rulemaking that FDA has conducted for the last 12 months.

A second course would have been to term the final rules published today "interim rules," with additional opportunity for comment and a commitment to publish "true" final rules based on further comment. The agency has concluded that there would be little gain from such a course. Calling the rules "interim rules" would only create confusion and could induce industry to postpone action to comply with the new regulations. Also, although the comment period on the November 27, 1991, proposals closed on February 25, 1992, FDA continued to receive and consider comments well into the early fall. FDA believes that, since that time, no new information has become available that would change the agency's regulatory approach. If such information exists, FDA's procedural regulations provide ways for bringing it to the agency's attention, e.g., a petition under 21 CFR 10.30.

A third course would be simply to leave the November 8 regulations in place. FDA has concluded that this course of action would make little sense. It would be unfair to both industry and consumers to forego promulgating the best regulations possible. The agency thus believes that, in publishing the new final rules today, it is acting in the best interests of industry and consumers.

The agency therefore urges all affected manufacturers, packers, and distributors to begin to act in accordance with the final rules published today. The agency has received numerous comments about how much work will be necessary to comply with the new regulations, and, in response, FDA is announcing elsewhere in this issue of the **Federal Register** that it is delaying until May 8, 1994, the application of section 403(q) and (r)(2) of the act. However, if there is to be compliance by the application date, work must begin now. The final rules published today establish the requirements that must be met.

III. Additional Comments

The final rules that FDA is issuing today are the product of notice-and-comment procedures, and no further such procedures are required. The Administrative Procedure Act provides for notice and opportunity for public comment on proposed agency rules to ensure meaningful public input into agency rules that affect the public. Public comment is not an end in itself. FDA believes that it has fulfilled any possible purpose of this requirement. The agency has provided three prior opportunities for public comment on food labeling reform: the 1989 advance notice of proposed rulemaking, proposed rules in 1990, and proposed rules implementing the 1990 amendments in 1991 and 1992. While additional comments are always possible, the agency believes the Administrative Procedure Act in no way requires an additional opportunity for them. Now, the public interest requires finality and expeditious actual reform of the label—to the benefit of both industry and consumers. Recognizing, however, that some people may argue that there is a technical requirement for further rulemaking procedures, FDA finds that there is also good cause to proceed without them. For the reasons discussed elsewhere in this document, and in light of the extensive rulemaking procedures that have already been followed, further notice and comment would be unnecessary, impracticable, and contrary to the public interest.

The agency firmly believes that all the final rules it is publishing today, including those superseding the November 8 regulations, are the logical outgrowth of the November 27, 1991, and July 28, 1992, proposals and are fully supported by the administrative record that has been developed. Although the agency does not believe that any public purpose would be served by reopening for further comment at this time the issues addressed in that rulemaking, FDA recognizes that in any rulemaking of this size there will be technical issues in specific provisions. Therefore, the agency is providing 30 days for comment on these final rules on such issues. FDA is not interested in receiving comments that it has already received and considered. Interested persons are urged to limit their comments to technical matters or technical unintended consequences in specific provisions if not raised in earlier comments. In order to assure consideration of any comments, interested persons must certify that their comments are so limited. Comments should be submitted to the specific docket of the final rule being commented on. If the comments identify any technical provision of the final rules that FDA agrees should be changed, FDA will take action to modify that provision. This approach will enable FDA to quickly address any unintended effects of the final rules, yet not delay the finality that FDA believes is imperative for both industry and consumers.

IV. Opportunity for Comments

Under § 10.40(e), an opportunity for comment on this final rule is being provided. Interested persons may, on or before February 5, 1993, submit to the Dockets Management Branch (address above) written comments regarding this final rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Therefore, the regulations that were considered final by operation of law on November 8, 1992, as announced in the

Federal Register of November 27, 1992 (57 FR 56347), are hereby revoked.

Dated: December 17, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 92-31499 Filed 12-28-92; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 5, 101, 105, and 130

[Docket Nos. 90N-0134 et al.]

RIN 0905-AD08 and 0905-AB68

Food Labeling: Establishment of Date of Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing this final rule to establish May 8, 1994, as the date on which it will apply the mandatory nutrition labeling and nutrient content claims provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). This action is in accordance with section 10(a)(3)(B) of the 1990 amendments which allows the Secretary (and, by delegation, FDA) to delay, for up to 1 year, the date on which FDA will apply those provisions to foods if the agency finds that compliance with the new provisions would cause "undue economic hardship."

DATES: The statutory effective date of sections 403(q) and 403(r)(2) of the Federal Food, Drug, and Cosmetic Act (the act) is May 8, 1993, except that section 403(q)(4) (raw agricultural commodities and raw fish) became effective November 8, 1991. However, FDA is delaying the date that it will apply sections 403(q) of the act (21 CFR 101.9) and 403(r)(2) of the act (21 CFR 101.13, all of the regulations in subpart D of 21 CFR part 101, and 21 CFR 130.10), except section 403(q)(4) of the act (21 CFR 101.42 through 101.45), until May 8, 1994. The effective date of the regulations published elsewhere in this issue of the **Federal Register** implementing sections 403(q) and 403(r)(2) of the act, except section 403(q)(4) of the act, is May 8, 1994.

FOR FURTHER INFORMATION CONTACT: Gerad L. McCowin, Center for Food Safety and Applied Nutrition (HFF-302), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5267.

SUPPLEMENTARY INFORMATION:

I. Background

On November 8, 1990, the President signed into law the 1990 amendments (Pub. L. 101-535). This statute adds section 403(q) (21 U.S.C. 343(q)), which makes nutrition labeling mandatory for all food, and section 403(r)(2) (21 U.S.C. 343(r)(2)), which gives FDA authority to define nutrient content claims, among other sections, to the act.

In accordance with the 1990 amendments, FDA published proposed rules on November 27, 1991, to implement these sections of the act. Under section 2(b)(1) of the 1990 amendments (21 U.S.C. 343 note), FDA is to adopt final regulations by November 8, 1992. If the agency fails to do so, under section 2(b)(2) of the 1990 amendments, the proposed rules are to be considered final rules. Under section 10(a)(1)(A) and (B) of the 1990 amendments (21 U.S.C. 343 note), sections 403(q) and 403(r)(2) of the act are effective 6 months after the promulgation of the final regulations or after the proposed regulations are considered to be final regulations. Thus, by statute, sections 403(q) and 403(r)(2) of the act will become effective no later than May 8, 1993.

However, section 10(a) of the 1990 amendments provides that if the Secretary of Health and Human Services and, by delegation, FDA "* * * find that compliance with sections 403(q) and 403(r)(2) of such Act would cause an undue economic hardship, the Secretary may delay the application of such sections for no more than one year." In its regulatory impact analysis (RIA) published in the **Federal Register** of November 27, 1991 (56 FR 60856), FDA tentatively found that compliance with the 1990 amendments by May 8, 1993, will cost $1.5 billion, and that 6-month and 1-year extensions of the compliance date would result in significant reductions in those costs. Therefore, given the extent of these costs, FDA felt that the possibility of "undue economic hardship" was raised. The agency consequently requested comments on the meaning of "undue economic hardship," and on whether a delay in the application of sections 403(q) and 403(r)(2) of the act was appropriate. The agency also requested comments on whether a determination of "undue economic hardship" should be based on aggregate costs to industry generally, on industry-by-industry costs, or on firm-by-firm costs.

Interested persons were given until February 25, 1992, to comment. FDA received comments from government organizations, retailers, consumer groups, State groups, and private organizations. A discussion of the agency's decision, and a summary of the comments and the agency responses, follow.

II. Undue Economic Hardship

The 1990 amendments provide that the Secretary may delay the application of sections 403(q) and 403(r)(2) of the act for up to 1 year if he "* * * finds that compliance with [either section] would cause an undue economic hardship." There is no relevant legislative history on this provision. Clearly, however, Congress foresaw that there would be a significant cost to complying with these sections of the act. Its use of the phrase "undue economic hardship" implies that Congress recognized that some economic hardship may result from efforts to comply with the 1990 amendments. The question is whether that cost is so great as to constitute "undue" economic hardship.

"Undue" is defined as "exceeding what is appropriate or normal," "excessive," or "not just [or] proper." Synonyms include inequitable, inappropriate, extreme, and immoderate. As yet, no court has construed the meaning of the 1990 amendments; however, parallels may be drawn with cases discussing similar language. Cases involving an employer's accommodation of an employee's religious practices have looked for a simple increase in costs in assessing whether the accommodation created an "undue hardship" for the employer. See *Transworld Airlines* v. *Hardison*, 432 U.S. 63, 84 (1977) (more than a de minimis cost to employer is an undue hardship); *State Division of Human Rights* v. *Carnation Co.*, 366 N.E.2d 869, 870 (N.Y. Ct. App. 1977) (a palpable or significant increase in costs is enough to establish undue hardship; threat to economic stability of enterprise is not required). In determining whether a punitive damage award was "excessive," a court looked at whether it was "out of all proportion to the defendant's financial position." *T.D.S., Inc.* v. *Shelby Mutual Insurance Co.*, 760 F.2d 1520 (11th Cir. 1985). Where a company was ordered to reopen a plant after closing it discriminatorily, the remedy was to be upheld unless the company could show an undue economic burden, which was interpreted as a "substantial outlay of new capital or [other] undue financial hardship." *Teamsters Local Union N. 171* v. *NLRB*, 863 F.2d 946 (D.C. Cir. 1988), cert. denied, 490 U.S. 1065 (1989). In a case involving the Pension Benefit Guaranty Corporation's (PBGC's) authority to grant waivers under the Employee Retirement Income Security Act (ERISA) when an employer faced "unreasonable hardship," a court upheld the PBGC's denial of a waiver where the PBGC had considered only unusual, substantial economic hardship. *A-T-O, Inc.* v. *Pension Benefit Guaranty*

Corporation, 634 F.2d 1013 (6th Cir. 1980). According to the court, the waiver provision was Congress' way of dealing with unforeseeable, unexpected situations of serious employer hardship. Id., 1023.

It appears from these cases that an undue economic hardship must entail at least an increase in costs and at most an unusual and substantial economic burden. Given Congress' implicit assumption that compliance with the 1990 amendments would involve an economic burden, the agency believes that the best interpretation of Congress' intent would require that an undue economic hardship be a substantial economic burden, in excess of what Congress would have envisioned, although not necessarily threatening the viability of a company, attributable to the 6-month compliance date established by the 1990 amendments.

1. The comments that the agency received were generally consistent with this view of what constitutes undue economic hardship. A comment from a trade group stated that "undue economic hardship" should be defined by the lost product lines and businesses that will occur as a result of a short compliance time. Another comment defined "undue economic hardship" as any increase in costs of goods to consumers in the current economic climate. A large company stated that undue economic hardship was shown where there were large costs "without appreciable benefit."

The agency agrees with the comments that a large increase in industry's costs attributable to the application of sections 403(q) and 403(r)(2) of the act 6 months from November 8, 1992, would provide evidence of undue economic hardship if that increase is more than what was likely to have been envisioned by Congress. However, a simple increase in costs alone is insufficient to demonstrate such hardship because Congress envisioned that there would be some economic burden to industry when it passed the 1990 amendments.

2. One comment from a consumer group argued that industry will not experience undue economic hardship. The comment stated that: (1) There is no undue burden on industry because consumers would bear the costs, not industry; and (2) since the public at large would be the recipients of the benefits of labeling, and the benefits outweigh the costs, the public should be willing to bear the costs.

The agency disagrees with the first point. It is likely that much of the costs of nutrition labeling will not be passed on to consumers, although the agency is not in a position to estimate exactly how much of the amount will be passed on to consumers. Because the costs per product are primarily fixed costs, it is likely that manufacturers with low volume products, which constitute 80 percent of all products, with higher per product costs will not be able to pass these costs on if they are in competition with high volume products.

The agency agrees that the public at large will be the recipient of the benefits of nutrition labeling. However, because it is likely that many manufacturers will not be able to pass the costs on, and because the agency received no information with which to estimate the amount that can be passed on, the agency is not persuaded by this argument.

3. Several comments suggested that "undue economic hardship" should be based on a cost-benefit analysis. Both industry and consumer groups provided their views that benefits should be balanced against the costs of implementing the labeling provisions. Industry groups generally found the costs to be disproportionate to the benefits, while consumer groups commented that the potential health benefits far exceeded the cost to industry.

The agency finds that there is no basis in the statute, the legislative history, or the case law to find that the assessment of undue economic hardship entails a balancing of the costs and benefits of a delayed application date. In fact, it can reasonably be inferred from the 1990 amendments that Congress balanced the competing interests in framing the statute and provided in section 10(a)(3)(B) of the 1990 amendments that should the economic burden imposed by meeting the statutory compliance date be greater than reasonable, FDA is authorized to grant relief to affected industry. The court held in *A-T-O, Inc.* v. *PBGC*, that Congress, before enacting the ERISA statute, engaged in just such a "finely tuned balance between protecting pension benefits for employees while limiting the cost to employers." *A-T-O*, 634 F.2d at 1021. In enacting ERISA, as in the passage of the 1990 amendments, Congress could not foresee all possible situations of undue economic hardship, so it granted discretion to the administrative agencies to determine the circumstances in which undue economic hardship exists. Id., 1023.

III. How to Assess Whether There is Undue Economic Hardship

In its November 1991 RIA, the agency requested comments on whether it should assess undue economic hardship on a firm-by-firm, industry-by-industry or on an aggregate basis.

4. Several comments argued that because FDA can expect requests for extension from most of the industry regulated by FDA as well as from many foreign firms, it would be difficult, if not impossible, for FDA to grant extensions on a firm-by-firm basis. Some comments stated that company-specific extensions would give some firms an unfair competitive advantage based solely on production and inventory schedules and would create consumer confusion. One comment stated that a firm-by-firm approach would not adequately judge economic hardship since many firms manufacture products that overlap different industries and, therefore, have different costs. Another comment appeared to advocate use of the firm-by-firm basis because it was seeking relief for itself.

In addition, one consumer advocate organization preferred that FDA assess undue economic hardship on a case-by-case basis. However, if this would be too burdensome, the comment suggested that FDA consider granting extensions by categories of firms, based on size or labeling capacity. Several other comments voiced similar requests by suggesting that if FDA does not determine the aggregate economic impact to be undue, then it should consider whether the impact is particularly burdensome to specific industries. Several comments, including two from governmental units, suggested that if FDA does not delay the application of sections 403(q) and 403(r)(2) of the act for all manufacturers subject to the 1990 amendments, FDA should consider applying a later date for small business. Other comments suggested that the industry-by-industry approach would create competitiveness problems and would be extremely difficult to apply fairly. The majority of comments expressed the opinion that undue economic hardship should be determined on an aggregate basis because it would be the only equitable and practical approach. The one consumer group that argued against an extension agreed that FDA should consider undue economic hardship on an aggregate basis.

FDA believes that it should determine whether there is undue economic hardship for the food industry as a whole. Because there are approximately 17,000 U.S. food companies in the portion of the food industry regulated by FDA, as well as a large number of foreign food manufacturers, it would be administratively infeasible for FDA to grant extensions on a firm-by-firm basis because the agency does not have the

resources to process and act on petitions. Similarly, the agency also is persuaded by the evidence provided by the comments that granting extensions on an industry-by-industry basis would be perceived as arbitrary because it would be extremely difficult to distinguish among industries on the basis of the costs that would have to be borne if there is early application of sections 403(q) and 403(r)(2) of the act. The overwhelming majority of comments provided evidence that such costs will have to be borne by most companies.

Moreover, from a compliance standpoint, FDA's job would be made more difficult if a delay was granted on other than an industry-wide basis. In such a situation, compliance checks would require not merely looking at the label but at whether the labeling requirement applied to the particular firm or segment of the industry. Therefore, FDA has decided to define "undue economic hardship" on an aggregate basis.

IV. Evidence of Hardship

A. General

In conformity with the case law cited above, the agency has interpreted the undue economic hardship standard to require a determination as to whether the costs of complying with sections 403(q) and 403(r)(2) of the act by May 8, 1993, impose an unexpected and excessive burden on industry. It is the costs that exceed the costs of implementing sections 403(q) and 403(r)(2) of the act that can reasonably be said to have been foreseeable that FDA has looked to in deciding whether there is undue economic hardship.

FDA has sought to determine the amount of those foreseeable costs even though the legislative history does not provide any explicit estimates of what Congress expected the costs of implementing sections 403(q) and 403(r)(2) of the act to be. However, the agency notes that Congress acted after FDA proposed to require nutrition labeling on food products in the **Federal Register** of July 19, 1990 (55 FR 29487). FDA's proposal contained a preliminary cost assessment of $315 million for implementation of the nutrition labeling proposals. Although this estimate was very rough and based on preliminary figures, and although there are differences between the agency's July 19, 1990, proposal and the 1990 amendments, Congress apparently was aware of, and may well have considered, FDA's estimate in considering the 1990 amendments (see H. Rept. 101–538, 101st Cong., 2d sess. 9 (1990)).

The agency now estimates the cost of implementation of all label changes required by the 1990 amendments to be $1.5 billion if the date of application of the nutrition labeling and nutrient content claims provisions is not delayed beyond May 8, 1993. Therefore, if $315 million is used as a baseline, the current estimated cost to industry of implementing sections 403(q) and 403(r)(2) of the act approximately quadruples it. In the RIA in which the 1990 estimate was calculated, for those costs that FDA did not have information to calculate, FDA stated that it was plausible that they would be considerable, but the agency was not specific as to exactly how large they could be. Therefore, the 1991 estimate, published in the **Federal Register** of November 27, 1991, as part of the RIA (56 FR 60856), can be considered unexpected and greatly increased because the available public data in July 1990, 4 months before the passage of the 1990 amendments, did not predict costs in that range. The 1991 estimate was based in large measure on data developed by FDA in interviews with food manufacturers and in a mailed survey that were conducted after July 1990.

Consequently, the agency concludes that the food industry will have significantly higher costs than could have been anticipated from the estimates and data at the time of passage of the 1990 amendments. The majority of comments that the agency received in response to its November 1991 RIA support the agency's cost estimates and demonstrate that there are substantial additional costs that result from a 6-month (November 1992 to May 1993), rather than a 1-year, 15-month, or 18-month, compliance date. These comments and the agency's responses are discussed in the section that follows.

B. Costs of Compliance with Section 403(q) of the Act

Having defined the term "undue economic hardship," the agency has considered whether compliance with section 403(q) of the act would cause an undue economic hardship for the affected industry. The comments received from industry overwhelmingly expressed concern regarding, and provided evidence of, such hardship.

5. Many comments stated that the cost of analytical testing for nutritional composition of products will be burdensome to meet within the proposed timeframe of May 8, 1993, especially for small companies that cannot afford the testing and that do not have their own laboratories to perform the nutritional analysis. Many of these comments stated that the increased demand for testing services would lead to increased costs for testing, which would burden all firms but especially smaller firms. The comments stated that as firms compete for laboratory services, preferred treatment will be given to the larger firms that can better afford these additional costs, thus exacerbating the competitive advantage of larger firms. One trade association estimated the average cost per product for nutrition testing to be $1,433 for small firms and between $627 and $864 for larger companies. Other comments provided estimates for the costs that ranged from $400 to $2,600 per product.

Based on the data developed by the agency in producing its November 1991 RIA, the agency believes that the estimates provided by these comments are accurate and thus finds that a short compliance period will increase the cost to firms of analytical testing. Food manufacturers will have to compete for position in the queue and to pay queuing costs to improve their position in line. In that RIA, FDA determined that 40 percent of the packaged food products covered by the labeling amendments are currently labeled and have undergone some analytical testing. The agency estimated the average cost per product to bring the product into compliance for products already nutritionally labeled to be $750, and for those not already so labeled, the agency estimated a cost of $1,785 per product (56 FR 50856 at 50864). Because less than half of all products have been tested, and because once the regulations become final, all firms will require at least some testing, the demand for laboratory services will more than double as a result of labeling regulations. The prices of these services will consequently increase substantially in the shortrun. However, because laboratory capacity is expected to increase based on an increase in long-term demand, FDA cannot predict the final price for these services. It is clear, however, that the increase in costs will be greatly mitigated by a delay in the date of compliance. Such a delay will reduce the pressure on the supply of these services because not all firms will test products at the same time, and therefore, a delay will mitigate the increase in prices for laboratory services.

6. Comments from small companies stated that the cost of laboratory testing could be reduced greatly by the use of nutrition data bases instead of requiring laboratory analyses of their products. One comment from a data base supplier

stated that a small data base product that could cover several products would sell for $1,000 to $2,000 and would last for several years--significantly cheaper than analytical tests, estimated in the November 1991 RIA at $723 to $1,785 per product.

The agency agrees with the comments. Nutrition data bases are currently under development throughout the food industry, particularly by large companies. There is no discussion of use of analytical data bases in the legislative history of the 1990 amendments, however, so Congress must have been unaware of the significant cost savings that these data bases would guarantee. The lack of data bases contributes to the costs of compliance, and a short compliance period limits the possibility of using data bases to mitigate costs. The agency has been informed that these data bases will not be operational in time to meet the May 8, 1993, deadline. To date, FDA has not approved any nutritional data bases for use in nutrition labeling. Many of those commenting, particularly small companies, requested at least a year beyond May 8, 1993, to develop and use these data bases. Assuming FDA will approve nutritional data bases, an extension will thus help in getting more data bases developed, approved by FDA, and in use by the food industry.

7. Some firms expressed concern that the capacity of analytical laboratories will be insufficient to provide all of the food testing needed by the 17,000 U.S. companies in the food industry by the 6-month effective date.

FDA does not have any data, nor was any submitted, on the number of laboratories equipped to perform nutrition analyses. FDA also does not know how many companies have inhouse facilities. However, a comment from an independent laboratory stated that it is increasing its capacity to meet "the huge surge of work brought about by the FDA mandatory labeling." Firms will continue to need to have their products tested as they reformulate their products or develop new ones. Also, firms will periodically retest their products to verify the information. The agency, therefore, anticipates that laboratory capacity will expand to meet this sustained demand. Thus, FDA does not believe that there will be undue economic costs associated with laboratory capacity.

8. Many firms expressed concern that labels could not be redesigned and printed on time to meet the statutory deadline of May 8, 1993, across the food industry because label designers and suppliers have stated that they do not have the capacity to handle the volume of business that will be generated as a result of the regulations. The comments stated that there is little incentive for printing and packaging firms to make capital improvements to meet the excess demand. The cost of capital improvements is high, and unlike the demand for analytic testing which will continue in the future, the demand for label printing is essentially a one-time label change for the entire industry. One firm estimated the cost to label printers for relabeling equipment to be $11,000 if compliance is required by May 8, 1993, with that cost dropping to $8,000 if compliance is delayed for 1 year. The comments suggested that the same scenario applies to printing capacity, whether inhouse printing or by contract. In some cases, if demand is high enough for a short compliance period, new equipment could be used which would result in excess printing capacity in the future. The comments pointed out that an additional problem with the earlier compliance date is the inability of some label suppliers to purchase and install new equipment and to find new personnel to operate such equipment within the established timeframe.

Packaging suppliers and label printers estimated that it would take between 2 to 5 months per label for redesign and printing. The comment said that time needed for other tasks, such as analytical testing, label approval, and distribution, would add considerable time to this estimate. Several comments stated that between one-third and one-half of all relabeling could be completed by May 1993, and that approximately two-thirds could be completed by November 1993. The agency also received a comment from a label printer who services 14,000 labels that stated that the company anticipates that the time that it will take it to do a job will double. Based on its present resources, the comment stated that even with a doubling of its capacity achieved by hiring new personnel, they will be almost 54 percent short of the estimated label changes needed by its customers.

FDA believes that redesign and printing of the food label to accommodate the new requirements of the 1990 amendments are compliance costs. FDA agrees that many firms may have difficulty relabeling their products in the 6-month compliance period in the statute. Because there is little incentive to increase printing capacity given the one-time nature of much of what needs to be done to print new labels, the agency does not anticipate additional printers entering the market to relieve the shortage. Because Congress did not have available to it printing cost differentials associated with different compliance periods, these costs may be construed as unexpected and undue.

9. Some firms commented that the costs of label inventory disposal would be great. According to the comments, small companies in particular carry large inventories of labels and will have a disproportionately large cost if forced to dispose of those inventories. One small firm stated that it would have to destroy 2 years worth of label inventory. In addition, specialty firms (e.g., manufacturers of gourmet products) noted that they have a large number of individual labels and a low volume of individual unit sales, which results in a large inventory of labels. Firms reported a cost of inventory disposal ranging from $79,000 to $3,603,000 for a May 1993 effective date and $0 to $227,000 for an extension to May 1994. Only one large food manufacturer provided an estimate of the cost of inventory disposal (i.e., approximately $800,000) for a compliance period ending in November 1993. One industry association representing supplement manufacturers estimated the cost of disposal for a November 1993 compliance date at $15 million. Another industry association, after conducting a survey of its members, stated that 37 member companies reported a total inventory disposal cost of $26 million and 1.5 billion labels for a compliance date of May 8, 1993. According to the comment, the cost to these 37 firms would decline to $2 million and 150 million labels with a 1-year extension.

In addition, several comments stated that another label disposal problem involves production of private labels for retail grocery and other companies. Typically, the manufacturer provides the art work and printing plates for private label customers. When orders for products are below normal, the manufacturer stores the packaging material at his cost. The comments stated that the new labeling changes will necessitate modification of all customer labels at the manufacturer's expense, and the manufacturer may have to write off as a loss considerable quantities of label and packaging material.

These figures do not conflict with those estimated by FDA in its November 1991 RIA. Based on a contractor's study of the food processing industry, FDA estimated the cost of disposal of remaining inventory to be $306 million. Although conducted before passage of the 1990 amendments, the information generated from this study was not available to Congress or to the public.

In the 1990 estimate, FDA assumed that 1 year was sufficient to dispose of all labels and thus did not estimate cost

of label disposal. Because the 1990 estimate was apparently the only information Congress had available to it, it may be presumed that these costs were unforeseen and, hence, are in excess of those anticipated by Congress.

10. Some small firms stated that the implementation of the nutrition labeling provisions would drive them out of business because the cost of compliance would eliminate their already low profit margins. These small firms claim that they cannot absorb costs, and relabeling will prevent their prices from being competitive.

FDA is aware that firms with low profit margins may be significantly affected by their effort to come into compliance with section 403(q) of the act. Although section 403(q) of the act includes a small business exemption, many small firms do not meet the requisite levels. Extending the date of application will help alleviate the impact on small businesses by mitigating increases in the cost of analytical, redesign, and printing services, and by reducing the amount of label inventory destroyed. Also, an extension will assist those firms forced to scale back or halt operations because they are unable to produce complying labels in a timely manner.

11. Comments from specialty food distributors noted that the cost of relabeling to be in compliance with section 403(q) of the act could result in the elimination of profitable product lines when the manufacturer decides that the unit cost of the labeling does not justify compliance or may trigger a price increase.

FDA agrees that some profitable product lines have such small profit margins that it is not unreasonable to expect that the cost associated with a short compliance period might increase the cost of manufacturing such that the product line is no longer profitable. The agency is currently exploring the possibility of legislation to relieve this undue hardship on small firms.

12. A European Community (EC) Commission expressed concern that overseas suppliers will be unable to meet the 6-month, May 8, 1993, deadline because of differences in definitions and analytical procedures between EC and the United States. The comment noted that the 6-month effective date would be impossible for EC producers to meet because there is a delay of several months between the labeling of products in Europe and their arrival in the United States because of travel time and customs formalities, giving overseas suppliers effectively only 3 months to analyze and relabel their products. Additionally, a trade association for herbal products confirmed that printing and analysis of the product for overseas suppliers would have to be accomplished in 3 months.

FDA agrees that foreign food manufacturers might need a longer compliance period than domestic manufacturers because of the differences in language, analytical methodology, and length of time it takes to transport the product. FDA believes the longer compliance period specified in this final rule will alleviate the concerns expressed by the comment. The agency notes that all products introduced into interstate commerce on or after May 8, 1994, must comply with sections 403(q) (except section 403(q)(4)) and 403(r)(2) and any final regulations promulgated to implement those sections.

13. A comment from a trade group for the sugar manufacturers pointed out that because in their industry the label is the package, the product cannot be packaged until it can be labeled. These manufacturers expressed concern that a substantial amount of sugar inventory will be misbranded and unmarketable, thus causing sugar to be destroyed or returned, opened, poured out, and reprocessed to be finally placed in packages conforming to label requirements. One sugar company estimated its cost of process and inherent losses to be $3.6 million.

As previously stated, FDA believes the longer compliance period specified in this final rule will alleviate the concerns expressed by the comment. Again, the agency notes that these manufacturers will have until May 8, 1994, to use up their inventory. They will also have ample time to develop their new packaging.

14. One trade association commented that their business was, in large part, seasonally based because of the holiday trade, such as Halloween, and that other businesses had special holiday or seasonal considerations. The comments noted that seasonal products need unusually long advance planning. Graphics and packaging must be finalized and ordered 9 months to 1 year in advance. The comment argued that label changes would occur in the middle of the packaging and shipping season for products that represent 20 percent of some of their members' product lines.

The agency agrees that the 6-month effective date might be impossible for some seasonal products and could result in some product lines being dropped. The agency believes that the loss of product lines would be an undue economic cost. The agency notes that a delay of applicability of section 403(q) of the act of approximately 15 total months will, according to the comments, be sufficient lead time for these products.

15. Some comments requested an extension of the date of application of the labeling provisions because initial analytical results might induce companies to reformulate their products in order to improve the nutritional composition of those products to appeal to the public. An industry association stated that the costs of reformulating products would be substantial--$20,000 per product. Another firm estimated the cost of reformulation to be $60,000 per item plus $400,000 to convert processing time to include controls.

The agency notes that one of the purposes of the 1990 amendments was precisely to encourage manufacturers to produce healthier products as a result of mandatory disclosure of food content. Reformulation, however, does not constitute undue economic hardship in itself because the industry is not required by statute to reformulate its products.

16. Several comments stated that the reduction in total costs that would result from a delay in the application of section 403(q) of the act would justify an extension. One comment from a major industry association stated that the total cost of food labeling would be reduced from $3.36 billion for the May 8, 1993, compliance date to $1.69 billion for a November 8, 1993, compliance date, and ultimately to $974 million for a May 8, 1994, compliance date. Another industry association stated that the total costs to its members would be reduced from $4.3 million to $900,000 if the compliance period were extended an additional year to May 1994. One large firm stated that total costs would be $251,146,000 for a May 1993, compliance date. Additionally, an industry association estimated that an extension from May 1993 to May 1994 would reduce total costs for its members from $160 million to one-tenth of that amount. Other firms stated their total costs would be reduced by 30 to 90 percent with a 1-year extension.

FDA finds that these comments are generally consistent with its own estimates. The agency estimates that the benefits of nutrition labeling and nutrient content revision will remain nearly the same ($3.6 to $3.4 billion) over the 1-year period from May 8, 1993 to May 8, 1994, while costs will decrease dramatically. In the November 1991 RIA, the agency estimated that a 6-month delay of the date of applicability would result in a savings of $600 million, a 9-month delay, $700 million

savings, and a 1-year delay, $835 million. As discussed in the final RIA published elsewhere in this issue of the **Federal Register**, FDA has found it appropriate to adjust these cost estimates upward somewhat.

C. Whether a Delay in Application of 403(q) of the Act is Appropriate

17. One comment from a consumer group favored no delay in applying section 403(q) of the act primarily because it wanted consumers to obtain health benefits as soon as possible from the mandatory disclosure of nutrients on food labels. A few comments tentatively favored an extension, but only if the food industry makes a strong case for undue economic hardship and provides substantial evidence of such hardship.

FDA has reviewed these comments and rejects the position that no extension of the May 8, 1993, deadline should be granted. FDA realizes that providing for early compliance with the 1990 amendments is desirable and follows the intent of Congress to implement promptly the provisions of section 403(q) of the act. However, the agency cannot ignore the evidence of undue economic hardship presented by industry comments and supported by FDA's own cost estimate. This hardship is particularly acute for small and medium-sized firms which will not be able to afford the analytical testing, printing, and inventory disposal costs if section 403(q) of the act is applied on May 8, 1993. Congress specifically provided that the Secretary may grant a delay of section 403(q) of the act of up to 1 year if such undue economic hardship is found.

Given the fact that a delay of the date of applicability for section 403(q) of the act will result in substantial cost reductions, and the evidence presented above that the costs of analytical testing, label printing, and inventory disposal far exceed the apparent expectations of Congress, a May 8, 1993, compliance date will generate a substantial economic burden. Therefore, the agency has decided that undue economic hardship will result from implementation of section 403(q) of the act on May 8, 1993, and has decided to delay the date of application of section 403(q), except for section 403(q)(4) (raw agricultural commodities and raw fish) which became effective November 8, 1991, as provided in section 403(q)(4)(B)(i).

D. Undue Economic Hardship from Application of Section 403(r)(2) of the Act

The agency also is authorized by the 1990 amendments to consider whether compliance with section 403(r)(2) of the act on May 8, 1993, will cause an undue economic hardship. Very few comments directly addressed the issue of undue economic hardship resulting from compliance with this section. Most comments did not distinguish between the two sections.

18. One comment from a consumer advocacy group stated that, because FDA's original estimates of the costs to restaurants represent roughly one percent of that industry's output, the economic burden to the food service industry cannot be deemed undue.

The agency disagrees with the comment. In its original assessment of the costs of food labeling (July 1990), FDA did not consider the costs to restaurants. Therefore, Congress had no information regarding the expense that would be incurred by restaurants as a result of the 1990 amendments. While no restaurant associations requested a delay of application of section 403(r)(2) of the act, according to a study conducted by the National Restaurant Association in a special analysis of their 1991 menu collection submitted in response to the November 1991 RIA, 89 percent of all menus would need to be changed to comply with the requirements of section 403(r)(2). While FDA is not including menus in the regulatory purview of this action, it is including restaurant signs and placards. Because this material is clearly reflective of the menu, much of it will have to be modified in response to the new law at significant cost. Thus, by any reasonable estimate, this figure is more than Congress could have envisioned and provides evidence of undue economic hardship.

The agency has decided not to undercut the relief that it is granting in delaying the application of section 403(q) of the act by forcing industry to comply with section 403(r)(2) of the act on May 8, 1993. The agency has considered that if a delay were granted in the application of section 403(q) of the act, but not in the application of section 403(r)(2) of the act, a substantial number of firms would still have to relabel their products to at least remove claims that are not in compliance with, or are not defined in, the regulations that FDA is issuing under section 403(r)(2).

The agency also notes that in section 10(a)(1)(B)(ii) of the 1990 amendments, Congress provided that persons who use a brand name that includes a term that is defined in section 403(r)(2)(A)(i) of the act have an additional 6 months, until November 8, 1993, to comply. FDA believes that the terms defined under section 403(r)(2)(A)(i) of the act will be most useful to consumers if they come onto the market at the same time. Therefore, FDA believes that an across the board delay in the application of section 403(r)(2) of the act for at least 6 months is appropriate.

E. Agency Finding of Undue Economic Hardship

The agency has considered the comments, relevant case law, and its November 1991 RIA, to determine whether undue economic hardship exists in implementing sections 403(q) and 403(r)(2) of the act by May 8, 1993. Having defined "undue economic hardship" above as a substantial economic burden in excess of what Congress would have envisioned attributable to the 6-month compliance date established by the 1990 amendments, the agency has examined the evidence presented and concludes the following:

The evidence from the comments demonstrates that undue economic hardship will occur in the aggregate because of increased analytical testing costs and pressures on printer capacity. Congress presumably was not aware that printing costs varied with different compliance periods. Therefore, a significant percentage of printing costs are unexpected costs. An estimate of label inventory disposal costs of $306 million was also not available to Congress. These costs have the greatest effect on small firms, which have low profit margins and which normally retain higher inventories of labels.

Consistent with agency figures, the comments demonstrate that the magnitude of the nutrition labeling costs are 4 times that which was reasonably expected by Congress. Additionally, these costs decrease dramatically with a 6-month, 9-month, or 12-month delay of the nutrition labeling and nutrient content provisions. Thus, the costs of applying sections 403(q) and 403(r)(2) of the act on May 8, 1993, are unnecessary and unexpected and constitute undue economic hardship for affected industry. Therefore, the agency concludes that there is an appropriate basis to delay the application of these sections.

V. How Long Should Application of Sections 403(q) and 403(r)(2) of the Act be Delayed?

Having concluded that there will be undue economic hardship to the food

industry if it is forced to comply with sections 403(q) and 403(r)(2) of the act on May 8, 1993, and that some delay is appropriate, the agency has considered how long to delay the application of these sections. Section 10(b)(3)(A) of the 1990 amendments permits the agency to delay the application of these sections for up to 1 year.

In deciding on the length of the delay, the agency notes that several factors are relevant. First, Congress has passed a second law that will require a change in food labels. The American Technology Preeminence Act of 1991 (Pub. L. 102–245) (amended in Pub. L. 102–329 (hereinafter referred to as "the metric amendments") which amended the Fair Packaging and Labeling Act (the FPLA), requires that manufacturers revise their labels and labeling by February 14, 1994, to declare net weight declarations in both the customary unit/pound system of measure and the International System of Units metric system on food labels. Second, as a result of circumstances beyond FDA's control, the issuance of the final regulations with which industry will have to comply was delayed by slightly more than a month. Both of these factors must be considered in deciding on an appropriate applicability date.

19. The agency received several comments related to the metric amendments, requesting that the agency apply sections 403(q) and 403(r)(2) of the act on the same date as the metric amendments in order to avoid a costly relabeling. One comment argued that the date of application of the nutrition labeling and nutrient content revisions and the effective date of the metric amendments should be May 8, 1994, while another comment requested simultaneous implementation on November 8, 1994, or May 8, 1995.

FDA agrees with the comments that it would be desirable if the date of application of sections 403(q) and 403(r)(2) of the act and the effective date of the metric amendments were the same. Section 107(b) of the metric amendments requires that the metric provisions take effect 2 years after the date of enactment of the act which will occur on February 14, 1994. While section 10(a)(3)(B) of the 1990 amendments provides for a delay of the date of application of sections 403(q) and 403(r)(2) of the act, the metric amendments contain no such provision.

Initially, FDA intended to make the regulations issued under section 403(q) and (r)(2) of the act effective on February 14, 1994, providing a 9-month extension and enabling manufacturers to coordinate their compliance with both laws. However, as stated above, events beyond the agency's control have led to a delay in the publication of these final regulations. Therefore, requiring compliance with the regulations implementing section 403(q) and (r)(2) of the act by February 14, 1994, would not provide industry with sufficient relief from undue economic hardship. The agency has thus decided that it is appropriate for those regulations to go into effect May 8, 1994. The resulting period provided to industry to comply with the regulations is in the range of the 15-month compliance period that the agency had earlier contemplated providing.

FDA recognizes that the metric amendments will take effect February 14, 1994. FDA encourages those firms that are able to consolidate their relabeling efforts and comply with both the metric amendments and the 1990 amendments by February 14, 1994, to do so. Moreover, FDA notes that under the metric amendments, firms are free to use up their existing label stocks before they are required to comply with the new provision. Thus, FDA is unlikely to bring an action against a product because it fails to comply with the metric amendments until after May 8, 1994.

20. Several comments favored the 6-month delay option because most of the cost burden will be alleviated by a delay of that length. The comments argued that a 6-month delay will have the effect of reducing the demand for printers, thereby causing a substantial decrease in printing costs. They also pointed out that inventory disposal costs will be significantly reduced because firms would be given additional time to use up old labels.

While the 6-month option relieves much of the economic hardship on industry by reducing the cost of labeling from $1.5 billion dollars to $800 million, the agency has rejected this option because it would leave firms in the position of having to make a second relabeling within 3 months to comply with the metric amendments. The agency has always sought to minimize the cost of relabeling. Furthermore, both seasonal products and products from other countries would have particular problems with only a 1-year compliance period which includes a 6-month delay in application of sections 403(q) and 403(r)(2) of the act.

21. Some comments suggested a phasein date of applicability over a longer period such as 18 to 24 months. One comment requested a period of trial application of the proposed regulations followed by a 90-day period for comment.

The agency rejects these comments because the 1990 amendments make no provision for such a trial period or for a longer than 1-year delay in application. Additionally, such a phasein period would be extremely difficult for FDA to administer because it does not have the personnel to ensure compliance with an application date that, as it is phased in, affects only some firms or products. Thus, the agency finds no basis to adopt the approach suggested by this comment.

22. One comment from a consumer favored a 2-year delay because the consumer believed that the costs of compliance by the May 8, 1993, deadline would be excessive ($10 billion), and that most of this added cost would be passed on to consumers. Several industry comments also requested a 2-year delay because of the cost of making label changes to meet the May 8, 1994, date.

The agency estimated in the November 1991 RIA that the cost of compliance with the 1990 amendments would be $1.5 billion. While some industry comments assert that the cost would be as high as $3 to $4 billion, there simply is no basis to find, as the comment suggests, that the cost of relabeling would be $10 billion. More importantly, a 2-year delay in the application of sections 403(q) and 403(r)(2) of the act cannot be granted because section 10(a)(3)(b) of the 1990 amendments authorizes a delay of no more than 1 year.

23. An ice cream manufacturer requested that FDA defer the date of applicability of the 1990 amendments to ice cream products until 12 months after the agency takes final action on the International Ice Cream Association's petition to establish specific standards for modified ice cream.

The agency disagrees with this comment. First, the agency does not have legal authority to grant the relief requested. As discussed above, the act grants the agency authority to delay application of sections 403(q) and 403(r)(2) of the act for 1 year from their effective date, not for a 1-year period from any particular date in the future. Secondly, the agency cannot presume that it will grant the petition in question. Even if it does, however, the modified ice cream products in question will be new foods. Thus, the costs involved in labeling these products will be the costs attributable to starting a new product line, and not costs attributable to the changes imposed by the act. Therefore, FDA finds no basis to grant the requested delay.

24. Two comments from food manufacturers stated that if the date of

applicability is delayed, two relabelings will occur because the ingredient labeling rules are statutorily mandated to take effect on May 8, 1993.

FDA finds no merit to these comments. By delaying the application of sections 403(q) and 403(r)(2) of the act until February 1994, FDA is not requiring firms to delay relabeling until that date. Quite the contrary, FDA urges firms to relabel their products as quickly as possible. However, FDA has no authority to delay the effect of the ingredient labeling provisions. Thus, whether a firm that must make labeling changes to comply with the ingredient labeling provisions makes all its changes at that time, or decides to take advantage in the delay of applicability and thus has two relabelings, is up to the firm.

25. The overwhelming majority of comments supported a delay of the date of applicability for the full 1 year for sections 403(q) and 403(r)(2) of the act. The primary reasons for these requests were that a 1-year delay is necessary to give printers time to meet the excess demand for labels imposed by the nutrition labeling provisions, and that printing and analytical testing costs, prohibitive in a short compliance period, would be reduced to more reasonable levels.

The agency agrees with these comments that a delay of the date of application of sections 403(q) and 403(r)(2) of the act will alleviate the undue economic hardship for the industry. As discussed above, FDA had intended to provide a 9-month extension to February 14, 1994, but considers that an extension to May 8, 1994, is now appropriate because of the delay in publication of these rules.

The agency is thus providing the most time for compliance permissible under the 1990 amendments, as requested by these comments, although the total compliance time provided will be closer to 15 than 18 months.

The agency fully expects that many firms will begin to comply well in advance of the May 8, 1994, date of application of the nutrition labeling and nutrient content claim provisions. For firms that have their own inhouse analytical testing or printing capability, the transition will be easier than for those who do not. Some firms are already conducting nutritional analysis of their products and may be able to comply before the required date. Some firms may receive favorable positions in the queue of label printers and may complete labeling well in advance of the May 8, 1994, date. As these firms complete nutritional analysis and labeling, they will begin to use the revised labels. Therefore, consumers will receive some of the expected health benefits of the label changes during the period between May 8, 1993, and May 8, 1994.

VI. Effective Date of Regulations Implementing Sections 403(q) and 403(r)(2) of the Act

The agency is announcing that the regulations implementing sections 403(q) and 403(r)(2) of the act will be effective May 8, 1994, the date that the agency will begin to apply these provisions. Under section 10(b)(1)(D) and (E) of the 1990 amendments, the effective date of the regulations implementing sections 403(q) and 403(r)(2) of the act need not be the same as the effective date of those provisions. There is nothing in the 1990 amendments nor in the legislative history that states when FDA's regulations are to be effective. FDA is, therefore, free to make them effective on whatever date it considers appropriate.

The agency has chosen May 8, 1994. As a result, the current regulations on nutrition labeling and nutrient content claims will remain in effect until the agency begins to enforce the new statutory provisions on these matters. The agency finds that it would be most appropriate to have the new regulations that implement those provisions take effect at that time. Thus, on the effective date of the final rule on nutrition labeling, current § 101.9 (21 CFR 101.9) will disappear and be replaced by the new provision.

Therefore, under the act and under authority delegated to the Commissioner of Food and Drugs, FDA is establishing May 8, 1994, as the effective date of the regulations implementing sections 403(q) and 403(r)(2) of the act (except section 403(q)(4)), with a date of applicability of May 8, 1994.

Accordingly, compliance with the implementing final regulations on mandatory nutrition labeling and nutrient content claims published elsewhere in this issue of the **Federal Register** in response to the following November 27, 1991, proposals: (1) Food Labeling: Reference Daily Intakes and Daily Reference Values and Nutrition Labeling, Mandatory Status and Content Revision (Docket Nos. 90N–0134 and 90N–0135) (56 FR 60366); (2) Serving Sizes (Docket No. 90N–0165) (56 FR 60394); (3) Nutrient Content Claims, General Principles, Petitions, and Definition of Terms (Docket No. 91N–0384) (56 FR 60421); (4) Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content (Docket No. 84N–0153) (56 FR 60478); (5) Use of Nutrient Content Claims for Butter (Docket No. 91N–0344) (56 FR 60523); (6) Food Standards: Requirements for Substitute Foods Named by Use of a Nutrient Content Claim and a Standardized Term (Docket No. 91N–0317 et al.) (56 FR 60512); and (7) Format for Nutrition Label (Docket No. 91N–0162) (57 FR 32058, July 20, 1992) may begin immediately. All products initially introduced into interstate commerce on or after May 8, 1994, shall comply.

VII. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive RIA that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), along with the food labeling proposals, and the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA, published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

Comments to the November 1991 RIA indicated that costs of complying with the proposed May 8, 1993, effective date would exceed FDA's estimate in the RIA. These costs would include queuing costs to food manufacturers trying to comply with the short deadline to relabel food products. The final RIA contains revised cost estimates for the societal costs involved, which, for the most part, do not include queuing costs. Such costs, which have been analyzed in this document, are largely transfers between food manufacturers and labeling firms.

FDA concludes, based on its review of available data and comments, that the costs of the overall food labeling reform initiative will be reduced by nearly one-

half (a cost savings of approximately $700 million) by extending the date for compliance with the food labeling requirements to May 8, 1994. Further, the agency concludes that this action will significantly alleviate the economic hardship that would otherwise result if sections 403(q) and 403(r)(2) of the act were made applicable, as proposed, on May 8, 1993.

VIII. Environmental Impact

The agency previously considered the environmental effects of the action being taken in this final rule. As announced in the reproposed rule for mandatory nutrition labeling (56 FR 60366, November 27, 1991) and the proposed rule for nutrient claims (56 FR 60421, November 27, 1991), the agency determined that under 21 CFR 25.24(a)(8) and (a)(11), these actions are of a type that do not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

Several comments on the proposed rule suggested that there would be significant adverse environmental effects from the final rules unless the agency allowed more time between the publication of the final rules and their effective dates. The concern in these comments was that, if the agency did not allow firms more time between the publication of the final rules and their effective dates to use up existing label inventories, large stocks of labels and labeled packaging would have to be discarded. These comments questioned whether the agency had sufficiently examined the impact of disposing of obsolete labels and labeled packaging on this country's solid waste disposal capabilities. Two comments estimated the amounts of labeling from their respective industries, i.e., dairy and confectionery, that would need to be discarded following publication of FDA's final rules on several food labeling actions, including this action. However, these comments did not: (1) Provide details on how these estimates were derived, (2) identify what portion of the estimated amounts are attributable to these two actions, or (3) describe what impact the discarded labels and packaging would have on the disposal of solid waste. In its November 27, 1991, reproposed rule for mandatory nutrition labeling and proposed rule for nutrient content claims, the agency proposed that the final rules for these actions would become effective 6 months following their publication in the **Federal Register**.

However, the agency has decided to not make these rules effective until May 8, 1994. FDA believes there will thus be ample time for food companies to use up most of the existing labeling and packaging stocks and to incorporate labeling language that complies with FDA's regulations into their food labels. Consequently, the comments on the potential for adverse environmental effects do not affect the agency's previous determination that no significant impact on the human environment is expected and that an environmental impact statement is not required.

Dated: December 17, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 101

[Docket Nos. 90N-0135, 91N-0162, 78P-0091, 87P-0194/CP, AND 90P-0052]

RIN 0905-AD08

Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to: (1) Require nutrition labeling on most foods that are regulated by FDA, (2) revise the list of required nutrients and food components and the conditions for declaring them in nutrition labeling, (3) specify a new format for declaring nutrition information, (4) allow specified products to be exempt from nutrition labeling, and (5) prescribe a simplified form of nutrition labeling and the circumstances in which such simplified nutrition labeling may be used. This final rule also responds to citizen petitions on the declaration of dietary fiber in nutrition labeling and on methodologies for determining protein content.

DATES: Effective February 14, 1994. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in 21 CFR 101.9(c)(1)(i)(A), (c)(1)(i)(B), (c)(1)(i)(C), (c)(1)(i)(E), (c)(6), (c)(7)(ii), (c)(7)(ii)(B), and (g)(2), effective (February 14, 1994).

FOR FURTHER INFORMATION CONTACT: Virginia L. Wilkening, Center for Food Safety and Applied Nutrition (HFF-200), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-205-4561.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 19, 1990 (55 FR 29847), FDA published a proposed rule entitled "Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision" (hereinafter identified as "the mandatory nutrition labeling proposal") to amend its food labeling regulations to require nutrition labeling on most food products that are meaningful sources of nutrients. FDA also proposed to revise the list of nutrients and food components that must be included in nutrition labeling by adding calories from fat, saturated fatty acids, cholesterol, and dietary fiber to that list. It proposed to make the listing of thiamin, riboflavin, and niacin optional rather than mandatory. In addition, FDA addressed the conditions under which other nutrients could be, or are required to be, included in nutrition labeling and proposed to allow manufacturers to voluntarily include a nutrition profile of selected food components in nutrition labeling.

During the comment period for these proposed regulations, Congress passed, and the President signed into law, the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101-535, November 8, 1990). The 1990 amendments amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 403(q) (21 U.S.C. 343(q)) which specifies, in part that: (1) With certain exceptions, a food is to be considered misbranded unless its label or labeling bears nutrition labeling, (2) certain nutrients and food components are to be included in nutrition labeling, although the Secretary of Health and Human Services (the Secretary) can add or delete nutrients by regulation if he finds such action necessary to assist consumers in maintaining healthy dietary practices, (3) nutrition labeling is to be provided for the most frequently consumed varieties of raw produce (fruits and vegetables) and raw fish according to voluntary guidelines or, if necessary, regulations, (4) a simplified nutrition label is to be used when the food contains insignificant amounts of most nutrients, and (5) FDA is to develop regulations governing labeling of foods to which section 411 of the act (21 U.S.C. 350) applies.

In response to these requirements of the 1990 amendments, FDA published in the **Federal Register** of November 27, 1991 (56 FR 60366; as amended (57 FR 8178, March 6, 1992)) a proposal (hereinafter identified as the supplementary proposal) to modify its July 19, 1990, proposal by: (1) Adding sugars and complex carbohydrates to the list of required nutrients in nutrition labeling, (2) prescribing a simplified form of nutrition labeling and the circumstances in which such simplified nutrition labeling must be used, (3) allowing specified products to be exempt from nutrition labeling, and (4) establishing regulations for the nutrition labeling of vitamin and mineral supplements. The agency also responded to a citizen petition regarding methodologies for determining protein quality. Interested persons were given until February 25, 1992, to comment.

Subsequently, FDA published in the **Federal Register** of July 20, 1992 (57 FR 32058; amended at 57 FR 37190, August 18, 1992), a proposal (hereinafter identified as the format proposal) to adopt a new format, specifically the PERCENT DV (Daily Value) with DRV (Daily Reference Value) format, for use in presenting nutrition information on the food label. Interested persons were given until August 19, 1992, to comment. In addition, on July 23, 1992, a notice was published in the **Federal Register** (57 FR 32750) of a public meeting to be held on the format proposal in Bethesda, MD, on August 17, 1992.

On October 6, 1992, Congress passed the Dietary Supplement Act of 1992 (H.R. 6181) (hereinafter referred to as the "DS Act") that, in section 202(a)(1), establishes a 1 year moratorium on the implementation of the 1990 amendments with respect to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances. Section 202(a)(2) requires the Secretary, and by delegation FDA, to issue new proposed regulations that are applicable to dietary supplements no later than June 15, 1993, and final regulations by December 31, 1993. In addition, section 203 instructs FDA to not promulgate regulations that require the use of, or are based upon, recommended daily allowances of vitamins or minerals before November 8, 1993 (other than regulations establishing the United States Recommended Daily Allowance (U.S. RDA) specified in 21 CFR 101.9(c)(7)(iv) as in effect on October 6, 1992).

FDA received approximately 1,500 responses to its July 19, 1990, mandatory nutrition labeling proposal, approximately 3,000 responses to the November 27, 1991, supplementary proposal, and approximately 1,000 responses to the July 20, 1992, format proposal, each of which contained one or more comments. Responses were received from consumers, health professionals, health promotion organizations, trade and retail associations, State and local governments, foreign governments, professional societies, consumer advocacy organizations, industry, and universities. The comments generally supported the proposals. Several comments addressed issues covered by other proposals that are a part of this overall food labeling initiative, and they will be addressed in those final documents, while other comments were outside the scope of these proposals and will not be discussed here. Many

comments dealt with issues pertaining to meat and poultry products whose labeling is regulated by the U.S. Department of Agriculture (USDA). Of those comments, comments pertaining to the content or format of the nutrition label are included in the following discussions. However, comments pertaining to issues covered exclusively by USDA, such as specific exemptions applicable to meat and poultry products, were considered to be outside the scope of this document.

A number of comments to both the July 19, 1990, and November 27, 1991, proposals suggested modifications in, or were opposed to, various provisions of the proposals. A summary of the suggested changes, the opposing comments, and the agency's responses follow.

II. Mandatory Nutrition Labeling—Legal Authority

1. Most comments agreed that the 1990 amendments clearly established FDA's authority to mandate nutrition labeling on most foods. One comment, however, argued that a requirement that labels say or not say certain things curtails freedom of the press.

The agency disagrees. FDA's authority to regulate the content of food labels has been broadly upheld against First Amendment challenges. This issue is discussed at length in both the final rule on nutrient content claims entitled "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms" and the final rule on health claims entitled "Food Labeling; General Requirements for Health Claims for Food," both of which are published elsewhere in this issue of the **Federal Register**. Those discussions are incorporated in this document by reference. As those discussions make clear, there is no merit to this comment. Therefore, FDA is taking no action on the basis of this comment.

2. One comment objected to FDA being given authority to mandate nutrition labeling on most foods on the basis that current nutrition labeling rules were legally questionable.

The question of FDA's authority to require nutrition labeling was a fundamental issue that led Congress to pass the 1990 amendments. As discussed in the legislative history, Congress concluded that legislation was needed to strengthen FDA's authority to require nutrition labeling on foods and to avoid the possibility of protracted litigation over the comprehensive nutrition labeling regulations that the agency adopts (Ref. 16). Therefore, there can be no question about FDA's authority to require nutrition labeling on most food products.

III. Content of the Nutrition Label

A. General Issues

1. Voluntary Declaration of Additional Information

3. A number of comments objected to the voluntary declaration of nutrients beyond those required in nutrition labeling. Numerous comments stated that the declaration of additional information on the food label would be confusing, or that it might mislead the consumer into believing that a product with additional nutrients listed is more nutritious or has greater public health significance than is the case. Some comments objected on the basis that the additional information would clutter the label and diminish the consumer's focus on mandatory nutrients. A few comments expressed concern that voluntary declaration of additional nutrients on the label will require smaller print on the food label to accommodate the inclusion of all the mandatory and voluntary information, and that the smaller type size would compromise the usefulness of the label information to the elderly or visually impaired.

A number of comments supported the voluntary listing of additional nutrients, pointing out that the 1990 amendments require that the regulations permit the label or labeling of food to include nutrition information, which is in addition to the information required by section 403(q) of the act and which is of the type described in subparagraph (1) or (2) of that section. A few comments supported the view that voluntary listing of additional nutrients may provide valuable information to an individual or aid the consumer in making an informed choice in food selection. Other comments supported voluntary listing of additional nutrients stating that some nutrients may satisfy nutrient needs of some individuals or pose a health risk to others. One comment pointed out that the Institute of Medicine (IOM) report (Ref. 1) recommends that regulations allow the declaration of all micronutrients for which Recommended Dietary Allowances have been established by the National Academy of Sciences.

Numerous comments that basically supported listing of additional information also supported limiting the information allowed. Some comments supported allowing voluntary information, but they suggested that FDA standardize the manner in which it is included on the label to the extent of requiring that it be separate from the nutrition label or in different type size. Five comments requested voluntary listing of specific nutrients including: Potassium; vitamins E, K, and B6; copper; manganese; iodine; maltodextrin; and L-glutamate, L-cysteine, and L-tryptophan. Two comments supported the listing of additional nutrients but recommended restricting the allowed nutrients to those for which Recommended Dietary Allowances have been set by the National Academy of Sciences (Ref. 23) or for which Reference Daily Intakes (RDI's) have been determined by FDA. One of these comments further suggested restricting the allowed nutrients to exclude nutrients that do not have Recommended Dietary Allowances but only have Estimated Safe and Adequate Daily Dietary Intakes (ESADDI's), which are also set by the National Academy of Sciences (Ref. 23). One comment suggested that additional information on the food label be restricted to information permitted by the Council of the European Communities (EC).

FDA, in its mandatory nutrition labeling proposal of July 19, 1990, proposed to allow the voluntary declaration of several nutrients (e.g., potassium and soluble fiber) and any naturally occurring vitamins and minerals for which RDI's had been proposed in § 101.9(c)(10)(iv) (21 CFR 101.9(c)(10)(iv)), which was redesignated as § 101.9(c)(11)(iv) in the November 27, 1991, proposal. Additionally, section 2(b)(1)(C) of the 1990 amendments states that regulations shall permit the label or labeling of food to include nutrition information that is in addition to the information required by section 403(q) of the act and that is of the type described in subparagraph (1) or (2) of that section. Section 403(q)(2) of the act refers to information that will assist consumers in maintaining healthy dietary practices.

FDA believes that it is required by statute to allow additional information on the food label insofar as it assists consumers in maintaining healthy dietary practices. However, the agency raised questions in the supplementary proposal about how the presence of these additional nutrients on the label would be interpreted by consumers, and whether the listing of some voluntary nutrients would actually be misleading (56 FR 60366 at 60372). The comments confirmed that unlimited additional information on the nutrition label would have the potential of being confusing or misleading.

FDA requested comments on whether it is necessary to include limits on the voluntary information that may be

provided on the nutrition label. The comments that FDA received on this issue have lead the agency to conclude that it has a responsibility to limit the number of nutrients permitted to be voluntarily listed on the food label. Such a limitation reflects the statement in the House report (Ref. 16, p. 18) that the regulations that FDA adopts should assure that the information that is included voluntarily does not interfere with the consumer's understanding of the information that is required to be included on the nutrition label. The agency finds that limits are necessary so that the emphasis is on the required information, and that the additional information does not clutter the food label or mislead or confuse the consumer.

Therefore, to limit the information that may be provided on the nutrition label, FDA is amending the proposed regulations to delete "calories from unsaturated fat," "calories from carbohydrates," "calories from protein," and quantitative declarations of "unsaturated fat" from the list of nutrients that are allowed to be declared voluntarily on the nutrition label. Each of these deletions is detailed below. FDA has decided to permit the voluntary declaration on the nutrition label of "calories from saturated fat," "polyunsaturated fat," "monounsaturated fat," "soluble fiber," "insoluble fiber," "sugar alcohol," "other carbohydrate," "potassium" and those vitamins and minerals for which RDI's have been established.

With respect to other nutrients suggested by individual comments for consideration for voluntary listing on the food label, the agency has not been persuaded that there are large numbers of consumers who desire a voluntary listing of the food components in question (e.g., maltodextrin or single amino acids. Therefore, FDA will not allow voluntary listing of these other substances or food components on the nutrition label. To implement this section, FDA has added a sentence to § 101.9(c) that states that no nutrients or food components other than those set forth in that section as either mandatory or voluntary may be included in the nutrition label. The inclusion of any other nutrient or food component would violate section 403(q) of the act and misbrand the food.

Also, while FDA supports efforts toward international harmonization of food labeling where possible, the 1990 amendments direct FDA to permit that a broad spectrum of nutrients be on the food label unless the agency finds that the information is not necessary to assist consumers in maintaining healthy dietary practices, a finding that FDA has generally not made. As a result, the spectrum of required and permitted nutrients exceeds those permitted by the EC.

FDA is not requiring that additional nutrients declared voluntarily be put in separate boxes or a different type size because it believes these actions would confuse consumers and would complicate and clutter the label needlessly. In some instances additional nutrients, whose declaration is usually voluntary, will be required to be declared. For example, in the case of fortified foods, enriched pasta must declare amounts of thiamin, riboflavin, and niacin, and margarine must declare vitamin D when it is added. In other cases, if certain claims are made, additional nutrients will be required to be declared. For example, when nutrient content claims are made about cholesterol, declaration of poly- and monounsaturated fats are required (see § 101.9(c)(2) (i) and (ii). Placing these nutrients in the principal box for nutrition labeling when required, and in a separate box (or different type size) when voluntarily added to the nutrition label would easily confuse consumers. Also, separating subcomponents that can voluntarily be declared, such as soluble and insoluble fiber, from the primary component, dietary fiber, for which declaration is mandatory, would unduly complicate the label.

However, in response to comments concerned that information on additional nutrients would clutter the label and to comments on the format proposal, FDA is providing in new § 101.9(d)(8) for a linear array of vitamins and minerals. This form of presentation, which is discussed in more detail in section V. of this document, is similar to that recommended in the IOM report (Ref. 1) which places more emphasis on the macronutrients.

2. Order of Nutrients

4. Several comments from industry, health promotional organizations, and academia supported the order of nutrients proposed by FDA in § 101.9(c) (56 FR 60366 at 60386 through 60390). One industry comment stated that the proposed sequence fairly prioritized the Dietary Guidelines for Americans (Ref. 4) and placed the proper emphasis on those dietary factors that affect the health of consumers. This comment, along with one from a health promotion organization, also endorsed the separation of vitamins and minerals from other nutrients seen in proposed formats (57 FR 32058), stating that this feature represented a logical break in the list of nutrition information and would both improve label readability and facilitate consumers' search for specific nutrient data. Another comment supporting the proposed order endorsed the listing of nutrients from those most important to consumers to those least important to consumers but questioned whether protein should be included.

On the other hand, several comments argued that the proposed order of nutrients has features that would mislead consumers. One comment characterized the proposed order as "an unwarranted effort to overemphasize some nutrients, such as fat, at the expense of the other important label components" and suggested that the decision on whether to emphasize one nutrient over another should be left to nutrition education programs that consider the total diet over a long period of time. Other industry comments criticized the proposed order of nutrients, stating that it would be consistent with the "good food/bad food" concept and would convey a negative impression to consumers. One industry comment supporting the current order of nutrients argued that protein should not be listed near the end, stating that beneficial nutrients should be listed at the beginning of the nutrient list. The comment suggested that from an educational standpoint, it is more positive to educate on the good points of nutrition labeling than to focus on negative aspects.

A number of comments advocated that the current order of nutrients be maintained, or that any modified order resemble the current order as closely as possible. Several comments supporting the current order of nutrients stated that consumers are already accustomed to the current order, and that changing the order would lead to unnecessary confusion and diminish consumers' understanding of the nutrition label.

A few comments suggested alternative nutrient orders. A comment from a professional organization stated that those nutrients whose overconsumption is related to increased risk of disease should be placed at the top of the list of required nutrients. One industry comment recommended that nutrients be regrouped to first list those nutrient whose Daily Value is dependent on calorie intake (i.e., total fat, saturated fat, carbohydrate, dietary fiber, and protein), followed by those whose Daily Value remains the same for varying calorie intakes (i.e., cholesterol and sodium). Another comment requested that sodium be listed with the vitamins and minerals rather than among the organic macronutrients.

A comment from a manufacturer addressed the issue of where to place the voluntary nutrients on the label. The comment suggested that voluntary nutrients should be sequenced in a logical manner with respect to the nutrients whose declaration is mandatory. The following examples were cited: Unsaturated fat should follow saturated fat (both should be indented), potassium should follow sodium, soluble and insoluble fiber should follow dietary fiber, and vitamins and minerals should follow those that are mandatory.

The agency is not persuaded by arguments stating that listing nutrients in order of public health importance will cast foods as either "good foods" or "bad foods." Listing nutrients in this manner will instead facilitate selection of an overall diet that is consistent with dietary guidelines based on what nutrients are present in a particular food and in what amounts. No data were presented to show that use of this nutrient order on the nutrition label is likely to be confusing to consumers.

The agency also does not agree with the request that sodium be placed with vitamins and minerals rather than with the organic macronutrients. Sodium is an electrolyte that is distinct from both organic nutrients and vitamins and minerals. However, excessive intake is associated with a potential increase in the risk of chronic diseases, as are excessive intakes of the other mandatory organic nutrients (i.e., macronutrients such as fat) in the nutrition label. Vitamins and minerals generally are associated with deficiency diseases. The agency believes this categorization supports the continued placement of sodium with the organic nutrients.

FDA agrees that the placement of voluntary nutrients should be sequenced in a logical manner with respect to the mandatory nutrients. FDA has provided in new § 101.9(c) that voluntary nutrients that are subcomponents are to be declared immediately beneath the primary components, and that potassium (the second electrolyte) is to be declared adjacent to sodium.

The agency believes that a revised order according to the public health significance of a nutrient will adequately convey nutrient information with no appreciable increase in consumer effort. This action is based on the order provided in section 403(q)(1) of the act (see Ref. 16, p. 13) and the comment recommending that nutrients whose overconsumption is related to increased risk of disease should be placed at the top of the list of required nutrients.

Accordingly, new § 101.9(c) is modified to require mandatory and voluntary nutrients to be arranged in the following order: Calories, calories from fat, calories from saturated fat, total fat, saturated fat, polyunsaturated fat, monounsaturated fat, cholesterol, sodium, potassium, total carbohydrate, dietary fiber, soluble fiber, insoluble fiber, sugars, sugar alcohol, other carbohydrate, protein, vitamin A, vitamin C, calcium, iron, and other vitamins or minerals in the order listed in proposed § 101.9(c)(11)(iv), redesignated as § 101.9(c)(8)(iv). This order deviates from that provided in section 403(q)(1) of the act only by reversing dietary fiber (and its subcomponents) and sugars. The reason for this reversal is discussed in comment 58 of this document.

Consequently, the paragraphs in § 101.9(c) are renumbered as discussed below for each nutrient. Redesignations also occur as a result of moving paragraphs (c)(1) and (c)(2) pertaining to serving size and servings per container, respectively, to new paragraph (d).

The agency believes that this amended order of nutrients, which lists them in order of public health significance, will benefit consumers. The agency's decision is a reasonable outgrowth of its commitment to present nutrition information in the context of a total daily diet, and it reflects the agency's commitment to link nutrient information with the dietary guidance considered important to public health (Ref. 4).

B. Calories

1. Total Calories

5. The majority of comments supported the proposal for mandatory declaration of calories with voluntary use of metric terminology (i.e., declaration of the number of kilojoules in addition to calories in proposed § 101.9(c)(3), redesignated as § 101.9(c)(1), and voluntary use of the term "energy" parenthetically as a synonym for calories, as provided in § 101.9(c)(11)(v), redesignated as § 101.9(c)(8)(v)).

Other comments expressed a preference for metric labeling. The comments argued that American consumers should become accustomed to the metric system of measurement and recommended the exclusive use of metrics to ensure compatibility with European markets. The comments suggested that the avoirdupois system of measurement used in the United States is outmoded and impedes international commerce and the exchange of scientific information. Several comments suggested that "energy" should be used in lieu of calories and requested that the conversion factor for calories to kilojoules be stated on each label.

Still other comments, taking the opposite position, suggested that metric units be disallowed to avoid consumer confusion and for the sake of simplicity.

Although FDA agrees that efforts should be made to familiarize consumers with metric units, the agency disagrees with the comments that urged the exclusive, mandatory conversion to metrics at this time. The technical amendments (August 3, 1992) to the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq., Pub. L. 102–329) require the use of the most appropriate units of both the customary inch/pound system of measure and the metric system on food labels for measuring quantity. These amendments do not require that kilojoules be declared in lieu of calories. Upon implementation, this act should further an awareness of metric measurement among American consumers and permit a greater concordance in units of measurement with the international market and scientific community. Until that time, the agency is not persuaded that the mandatory use of metric terminology, or the declaration of factors to convert calories to kilojoules, is justified. Accordingly, the agency is not making the requested changes.

2. Calories From Fat

6. Many comments were received from consumers, state and local governments, universities, professional associations, consumer groups, manufacturers, and health associations on the issue of calories from fat. The majority agreed with the proposal that the declaration of calories from fat should be mandatory on the nutrition label.

Several other comments suggested that calories from fat be voluntarily listed or disallowed because this information might be confusing or misleading to consumers and might establish artificial "good food" and "bad food" categories. These comments stated that consumers may tend to exclude foods with a significant amount of calories from fat, possibly creating nutritional deficiencies. Further, these comments stated that it is important that consumers view fat as part of a day's diet rather than in the context of individual foods. A few comments suggested that declaring the calories from fat is unnecessary because calories from fat can be easily calculated by multiplying the number of grams (g) of fat by nine, the number of calories per g of fat. A few comments suggested that

there be further study of the effectiveness of the declaration of calories from fat in nutrition labeling as a nutrition education tool. One comment suggested that low fat foods, such as fruits and vegetables that contain less than 2 g of fat, be exempted from the requirement to list calories from fat.

FDA is not persuaded by the arguments that the declaration of calories from fat should be voluntary or disallowed. The declaration of calories from fat is required by section 403(q)(1)(C)(ii) of the act. While section 403(q)(2)(B) of the act allows the Secretary to delete nutrient information that is not necessary to assist consumers in maintaining healthy dietary practices, no data were presented that would support making such a finding with respect to the declaration of calories from fat.

It is well established that diets that are high in fat pose significant health risks. Dietary fat contributes more than twice the calories per g than does protein or carbohydrate. Overconsumption of fat is associated with higher rates of obesity (Refs. 2 and 3), and there is evidence from epidemiological and animal studies that high fat intakes are associated with some types of cancer (Refs. 2 and 3). The most common and consistent dietary recommendation for the general population is for calories from total fat to be reduced to less than or equal to 30 percent of total calories (Refs. 3 and 4).

Currently, the consumption of total fat in the general population is approximately 37 percent of total calories, an amount well above the recommended level (Ref. 2). Further, consumption of total fat in the United States is significantly higher than that consumed in countries with much lower rates of coronary heart disease, such as Japan, China, and the Mediterranean countries (Ref. 2).

Based upon this body of evidence, FDA believes that reducing total fat intake is an important public health priority. The agency is not persuaded that the declaration of calories from fat will automatically lead to consumers viewing foods in strict "good food," "bad food" categories, or that consumers cannot make appropriate decisions regarding the consumption of foods that may have a significant number of calories from fat in their diets. No evidence was presented demonstrating a relationship between the declaration of calories from fat in nutrition labeling and nutritional deficiencies.

Although calories from fat can, in fact, be readily calculated (FDA is requiring that information on the number of calories per g of fat, carbohydrate, and protein, be included as part of the nutrition label (see § 101.9(d)(10)), the declaration of calories from fat will be beneficial in assisting consumers to moderate their fat intake by providing an additional method, other than g of fat, for monitoring their fat intake.

However, the agency concurs that fat should be viewed as a part of the complete daily diet. Foods that may have a significant number of calories from fat may readily be included in the daily diet when the overall fat intake for the day is moderate. The agency intends to build this concept into its consumer education program, discussed later in this document. Further, FDA welcomes further study on the health implications of overconsumption of calories from fat and the effectiveness of this method of depicting fat content.

7. Many comments advocated the mandatory declaration of the percent of calories from fat. Other comments suggested that calories from total fat should be replaced by the percent of calories from fat. The comments stated that the process of determining the percent of fat is time consuming and unfamiliar to many consumers. Further, the comments argued that it is unlikely that substantial numbers of consumers would or could keep running totals of their fat intake in order to calculate the percent of daily fat consumed. The comments argued that the best way to determine whether a food is high or low in fat is to have fat content declared by percent of total calories.

A few comments suggested that percent of calories from fat for individual foods is incomplete information, while the percent of calories from fat for a complete meal or the daily diet is useful information. These comments suggested that the percent of calories from fat be voluntary and limited to meal-type products, such as frozen dinners, and disallowed for other foods.

The agency is not persuaded by the comments that the declaration of percent calories from fat is warranted. As discussed in the July 19, 1990, mandatory nutrition labeling proposal (55 FR 29487 at 29493 and 29494), information on the percent of calories from fat is only valuable in the context of a total daily diet. Recommendations from various health organizations to limit dietary fat intake to 30 percent or less of calories pertain not to individual foods but to the entire day's intake.

In addition, the percent of calories from fat in low calorie foods can be quite misleading. For instance, in radishes, over 25 percent of calories are from fat. Despite this relatively high percentage, radishes contain very low amounts of fat and readily fit within a daily diet that meets current dietary recommendations.

The agency agrees that calculating the percent of calories from fat consumed in a day may be difficult for many consumers. The agency notes that the PERCENT DV format (see section V.G.2) facilitates monitoring of dietary fat because the Daily Value for fat is set at 30 percent of calories from fat. Consumers need only add the percent DV for total fat with a target of no more than 100 percent or a target percentage adjusted for their individual caloric intake. Alternatively, consumers can determine the maximum number of g of fat recommended per day at their calorie level and track the number of g of fat. There are several publications listing recommended daily maximum amounts of fat according to caloric intake or that have simple arithmetical methods for deriving this information (Refs. 26 through 29). In a similar fashion, the DRV for fat, which is established in the companion document entitled "Food Labeling; Reference Daily Intakes and Daily Reference Values" (hereinafter identified as the "RDI/DRV proposal") published elsewhere in this issue of the **Federal Register**, can be used as a guide, with levels being adjusted upward or downward depending on caloric intake. The agency encourages other organizations to develop and publish similar approaches.

8. One comment objected to that section of § 101.9(c)(3)(i) in the July 19, 1990, mandatory nutrition labeling proposal that allowed "calories from fat" to be omitted and replaced with the statement "Not a significant source of calories from total fat" if the product contains less than 1 g of fat per serving. The comment objected to similar provisions for saturated fat, cholesterol, and dietary fiber on the basis that it made the regulations complex and confusing. These provisions were carried forward in the November 27, 1991, supplementary proposal with the 1-g criterion being changed to ½ g, and similar provisions being added for complex carbohydrates and sugars.

These provisions were included in the July 19, 1990, mandatory nutrition labeling proposal (55 FR 29487 at 29502), which was published before the adoption of the requirement in section 403(q)(5)(C) of the act for a simplified format, to minimize the space required for nutrition labeling. This provision is similar to that allowed in current § 101.9(c)(7)(i) for vitamins and minerals that are present in amounts less than 2 percent of the U.S.

Recommended Daily Allowance (U.S. RDA). FDA did not delete these provisions in the November 27, 1991, supplementary proposal because the agency believed they might be helpful in minimizing space requirements on foods that do not qualify for the simplified format under proposed § 101.9(f).

FDA finds that the added flexibility that these provisions provide outweighs any added complexity they may create. USDA's final nutrition labeling regulations, which are being published simultaneously with these final rules, include similar provisions. Under FDA's regulations, with the exception of the core nutrients (i.e., calories, total fat, total carbohydrate, protein, and sodium), nutrients that are present in insignificant amounts may be omitted from the list of nutrients and grouped in a summary statement (e.g., "Not a significant amount of calories from fat, saturated fat, and cholesterol"). Therefore, the agency is retaining in § 101.9(c)(3)(i), redesignated as § 101.9(c)(1)(ii), for calories from total fat; in § 101.9(c)(4)(i), redesignated as § 101.9(c)(2)(i), for saturated fat; in § 101.9(c)(5), redesignated as § 101.9(c)(3), for cholesterol; in § 101.9(c)(6)(ii)(A), redesignated as § 101.9(c)(6)(ii), for sugars; in § 101.9(c)(7), redesignated as § 101.9(c)(6)(i), for dietary fiber; and in § 101.9(c)(11)(iii), redesignated as § 101.9(c)(8)(iii), for vitamins and minerals a provision that allows the nutrients to be omitted and replaced with a statement "Not a significant source of _____" when present in insignificant amounts. An example of this shortened format is given in appendix A of this document.

3. Calories From Saturated Fat

9. Several comments agreed with the proposal that declaration of calories from saturated fat should be voluntary. A few comments suggested that this information should be mandatory and referred to national dietary guidelines recommending that saturated fat be limited to less than 10 percent of total daily calories. A few comments requested that declaration of percent of calories from saturated fat be made mandatory.

Several comments believed that the declaration of calories from saturated fat should be disallowed. The comments argued that this information is redundant, confusing, and misleading.

FDA acknowledges that research has established the role of saturated fats in the etiology of atherosclerotic vascular disease and recognizes that there are national consensus recommendations regarding the levels of intake for saturated fat. However, section 403(q)(2)(A) of the act permits the Secretary to require the inclusion of information on additional nutrients in nutrition labeling if he determines that such information "will assist consumers in maintaining healthy dietary practices." The agency is not persuaded that the mandatory declaration of calories from saturated fat or the percentage of calories from saturated fat meet this criterion.

First, this information may be obtained by simple calculation if needed (i.e., calories from saturated fat can be calculated by multiplying the g of saturated fat by nine, the number of calories per g of fat; the percentage of calories from saturated fat can then be determined by dividing the number of calories from saturated fat by the total calories). Secondly, concerns have been expressed in comments that consumers will be faced with so much information that they will avoid using any of it. To minimize the possibility of this happening, FDA believes that it is preferable to have consumers concentrate on the number of calories from total fat. By controlling dietary intake of calories from fat, intake of calories from saturated fat will also be controlled.

However, in recognition of dietary recommendations that Americans should consume less than 10 percent of calories from saturated fat (Refs. 3, 4, and 30) FDA is continuing to allow voluntary declaration of calories from saturated fat in § 101.9(c)(3)(ii)(A), redesignated as § 101.9(c)(1)(iii).

4. Calories From Unsaturated Fat

10. Several comments agreed with proposed § 101.9(c)(3)(ii)(B) that the declaration of calories from unsaturated fat should be voluntary. A few comments suggested that the declaration of calories from unsaturated fat should be mandatory. These comments stated that caloric information on unsaturated fat would be helpful in monitoring unsaturated fat intake to maintain consumption of unsaturated fat at not more than the 20 percent of total calories.

Several other comments suggested that this information be disallowed because it will not be useful to the consumer in evaluating a total day's food intake, and because the information is potentially confusing.

A few comments requested that declaration of calories from monounsaturated and polyunsaturated fats be mandatory. One comment requested that declaration of the percent of calories from monounsaturated and polyunsaturated fats be mandatory. These comments stated that caloric or percentage information on monounsaturated and polyunsaturated fats would be helpful in limiting consumption of each of these two classifications of fatty acids to not more than 10 percent of total calories each.

The agency has decided not to permit declarations regarding calories from unsaturated fats because there is considerable uncertainty and controversy about the term "unsaturated fat" and its definition, specifically whether the "*trans*" isomers of monounsaturated fat should be included in this category of fats. These isomers have been implicated in the development of coronary heart disease and cancer (Ref. 31) and are discussed in the subject health claims rules published elsewhere in this issue of the **Federal Register.**

Further, the agency is not persuaded that it should allow the voluntary declaration of calories from monounsaturated and polyunsaturated fats. Definitions of monounsaturated and polyunsaturated fats include *cis* isomers only. *Trans* isomers are excluded. The declaration of calories from monounsaturated and polyunsaturated fats would therefore underrepresent the total caloric value of these fats because of the exclusion of the *trans* isomers. Such an underrepresentation would be misleading to consumers. Therefore, the agency is not allowing the declaration of calories from polyunsaturated and monounsaturated fats in the nutrition label.

11. One comment suggested that § 101.9(c)(3)(ii)(A) and (c)(3)(ii)(B) be modified to clarify that when the declaration of calories from saturated fat is declared adjacent to the declaration of g of saturated or unsaturated fat, that it be in a column headed "calories" as was stated in § 101.9(c)(3)(i) for calories from total fat.

The agency has reconsidered the proposed format in the supplementary proposal that would have allowed a separate column for listing calories. As discussed in section V. of this document, FDA is incorporating additional columns into the nutrition label to declare the percent of daily value and the daily value list. For this reason, the agency believes a column headed "calories" would add to label clutter and, therefore, has not made the suggested change. FDA has modified § 101.9(c)(1)(ii) to delete the option that calories from total fat be declared in a column headed "calories."

5. Calories From Carbohydrate

12. Several comments requested that the declaration of calories from carbohydrates be made mandatory so that consumers can monitor and adjust their intake of calories from carbohydrate to approach the recommended 50 to 60 percent of total calories. A few comments requested that the declaration of percent of calories from carbohydrate be made mandatory. Several comments agreed with the proposal to allow the voluntary listing of calories from carbohydrate. Several other comments requested that FDA not permit the declaration of calories from carbohydrate because this information is potentially confusing to consumers. These comments suggested that this information would not be helpful in evaluating a total day's food intake. A few comments argued that too much information is burdensome to the consumer, and that if it results in the manufacturer using smaller type size, it could make the information more difficult for the elderly to read. Further, the comments suggested that there was a danger of "information overload" and "label clutter."

Based on the comments to the July 19, 1990 and November 27, 1991, proposals, the agency has reconsidered its proposal to permit the voluntary declaration of calories from carbohydrate and has decided not to permit this declaration. As discussed in the mandatory nutrition labeling proposal of July 19, 1990 (55 FR at 29493), FDA's intent is to require the listing of only those nutrients that present public health concerns and for which quantitative intake recommendations have been made. FDA proposed to permit the voluntary declaration of calories from carbohydrate because of general recommendations that suggested that intake of carbohydrate should be increased to 50 to 60 percent of total calories but recognized that carbohydrate is not of pressing public health significance.

Based on its evaluation of the comments, FDA has become concerned that it will overemphasize the public health significance of carbohydrate if it allows the declaration of calories from this nutrient. Additionally, the legislative history of section (2)(b)(1)(C) of the 1990 amendments (Ref. 16) makes clear that while FDA must allow the declaration of additional nutrients in nutrition labeling, it must ensure that such information does not interfere with the consumer's understanding of the information required by the act. Thus, FDA considers it important to ensure the comprehensibility of the nutrition label.

The 1990 IOM report "Nutrition Labeling: Issues and Directions for the 1990s" (Ref. 1) emphasizes the importance of considering information quantity and complexity when determining the components of the food label (Ref. 1). The report suggests that too much information compromises the ability of many consumers to understand the label.

The agency is persuaded that because the amount of calories from carbohydrate is not of pressing public health significance, it should not provide for inclusion of this information in nutrition labeling. Accordingly, FDA has deleted proposed § 101.9(c)(3)(ii)(C) from the final regulation.

Consumers interested in determining the calories from carbohydrate for the vast majority of individual foods may simply multiply the number of g of carbohydrate by four, the number of calories per g of carbohydrate. Consumers attempting to compare their intake of carbohydrates to the recommended amounts of 50 to 60 percent of total caloric intake can use the Percent Daily Value format in the same way described for monitoring fat intake. Because the Daily Value for carbohydrate is set at 60 percent of calories, consumers need only add the percent DV for total carbohydrate with a target of 100 percent or a target of a percentage adjusted for their individual caloric intake. Alternatively, consumers can sum the g of carbohydrate consumed for the day, multiply the total by four, divide the result by the total calories consumed in that day, and multiply by 100 to obtain percent.

13. Although FDA chose not to propose the declaration of calories from sugars and complex carbohydrates, a few comments addressed this topic. Some of these comments stated that the declaration of calories from sugars and complex carbohydrates should be voluntary, and that this information, especially for sugars, was of interest to consumers. Other comments felt that the declaration of calories from sugars and complex carbohydrates should be mandatory. Both sets of comments felt that this information is potentially valuable to diabetics and parents of young children who are concerned about dental caries and excessive sugar intake. A few additional comments argued that the declaration of calories from sugars and complex carbohydrates is unnecessary and should not be permitted.

Interest in having calories from sugars and complex carbohydrates declared in the nutrition label was slight, and no data were presented to support the requests for such information. Further, dietary guidelines have not recommended specific quantitative amounts for caloric intake from sugars or complex carbohydrates. Therefore, the final rules do not permit the inclusion of such information in the nutrition label. FDA advises that the calculation of calories from sugars, which was of the most interest to the comments, can be easily calculated by multiplying the number of g of sugars present by four, the number of calories per g of sugars.

6. Calories From Protein

14. A few comments requested that the declaration of calories from protein as well as the percent of calories from protein be made mandatory to permit consumers to evaluate the quality of the food. Other comments agreed with the proposal for the voluntary declaration of calories from protein. On the other hand, additional comments suggested that this information would be confusing and misleading. These comments pointed out that concerns about protein intake are of limited public health significance in the United States and suggested that the declaration of calories would not be helpful in evaluating a total day's diet. The comments urged, therefore, that this declaration should not be permitted. One comment suggested that consumers would be tempted to overconsume protein if calories from protein were listed.

Upon consideration of the comments, FDA has reassessed its position. The agency agrees that the declaration of calories from protein and the percent of calories from protein are of limited usefulness to the consumer because the diets of the majority of Americans exceed the Recommended Dietary Allowances (Ref. 23) for protein. This lack of usefulness appears to outweigh any of the potential benefits of allowing the declaration of calories from protein. For this reason, and in an effort to reduce unnecessary information that might interfere with the consumer's understanding of required information, FDA is amending the final regulations by deleting proposed § 101.9(c)(3)(ii)(D) which allowed for the voluntary declaration of calories from protein.

Consumers interested in determining the calories from protein for an individual food may simply multiply the number of g of protein by four, the number of calories per g of protein. Consumers interested in determining the percent of calories from protein consumed in one day may add the g of protein consumed for the day, multiply

the total by four, divide the result by total calories consumed that day, and multiply by 100 to obtain percent.

7. Increments for Calories

15. The agency received only a few comments concerning the proposed change in § 101.9(c)(3) to delete the use of 2-calorie increments for expressing caloric content up to and including 20 calories per serving. Most of the comments agreed with the proposal which would express caloric content to the nearest 5-calorie increment up to and including 50 calories and to the nearest 10-calorie increment above 50 calories. While one comment disagreed with the proposed change to delete the 2-calorie increments on the basis that it would permit less accurate information for very low calorie foods, another comment considered 2-calorie differences as inconsequential to the consumer. Another suggestion was made to round all calorie levels to the nearest 5-calorie increment.

FDA is not persuaded by the comments that there is sufficient reason to maintain the use of 2-calorie increments for foods containing 20 or fewer calories or to use only 5-calorie increments. FDA acknowledges the concern expressed about very low calorie products. However, only a relatively small number of products will be affected by the change. In fact, the agency traditionally has been tolerant of slight differences in the declared and actual amounts of calories. Current § 101.9(e)(6), redesignated as § 101.9(g)(6), states that "Reasonable deficiencies of calories * * * under labeled amounts are acceptable within current good manufacturing practice." Thus, FDA is adopting this aspect of § 101.9(c)(3), redesignated as § 101.9(c)(1), as proposed.

C. Total Fat, Fatty Acids, and Cholesterol

1. Total Fat

In the mandatory nutrition labeling proposal, FDA proposed to require the declaration of fat, saturated fat, and cholesterol. In addition, FDA proposed definitions for saturated fat, unsaturated fat, polyunsaturated fat, and monounsaturated fat. The agency did not define "fat" (i.e., total fat) for nutrition labeling purposes. For compliance purposes, FDA has used as its definition the sum of compounds with lipid characteristics that are extracted by the Association of Official Analytical Chemists International (hereinafter referred to as AOAC) methods or by other reliable and appropriate analytical procedures (current § 101.9(e)(2)).

16. The agency received a number of comments concerning the agency's standards for assessing total fat. A few comments from food manufacturers and trade associations agreed with the customary method of estimating dietary fat. Comments from other food manufacturers, trade associations, college and university nutrition professionals, consumer advocate groups, other Government agencies, and foreign governments, disagreed with the agency's position regarding the determination of fat content. Some of these comments expressed uncertainty about what current declarations of fat represent. It became evident that some persons considered that the agency had implied a definition of total fat as the sum of all triglycerides by stating in current § 101.25(c)(2)(ii) that the amount of fatty acids was to be calculated as triglycerides. This statement led some comments to assume that mono- and diglycerides did not need to be included in the declaration of total fat.

Several comments suggested that the definition of fat should include all dietary lipids, especially mono-, di-, and triglycerides, phospholipids, and free fatty acids. These comments pointed out that advances in food technology have led to the development of fats and oils that reduce the triglyceride content found in foods by replacing triglycerides with mono- and diglycerides and phospholipids. These new forms of fats provide calories and should be included in total fat values declared in nutrition labeling.

One comment suggested changing the definition of fat to "substances possessing the physiological properties of fat." This comment stated that this definition would encompass all types of dietary fats. Another comment suggested that the definition be the "sum of fatty acids from a total lipid extraction." These comments pointed out that dietary lipids not only contribute to the total dietary caloric intake but have other physiologic functions attributable to fats. These functions include transporting of lipids and fat soluble vitamins in the body and structural functions in cell membranes, as well as serving as essential fatty acids and as precursors of certain hormones and eicosanoids.

Several comments suggested that FDA's position on total fat is not consistent with the definition found in Codex Alimentarius or with that used by the Canadian government and the EC. According to the comments, the international definition of fat is not restricted to triglyceride-releasable fatty acids but includes total free fatty acids and other lipids, including phospholipids.

A couple of comments suggested that the definition of fat should exclude some types of lipids (i.e., phospholipids, plant sterols, and novel lipids) because these lipids constitute only a small portion of total fat consumed, and, according to the comments, these types of lipids have not been reported as having a causal role in disease.

The agency is concerned about the obvious confusion caused by the lack of a precise definition for total fat. Because of the importance given to dietary recommendations to reduce the intake of total dietary fat, it is critical that all parties (i.e., Government agencies, food manufacturers, health professionals, nutrition scientists, and consumers) clearly understand what the values declared on the nutrition label represent.

Concerns that the total fat value not be underrepresented have persuaded the agency that it is not adequate to continue only using a reference to AOAC methods or "other reliable, appropriate analytical procedures." Such an approach allows for the use of many methods that measure different analytes. For example, according to AOAC procedures, "fat" content can be determined by ether or chloroform-methanol extraction. In the case of an ether extraction, results yield a value for neutral lipids which are primarily triglycerides (a complex lipid composed of glycerol and three fatty acids) and some mono- and diglycerides. In contrast, the chloroform-methanol extraction method extracts all classes of lipids. The two methods, which are both acceptable according to current regulations, may result in different values for total fat being obtained for the same product and different values being declared on the nutrition label.

The agency believes that the use of the implied definition of total fat as the sum of triglyceride fatty acids from saturated, polyunsaturated, and monounsaturated fatty acids, would in some cases underestimate both total g of fat and the caloric intake from fat. The agency agrees that all forms of fatty acids that contribute to energy intake of foods should be included in the calculation of total fat, particularly in view of dietary recommendations that target total fat intakes at 30 percent or less of calories.

For these same reasons, the agency disagrees with the suggestion that some lipids (e.g., mono- and diglycerides and phospholipids) be excluded from the definition of fat.

Therefore, the agency has decided to define total fat as total lipid fatty acids, that is, the sum of fatty acids from mono-, di-, and triglycerides, free fatty acids, phospholipid fatty acids, and sterol fatty acids. This definition includes all sources of fatty acids that provide energy, preventing underestimates of energy from total fat. It also acknowledges that certain lipid components, such as cholesterol and other sterols, do not contribute metabolizable calories and constitute only a very small amount of the total weight of lipids.

This definition represents all fatty acids obtainable from a total lipid extraction. The definition does not require that a single extraction method be used. The extraction method will depend upon the type of lipid being sought in the food and the type of food (i.e., the food matrix). Analytical procedures are discussed further in section IV. of this document.

The agency finds that this definition is more consistent with, although not identical to, international definitions for dietary fat. The Codex Alimentarius considers any source of dietary energy to be a nutrient (that would include nontriglyceride sources of fatty acids), and declaration of dietary fat would reasonably include all sources of fatty acids. The EC definition of fat is total lipids, including mono- and diglycerides and phospholipids. The difference between the EC definition and the agency's definition is that the agency excludes the sterol fraction, not a large difference in quantitative terms. Furthermore, the agency's definition reflects dietary goals for consumption of only 30 percent of calories from fat, because the sterols are not absorbed and therefore do not contribute calories.

However, the agency also recognizes that the definition of total fat as total lipid fatty acids does not account for the weight of glycerol to which the fatty acid chains are linked in the formation of mono-, di-, and triglycerides. Unless the glycerol is included in the weight of the total fat, it will be reported as carbohydrate. In this case, foods in which the fat is mostly triglyceride, e.g., corn oil and lard, will appear to have 95 percent total fat and 5 percent carbohydrate, while other products such as muscle meats which have never been reported to contain carbohydrate may now contain measurable amounts. These values would conflict with common perceptions of food composition because nutrient data bases and food composition tables routinely include the weight of glycerol in the declaration of total fat.

Therefore, the agency has decided to require that the declaration of total fat be expressed as the amount of triglyceride that would provide the analytically measured amount of total lipid fatty acids in the food. This position is supported by a recent report in The Referee, a publication of the AOAC International (Ref. 32). Likewise, because food composition data bases do not include glycerol in the declaration of fatty acids (i.e., values represent free fatty acid), the agency is not requiring that the amount of saturated fatty acids or other classes of fatty acids be expressed as triglycerides (see comment 30 of this document).

While the inclusive term "total lipid fatty acids expressed as triglycerides" would be the more accurate term to use in the nutrition label, the agency will continue to require use of the term "total fat" to be consistent with the terminology used in dietary recommendations and to avoid consumer confusion.

17. Several comments from manufacturers, trade associations, a consumer advocacy group, and a research firm addressed the issue raised in the preamble to the supplementary proposal (56 FR 60366 at 60371) of the increased use of fats containing very long (longer than 18 carbons) chain fatty acids in the food supply. These compounds provide the potential for marketing novel compounds in which fatty acids are linked to carbon structures in a manner that reduces their digestibility. As a result, these compounds have the technical effect of fat with less calories than traditional fats.

Comments requested that fat be defined to exclude various types of very long chain fatty acids because of their poor absorbability and reduced digestibility. A recent article was cited as evidence of the poor absorption of the very long chain fatty acids (Ref. 33). One comment stated that the definition of fat should exclude extractable compounds that do not have the physiological effects of fatty acid compounds. Two comments suggested the omission of these fatty acids from fat and calorie declarations similar to the omission of insoluble dietary fiber from calorie declarations. According to these comments "total fat" should be defined as "total 'digestible' fat" to allow for the use of fat-type ingredients that have reduced digestibility and therefore fewer calories than the fats they replace. The declared amount of fat would then be the total analytically determined fat times the fat digestibility coefficient.

FDA acknowledges the effect that the use of certain very long (longer than 18 carbons) chain saturated fatty acids with reduced digestibility have on the fat and calorie content of foods. In an effort to encourage innovation in the creation of products that provide lower fat and lower calorie contents to enable the consuming public to have a healthier diet and thus to meet one of the primary objectives of the Surgeon General's report on Nutrition and Health (Ref. 2), the agency is willing to consider the digestibility of novel fat compounds. However, the agency has concluded that because of the diversity of possible products, it is not appropriate to modify the definition of total fat in § 101.9(c)(2) to allow for alternate values because of reduced digestibility of very long chain fatty acids. Rather, the agency will address the digestibility of new ingredients containing these fatty acids on a case-by-case basis.

Because the digestibility of a substance is one of the identifying characteristics of the substance, the agency requests that manufacturers who wish to declare adjusted values of total fat based on reduced digestibility include information on the digestibility of the compound, analytical assay procedures for the compound, and data on interference with required methods of analysis in food additive petitions (21 CFR part 171) or in petitions for affirmation that the use of the substance is GRAS (21 CFR 170.35). The agency will include the specific digestibility coefficients that can be used in determining the quantitative declaration of fats and the caloric contribution from fats as part of the statement of identity for the substance in the listing regulation in part 172 for food additives and in part 184 for substances whose use is affirmed as GRAS. However, FDA recognizes that mechanisms other than food additive or GRAS petitions may be appropriate to bring issues involving the digestibility of a substance to the attention of the agency. Interested persons may wish to use the mechanism in § 101.9(g) to request to use specific digestibility coefficients.

18. Several comments said that there is a need for adequate analytical methods for assaying novel forms of fat in new low-fat foods. They noted the difficulty of isolating new ingredients by the traditional or AOAC determinations for fat. As one comment stated, the current acid hydrolysis analysis may not be appropriate for these type of substances.

FDA agrees with the concern about analytical methodology and is aware that different methods might be needed for each product or type of product. Because of this concern, and as noted in the preceding comment, the agency

finds that it is necessary that manufacturers delineate, in the documentation submitted to FDA in support of the lower fat content declarations, the methodology needed to assay for the novel fat compound. Use of the method by the manufacturer and the agency in lieu of conventional methods found in the AOAC or other recognized sources should alleviate labeling compliance concerns.

19. One comment urged the agency to allow manufacturers to use calculations from product formulas to arrive at the calorie or fat content of products containing these alternate ingredients.

As discussed in previous comments, the supporting documentation submitted to the agency to substantiate different caloric levels for novel fats should contain adequate information regarding the digestibility coefficient, analytical methodology, and other factors to ascertain an accurate label value for the fat and calorie declarations. FDA will use the information and analytical methodology for each such fat to determine whether the values for fat and calories stated on the label are correct. Manufacturers may use other methods, such as calculations from product formulas, to determine fat and calorie values if they have a reasonable basis on which to believe that the values so obtained will be consistent with values determined analytically. However, they do so at the risk that FDA will disagree.

2. Saturated Fat

a. *Definition.* FDA proposed (55 FR 29487 at 29495) to make the amount of fat, saturated fatty acids, and cholesterol mandatory elements of nutrition labeling. At the same time, FDA proposed in § 101.9(c)(4)(i) to continue to define saturated fatty acids as the sum of lauric (C12:0), myristic (C14:0), palmitic (C16:0), and stearic (C18:0) acids, the major saturated fatty acids in the U.S. food supply. FDA requested comments on the questions of what fatty acids should be considered as saturated fatty acids, and on what basis these decisions should be made (55 FR 29487 at 29495).

20. Many comments, including comments from food manufacturers and distributors, trade associations, professional organizations, nutritionists, and state health departments agreed with FDA's proposal to include only the four saturated fatty acids with 12 to 18 carbons (lauric, myristic, palmitic, and stearic acids) in the definition of saturated fat for labeling purposes. The reasons given included: (1) Lauric, myristic, palmitic, and stearic acids comprise the vast majority of saturated fatty acids in the American diet; (2) C12:0–C16:0 fatty acids raise total and low density lipoprotein (LDL)-cholesterol; (3) although some clinical and metabolic evidence suggests that C18:0 fatty acid (stearic acid) does not have the same blood total and LDL-cholesterol-raising effect as C12:0–C16:0 saturated fatty acids, the effect of C18:0 on blood total and LDL-cholesterol is not conclusive enough to warrant deletion of C18:0 from the definition; (4) stearic acid may be associated with other risk factors of cardiovascular disease such as thrombosis and platelet aggregation; and (5) a separate analysis for stearic acid would be costly.

Many other comments, including comments from other food manufacturers, trade associations, and health professionals, suggested that FDA include only lauric acid (C12:0), myristic acid (C14:0), and palmitic acid (C16:0) in the definition of saturated fat for labeling purposes. These comments stated that there is no evidence that stearic acid has a cholesterol-raising effect, and that the postulated role of stearic acid in thrombosis is open to dispute. With regard to the latter point, the comments cited the conclusion of a workshop on Dietary Fatty Acids and Thrombosis that there is no direct evidence of a prothrombotic effect of long chain fatty acids (e.g., C18) in humans (Ref. 34).

One comment from a trade association suggested that FDA not include palmitic acid in the definition of saturated fat because palmitic acid does not raise blood total and LDL-cholesterol. The comment cited recent research articles (Refs. 35 and 36) as the evidence.

A comment from a major food manufacturer suggested that FDA not include saturated fatty acids with less than 10 carbons in the saturated fat category. Other comments suggested FDA exclude lauric acid or myristic acid from the saturated fat category for labeling purposes. The reasons given were: (1) That the medium chain fatty acids (C6:0–C10:0), lauric acid (C12:0), and myristic acid (C14:0) are readily absorbed and oxidized and may not raise blood total and LDL-cholesterol, and (2) that medium chain fatty acids are minor sources of saturated fat in the American diet. In contrast, a consumer and a state agency suggested that FDA include saturated fatty acids with carbon numbers less than 12 in the saturated fat category because they may elevate blood cholesterol.

Some comments from a major food manufacturer and a state public health department stated that saturated fatty acids with carbon chains longer than 18 (i.e., C20–C24) should not be categorized as saturated fatty acids. The reasons given included: (1) These fatty acids compose a small part of saturated fat content in the U.S. diet, and (2) these fatty acids are poorly absorbed, have no or little physiological effects, and therefore do not contribute to heart disease.

Several comments, from a food manufacturer, a consumer, and foreign governments, suggested that FDA use a chemical definition of saturated fatty acids for labeling purposes. Two other comments from the meat industry suggested that FDA use a chemical definition if it is not possible to set a definition on the basis of the relationship of saturated fatty acids to the risk of cardiovascular disease. The reasons included in these comments were:

(1) Underrepresentation of the content of saturated fat. Several comments stated that the proposed definition, limiting saturated fat to only the four saturated fatty acids with 12 to 18 carbons, would result in underrepresentation of the saturated fatty acid content of foods, particularly of those foods that contain significant amounts of saturated fatty acids with less than 12 carbons or more than 18 carbons. They further stated that this underestimation of saturated fat contradicts the current dietary recommendation that Americans consume less than 10 percent of calories as saturated fats. The examples that they presented of foods in which the definition of saturated fat as C12–C18 would underrepresent saturated fat were milk, underrepresented by 8 percent; coconut oil, by 14 percent; and palm kernel oil, by 7.2 percent.

(2) Oversimplification. A consumer stated that FDA's proposal is an oversimplification and suggested that all saturated fatty acids be included.

(3) International harmonization. The Canadian Government and the EC stated that FDA's proposal to restrict the definition of saturated fat to only lauric, myristic, palmitic, and stearic acids is at variance with the Codex Alimentarius Commission, EC, and Canadian definitions. They stated that the proposed deviations from international definitions present serious problems for food companies in the EC and would be confusing for consumers. They suggested that FDA include all saturated fatty acids without double bonds in the saturated fat definition. A major food manufacturer also stated that it already had encountered minor problems with different definitions in labels for Canada and the United Kingdom and suggested that FDA consider international

harmonization in its decision on the definition of saturated fat.

FDA is persuaded by the comments that there is substantial controversy regarding the inclusion or exclusion of specific fatty acids in a definition of saturated fat that is based on effects on blood total and LDL-cholesterol.

Therefore, the agency has reconsidered its position of linking the definition of saturated fatty acids to effects of particular fatty acids on blood total and LDL-cholesterol levels and has determined that a chemical definition is appropriate for the following reasons.

First, a chemical definition avoids much of the controversy regarding the blood cholesterol effects of palmitic acid, very long (longer than 18 carbons) chain fatty acids, and short and medium chain fatty acids, because the definition is not subject to changes in knowledge about the physiologic effects of particular fatty acids. The chemical definition also avoids uncertainties about physiologic effects other than those regarding blood total and LDL-cholesterol, such as effects on thrombosis, and other possible health effects of very long chain, medium chain, and short chain saturated fatty acids.

Secondly, FDA agrees that the amount of saturated fat in some foods could be underrepresented when the definition of saturated fat is confined to the sum of four fatty acids. This underreporting of saturated fat may be increased as new foods containing saturated fatty acids less than C12 and more than C18 appear in the marketplace.

Thirdly, the agency also notes that the chemical definition is in line with EC and Canadian definitions of saturated fat and, hence, will promote international harmonization.

Finally, the agency notes that the chemical definition of saturated fat is more consistent with dietary recommendations to reduce fat consumption to 30 percent of calories and saturated fat consumption to less than 10 percent of calories. Food composition data tables have generally been used in epidemiologic investigations that relate diet to risk of chronic diseases, and these tables group all the chemically defined saturated fatty acids together as a class. Thus, the term "saturated fat" used in these dietary recommendations pertains to the chemical classification of fatty acids, not FDA's current, more restricted definition.

Accordingly, FDA has amended § 101.9(c)(4)(i), redesignated as § 101.9(c)(2)(i), to define saturated fat as the sum of all fatty acids containing no double bonds.

b. *Voluntary declaration of specific saturated fatty acids.* 21. Some comments specifically requested that the agency provide for labeling that distinguishes those fatty acids associated with increased blood total and LDL-cholesterol levels from those not associated with increased cholesterol. One approach that was identified in the comments and in a published commentary (Ref. 13) would allow a declaration of "cholesterol-raising fatty acids," so that a manufacturer could show that a particular food contained little or none of these fatty acids.

The agency recognizes that there is substantial uncertainty as to which saturated fatty acids are cholesterolemic and which are not. Conclusions of authoritative documents and review papers are not consistent on this issue (Refs. 2, 3, 37 through 41). The effects of most individual saturated fatty acids on blood total and LDL-cholesterol are not fully understood. The agency finds that the only saturated fatty acid that has been consistently reported as cholesterol-raising is myristic acid. The effects of palmitic acid and lauric acid are not as clearly associated with increased blood cholesterol, although the prominence of palmitic acid in the diet makes any contribution of this fatty acid important in the control of blood cholesterol. On the other hand, it has consistently been reported that stearic acid, when substituted for other saturated fatty acids in the diet, has a neutral effect on blood total and LDL-cholesterol concentration (Refs. 37 through 40). As a result, the agency is concerned that there is not an adequate basis for deciding which fatty acids should be included in the term "cholesterol-raising fatty acids."

In addition, the agency is concerned that the term "cholesterol-raising fatty acids" will be confusing to consumers. Since consumers are unfamiliar with the term "cholesterol-raising fatty acids," there is a possibility that they would misinterpret it and would avoid foods with such a declaration on the nutrition label, even if the intent of the labeling was to indicate the absence of these fatty acids. Also, given that the only fatty acid declaration the agency is requiring is saturated fat (defined as the sum of all saturated fatty acids), any added declaration of "cholesterol-raising fatty acids" would be on a voluntary basis. Under these circumstances, manufacturers could be expected to only include this declaration when the level of such fatty acids is low to emphasize the absence of such components from the product.

A variation of this term that avoids the negative connotation and applies positively to the composition of the product is the term "noncholesterol-raising fatty acids." However, this term suffers from the other problems with respect to cholesterol-raising fatty acids (i.e., the scientific uncertainty concerning what fatty acids to include and the likelihood of increased consumer confusion).

FDA is also concerned that either of the terms "cholesterol-raising fatty acids" or "noncholesterol-raising saturated fatty acids" could be seen as a health claim. Section 403(r)(1) of the act states that information that is required or permitted under 403(q) of the act to be included in the nutrition label is not a nutrient content or health claim. Because of the relationship between fatty acids and increased blood cholesterol and, thereby, heart disease, however, the agency is concerned that the use of either of the subject terms goes beyond the factual reporting of nutrients that is characteristic of the nutrition label.

For the reasons enumerated above, FDA has concluded that it is not appropriate to distinguish among fatty acids by the terms "cholesterol-raising fatty acids" or "noncholesterol-raising saturated fatty acids."

Another approach to distinguishing among fatty acids is to declare specific saturated fatty acids without any reference to effects on blood total and LDL-cholesterol. This approach is consistent with the agency's intention of providing factual information on the nutrition label. Because some comments strongly opposed the inclusion of stearic acid in the declaration of saturated fat because of the consumer's association of saturated fat with increased blood cholesterol levels, it is reasonable to indicate the extent of the saturated fat content of the food that is stearic acid and, thus, not associated with increased blood cholesterol. As noted above, a consensus that seems to be emerging is that stearic acid, when substituted for other saturated fatty acids, does not raise or lower blood total and LDL-cholesterol level. Consumer education programs could advise consumers that when a large portion of the saturated fat in a product consists of stearic acid, the fat content of the food is not likely to increase blood total and LDL-cholesterol levels.

The agency, however, has some reservations about allowing for the voluntary labeling of stearic acid in that: (1) Other saturated fatty acids that may raise blood total and LDL-cholesterol are not addressed; (2) only one risk factor of cardiovascular disease, blood

cholesterol level, is addressed; (3) it may complicate and overcrowd the label; and (4) it would require a consumer information program to have any meaning to consumers.

In addition, recognizing particular saturated fatty acid effects on blood cholesterol may require that the agency redefine the saturated fat threshold criterion for cholesterol claims in § 101.62(d) (cholesterol claims are not allowed on foods containing more than 2 g saturated fat, defined as the sum of all fatty acids containing no double bonds, per serving), as described in a companion document on nutrient content claims published in this issue of the **Federal Register**. Because of the agency's reservations about the meaningfulness of labeling of individual fatty acids and the need to reconsider criteria for cholesterol claims if such action was to be taken, the agency concludes that more information, including public comment, is necessary before taking further action on this approach. The agency intends to further address this issue at a later date, and would welcome submission of information and views on this question.

3. Polyunsaturated and Monounsaturated Fat

a. *Use of the term "unsaturated fat".* FDA proposed in both the July 19, 1990, and November 27, 1991, documents in § 101.9(c)(4)(ii) to permit the voluntary declaration of the quantitative amount of unsaturated fat in nutrition labeling. The agency proposed to make the declaration of unsaturated fat mandatory if claims were made about fatty acid or cholesterol content or if the manufacturer voluntarily declared the number of calories from unsaturated fat. Alternatively, the agency proposed to allow separate declarations of polyunsaturated and monounsaturated fats.

22. The agency received comments that either agreed or disagreed with the proposed definition and voluntary use of the term "unsaturated fat". Comments that supported the use of the inclusive term did so because neither monounsaturated nor polyunsaturated fats have been shown to increase the risk of coronary heart disease, and because both types of unsaturated fats decrease the risk of coronary heart disease relative to saturated fat.

Comments objecting to the term "unsaturated fat" argued that the term is not useful, that it offers no additional information that could not be obtained by subtracting the saturated fat content from total fat, and that it obscures the presence of essential fatty acids. Other comments were concerned that the term was misleading in that it suggests that all unsaturated fats are synonymous by including both *cis* and *trans* isomers and both poly- and mono-unsaturated fats together. These comments argued that in light of the current uncertainty and controversy surrounding the physiological effects of *trans* fatty acids (which are a particular type of unsaturated fatty acid having some physical properties of saturated fatty acids), use of the term "unsaturated fat" would not only be misleading to the consumer but possibly could have an adverse effect on the health of some individuals. This opposition to the inclusion of *trans* isomers in the definition of "unsaturated fat" was the most frequently repeated concern.

Comments suggesting that it would be misleading to group poly- and mono-unsaturates together argued that this action would imply that the two types of fatty acids are the same and have similar effects on blood total and LDL-cholesterol when, in fact, they do not. It has been reported that monounsaturates do not effect blood total and LDL-cholesterol levels and do not reduce high density lipoprotein-cholesterol when substituted for saturated fats. On the other hand, polyunsaturates have often been reported to reduce blood total and LDL-cholesterol levels and to decrease blood pressure.

A few comments suggested that if the term "unsaturated fat" is permitted, the declaration of the *cis* forms of polyunsaturates and monounsaturates should either be permitted or required at the same time. Comments also argued that there is no scientific consensus supporting the use of the inclusive term, and that it was not a term used in international trade.

FDA is persuaded by these comments that the use of the term "unsaturated fat" is potentially confusing to consumers, does not provide useful information, and could result in consumer deception. Accordingly, the agency is revising the regulation by not providing for the voluntary declaration of unsaturated fat in nutrition labeling. As a result, the proposed listings of polyunsaturated fat and monounsaturated fat in § 101.9(c)(4)(ii)(A) and (c)(4)(ii)(B), respectively, are redesignated as § 101.9(c)(2)(ii) and (c)(2)(iii). In addition, each paragraph has been modified to incorporate provisions that had been included in proposed § 101.9(c)(4)(ii). The revised listings provide that the disclosure of the level of polyunsaturated fat and monounsaturated fat is voluntary unless claims are made on the label about fatty acid or cholesterol content, and that, if either polyunsaturated or monounsaturated fat is declared, the other must also be declared.

b. *Trans Fatty Acids.* In its July 19, 1990 proposal on mandatory nutrition labeling (55 FR 29487 at 29496), the agency tentatively concluded that there is no basis for declaring *trans* isomers of fatty acids on the nutrition label. This conclusion was based on a consensus report that noted that current evidence does not support a blood cholesterol-raising effect for *trans* isomers when they are substituted for saturated fatty acids in the diet. The agency requested comments on this issue. Later that year new research and commentary was published (Refs. 12 and 13) which led FDA to request in the supplementary proposal (56 FR 60366 at 60371) comments on the significance of the new findings and a reevaluation of any comments submitted on *trans* fatty acids in response to the July 19, 1990 proposal.

23. Several comments, from a major food manufacturer, health professionals, a professional health organization, a state agency, a trade association, and a consumer, suggested that FDA include *trans* fatty acids in the saturated fat category because research suggests that *trans* fatty acids raise blood total and LDL-cholesterol. On the other hand, several comments were against the inclusion of *trans* fatty acids in the saturated fat category because the evidence of a cholesterol-raising effect of *trans* fatty acids is not conclusive. Several comments suggested that *trans* fatty acids should be declared separately because it may increase blood cholesterol.

FDA disagrees that there is sufficient evidence that indicates that *trans* fatty acids raise blood total and LDL-cholesterol. In 1985, a report of the Federation of American Societies for Experimental Biology on "Health Aspects of Dietary *trans* Fatty Acids"(Ref. 42) concluded that human studies indicate that *trans* isomers are little, if any, more cholesterolemic than *cis* isomers. In animals (rabbits, swine, and monkeys), *trans* fatty acids are cholesterolemic but not atherogenic. Since the publication of the Federation of American Societies for Experimental Biology report, a scientific review article, (Ref. 40) concluded that reports are inconsistent regarding the effects of *trans* unsaturates on blood total and LDL-cholesterol levels in humans.

Recently, two studies in The Netherlands (Refs. 12 and 43) have shown that a high intake of *trans* fatty acids may elevate blood total and LDL-cholesterol concentration. Concerns

have been raised about the applicability of these studies to U.S. diets because of certain methodologic limitations, because the level of *trans* fatty acid tested was 2–3 times higher than the current average consumption of the U.S. population, and because the methods for generating *trans* fatty acids might have been different from those used in the United States.

In contrast, another study (Ref. 44) seems to indicate that *trans* fatty acids do not raise blood total and LDL-cholesterol in mildly hypercholesterolemic, normotensive men, although diet differences other than *trans* fatty acids may have been responsible for the effects.

Finally, the agency is aware of preliminary results from a very recent unpublished study designed to address the criticisms of the studies from The Netherlands (Ref. 45) that suggests that *trans* fatty acids raise LDL-cholesterol.

In the absence of the fully analyzed data from this study, the agency considers it premature to require the labeling of *trans* fatty acids because of their effects on total or LDL-cholesterol. However, even if there was a need for labeling of *trans* fatty acids, the agency does not agree that *trans* fatty acids should be included in the category of saturated fats. The agency has argued against inclusion or exclusion of particular saturated fatty acids in the definition of saturated fat solely on the basis of their effect on blood total and LDL-cholesterol. In addition, the agency recognizes that inclusion of *trans* fatty acids in the definition of saturated fat is not consistent with the EC, Codex, or Canadian definitions of saturated fat.

Because of the current uncertainties, the agency does not agree that a separate declaration of *trans* fatty acids is appropriate at this time. Because new data are rapidly emerging (Ref. 45) that imply that *trans* fatty acids raise LDL-cholesterol, however, the agency recognizes that it may be necessary to readdress the labeling of *trans* fatty acids in the near future.

24. One comment suggested that not all foods voluntarily declaring levels of monounsaturates and polyunsaturates need to be analyzed to differentiate *cis* and *trans* fatty acids because only those containing hydrogenated fats would contain *trans* isomers.

The agency agrees with this comment in the case of vegetable oils and other plant lipids. However, naturally occurring *trans* fatty acids are found in some animal lipids (e.g., dairy products). If there is adequate and reliable reason to believe that a nutrient is not present in a food, there is no need to analyze for that nutrient. However, a manufacturer is responsible for ensuring that its labeling is truthful and not misleading.

c. *Definition of polyunsaturated fatty acids.* FDA proposed in §§ 101.9(c)(4)(ii)(A) and (c)(4)(ii)(B) in July 19, 1990 and November 27, 1991 to define polyunsaturated and monounsaturated fats as *cis*, *cis*-methylene interrupted polyunsaturated fatty acids and cis-monounsaturated fatty acids, respectively. These definitions exclude *trans* isomers. The definition of polyunsaturated fat is consistent with current § 101.25(c)(2)(ii)(*a*). FDA has not previously defined monounsaturated fat for labeling purposes.

25. Comments from food manufacturers, trade associations, health promotion organizations, consumer groups, and international agencies supported the agency's definition for polyunsaturated fat. However, some comments urged FDA to change the definition to reflect the various physiological roles of specific types of polyunsaturated fats, in particular to allow for the identification of omega-3 (n–3) and omega-6 (n–6) fatty acids, indicating that these are essential in the diet and that the ratio of consumption of these fatty acids can be important.

FDA is not persuaded that there is a need to require further breakdown of polyunsaturated fats in the nutrition label. As discussed above, FDA is concerned that additional information on the nutrition panel may confuse consumers and interfere with their understanding of other required information.

However, the agency agrees that there are valid reasons to consider the voluntary labeling of omega-3 and omega-6 fatty acids. These chemical distinctions are important nutritionally, because the omega-3 fatty acids (with the first double bond at the third carbon from the methyl end of the fatty acid) and omega-6 fatty acids (with the first double bond at the 6th carbon from the methyl end) are not interchangeable during metabolism in the body; rather each must be supplied by diet. Each subcategory has members that are considered essential nutrients (α-linolenic acid and linoleic acid, for the omega-3 and omega-6 classes, respectively) (Ref. 23). Dietary omega-3 and omega-6 fatty acids are precursors for biologically active compounds, e.g., prostaglandins, eicosanoids, and the nutritional balance of omega-3 and omega-6 fatty acids modulates the production of many of these biologically important substances. Furthermore, omega-3 and omega-6 fatty acids are important components of cell membranes.

Although the National Research Council has not yet established a Recommended Dietary Allowance for omega-3 and omega-6 fatty acids, they recognized in 1989 that "[T]he possibility of establishing Recommended Dietary Allowance's for these fatty acids should be considered in the near future." (Ref. 23)

FDA agrees that information on the amount of omega-3 and omega-6 fatty acids may be useful to allow interested consumers to select foods that provide these fatty acids. It is not difficult to consume a diet rich in omega-6 fatty acids because vegetable oils are rich in these fatty acids. However, vegetable oils vary widely in their content of omega-3 fatty acids, and labeling may be useful to identify those foods that contain substantial amounts of omega-3 fatty acids to encourage a balanced intake of these two classes of fatty acids.

However, FDA is not fully persuaded about the usefulness of additional label information on omega-3 and omega-6 fatty acids, and whether there are many consumers who desire this information. As discussed above, the agency is concerned that additional information on the nutrition panel may confuse consumers and interfere with their understanding of other required information. Because of these concerns, FDA concludes that it is not appropriate to allow for the voluntary declaration of these subcomponents of polyunsaturated fats at this time. The agency intends to address this issue at a later date and would welcome submission of information and views on this issue.

26. The majority of comments supported the voluntary declaration of polyunsaturated fats. However, a few comments suggested that their declaration be mandatory rather than voluntary. One of these comments was concerned with possible safety issues associated with increased consumption of polyunsaturated fats. The comment alleged that polyunsaturated fats convey a potential source of free-radical peroxidation products, and that consumers should be informed of the amounts of polyunsaturated fat present in a food. Other comments merely stated that mandatory declaration of polyunsaturated fat would provide consumers with valuable and more complete nutritional information.

FDA is not persuaded that there is a need to require the inclusion of polyunsaturated fats on the nutrition label. These fatty acids do not meet the criteria for mandatory declaration set forth in the mandatory nutrition

labeling proposal (55 FR 29487 at 29493) that the nutrient or food component be of particular public health significance, and that quantitative intake recommendations for the nutrient be given in major scientific consensus reports. The comments largely support this view, and the agency therefore rejects the suggestion that the declaration of polyunsaturated fats be mandatory.

The agency disagrees with the contention that commonly consumed amounts of polyunsaturated fats would pose any safety concerns. While the potential exists for formation of oxidative products as a result of the increased number of double bonds—present in polyunsaturated fats, any risk would only occur at very exaggerated levels of consumption.

d. *Monounsaturated fats.*

27. Comments both agreed and disagreed with the proposed definition of "monounsaturated fat." Those opposed generally requested that the definition not exclude *trans* fatty acids on the basis that they have not been proven to have an adverse effect on health or disease in humans, or that *cis* and *trans* isomers have similar metabolic and physiologic properties. One comment asked the agency to include *trans* fatty acids in the definition of monounsaturated fats until an expert panel can determine if *trans* or unusual *cis* isomers formed as components of commercial hydrogenation increase the risk for coronary heart disease or other health related conditions.

Comments from medical associations, trade associations, a consumer advocacy group, the Canadian government, and the EC supported the proposed definition, focusing particularly on two considerations. First, *trans* fatty acids or unusual *cis* isomers formed during commercial hydrogenation of unsaturated fats may increase the risk of coronary heart disease, and, second, monounsaturated fats, as defined in the proposal, may reduce blood total and LDL-cholesterol and reduce the risk of coronary heart disease. Comments also suggested that the inclusion of *trans* fatty acids may mislead consumers, who perceive monounsaturates as healthful or at least as not harmful.

FDA concludes that there is no need to amend the proposed definition of "monounsaturated fat." The comments received, the scientific reports they discuss (Refs. 12 and 43), and the concerns addressed in the preceding discussion of *trans* fatty acids establish that to include *trans* isomers in the definition of "monounsaturated fat" would be misleading and will not assist consumers in maintaining healthy dietary practices. The agency is not willing to include *trans* isomers in the label definition of "monounsaturated fat" until there is further consensus based on publicly available, well-designed, and well-conducted studies. However, as more data concerning the action and safety of *trans* fatty acids become available, the agency may reconsider its decisions to define monounsaturates as the usual *cis*-monounsaturated fatty acids.

28. One comment also objected to the proposed definition of "monounsaturated fat" because it would require manufacturers to conduct a further analysis of lipids to differentiate between *cis* and *trans* isomers. The comment argued that this extra analysis was not justified by available scientific data and would cause a financial burden.

The agency disagrees with the comment. The declaration of poly- and mono-unsaturates is voluntary. Therefore, an analysis of unsaturated isomeric forms is only required if the manufacturer chooses to declare poly- or mono-unsaturates or to make fatty acid or cholesterol claims. In such cases, given the controversy on the effect of *trans* fatty acids, the additional analysis is necessary to ensure that the declaration or claims are not misleading.

29. One comment suggested that the agency should include stearic acid in the definition of monounsaturated fat by virtue of its effects on blood total and LDL-cholesterol. The comment stated that scientific data suggests that stearic acid does not increase blood LDL-cholesterol, and that it is rapidly converted to oleic acid, an unsaturated fat that does not raise blood total and LDL-cholesterol levels.

FDA does not agree that stearic acid should be included in the definition of monounsaturated fat. Chemically, stearic acid is a saturated fat, and the agency, therefore, finds that it would be inappropriate to include it with monounsaturated fats. The agency has acknowledged above that some studies and some consensus statements suggest that stearic acid does not increase LDL-cholesterol relative to other saturated fats. However, stearic acid does increase LDL-cholesterol relative to monounsaturates and polyunsaturates (Refs. 12 and 43). Accordingly, the agency is not including stearic acid in the definition of monounsaturated fat.

4. General Issues Related to Declaration of Fats and Fatty Acids

a. Calculation of fatty acids as triglycerides.

30. A comment was received that disagreed with proposed § 101.9 (c)(4)(i) and (c)(4)(ii), which would require saturated fat and unsaturated fat content to be calculated as triglycerides. The comment noted that values in current data bases are reported as the free fatty acids.

Current § 101.25(c)(2)(ii) requires that fatty acids be calculated as triglycerides. This requirement dates back to the initial nutrition labeling regulation promulgated in 1974. This requirement was a result of comments from industry at that time.

To provide consumers with nutrition information that can readily be used for comparison to available nutrient data bases, FDA agrees that saturated and poly- and mono-unsaturated fat should be declared as free fatty acids instead of as triglycerides. As a consequence of the change in method of reporting, slightly lower values for the various fatty acid declarations will appear on the label because the weight of the glycerol molecule in triglycerides is not included when free fatty acids are declared. Also, fatty acids from mono- and di-glycerides used as a source of fat in many products will be included using this revised means of reporting fatty acids. Accordingly, FDA is amending § 101.9(c)(2)(i) for saturated fat and § 101.9(c)(2) (ii) and (iii) for polyunsaturated and monounsaturated fat, respectively, to remove the requirement that the fatty acids be "calculated as triglycerides."

b. Increments for declaring fats and fatty acids. The mandatory nutrition labeling proposal retained the current requirement for the declaration of fat in g and added, as a requirement, the amount of saturated fatty acids in g (55 FR 29487 at 29495). In the supplementary proposal, FDA proposed to change the increments for declaring fats and fatty acids (56 FR 60366 at 60380). The agency proposed to require the declaration of total fat, saturated fat, unsaturated fat, polyunsaturated fat, and monounsaturated fat in 0.5 (½)-g increments. The agency made this change in the proposed provisions to make the increments in which these nutrients are declared more consistent with the levels at which these substances will have nutritional significance. FDA believed the proposed change would consequently provide consumers with more precise information and a greater ability to discriminate among products. In this context, a level of less than 0.25 g per serving was established as the level at which saturated and unsaturated fat content would be expressed as zero.

31. Over 25 responses concerning fat increments were received in response to the request for comments. Almost twice the number of comments disagreed with the proposal to declare total fat and fatty acids in 0.5-g increments as those who agreed with the proposal to do so. The rationale given by essentially all who disagreed with the proposed change was the lack of analytical methods that are adequate and sensitive enough to provide data to that degree of precision. Several comments recommended that the fat content of foods containing 3 or less g fat be declared in 0.5 (½)-g increments, and the fat content of foods containing more than 3 g be declared in whole g increments. These comments suggested that the precision of 0.5 g increments for fat declarations is less important for higher fat foods. Additionally, these comments stated that the variability of some fat assays warrants whole-g increments, especially for moderate and high levels of fat. It should be noted, however, that several comments stated that methodology does exist to support the 0.5-g increment declaration. One comment noted the desirability of keeping all macronutrients, including fat, in whole-g increments. Several comments cited the cost of assaying to the 0.5 (½)-g level of precision as a reason for retaining the whole-g increment declarations for these nutrients.

FDA has given careful consideration to the comments. The agency recognizes that labeling requirements must not only convey desired nutrition information for the consumer but must also be enforceable. Because of concerns about analytical precision, variability, and the effect of product matrices on the methods necessary to quantify total fat, saturated fat, and poly- and mono-unsaturated fat declarations in 0.5-g increments, FDA has concluded that such precision is not necessary for amounts of fat above 3 g per serving of food. Consequently, the agency is modifying § 101.9(c)(2) and (c)(2)(i) through (c)(2)(iii) to require that levels below 3.0 g per serving be declared in 0.5 (½)-g increments and levels above 3.0 g be declared in g increments.

The agency disagrees that cost, although a factor, is a sufficient reason in and of itself to retain the current whole-g increments for total fat, saturated fat, and poly- and mono-unsaturated fats. The public health benefits attributed to decreasing dietary intakes of fat (Refs. 2, 3, 4, and 47) justify the use of 0.5-g increments to allow consumers to differentiate between products containing low levels of fats.

32. A few comments urged that fats not be declared in 0.5 (½)-g increments to improve the legibility of the label.

The agency is concerned about the legibility of the label. However, because of the public health significance of dietary intake of fats, FDA believes it is important to provide the increased precision at low levels of fat. Inasmuch as legibility is more dependent upon factors such as type size and color contrast than the addition of a decimal point and digit, FDA urges manufacturers to consider the readability factor and use great care to ensure that the information is legible.

33. Two comments requested that the agency permit the declaration of total fat and saturated fat in tenths of a g.

FDA does not agree. It is not possible to require the declaration of total fat and saturated fat in tenths of g increments because this degree of precision cannot be reliably obtained in all foods with available methodology.

34. Comments stated that the change from whole-g increments would be confusing and cumbersome to consumers. One comment requested that the agency adopt a consistent rule for all macronutrients by rounding values to the nearest g.

FDA does not agree that the use of different increments for different nutrients will be confusing and cumbersome. These final rules allow for calories to be declared to the nearest 5 or 10 calorie increment depending on amount, for fats to the nearest 0.5 (½) or whole g, for cholesterol to the nearest 5 milligram (mg) amount, for carbohydrates and protein to the nearest g and for sodium to the nearest 5 or 10 mg increment. The rationale for each of these increments was explained when the increments were proposed.

c. *Amounts of fatty acids to be rounded to zero.*

35. A few comments disagreed with 0.25 g as the cut-off level at which fatty acids could be declared at zero. The primary reason given for disagreeing with the 0.25 g cut-off was that the analytical methods are not sensitive and precise enough to detect that level with any degree of reliability. One of the comments noted that FDA had, in its proposal on serving sizes, referenced consumer complaints about fractional numbers. The comment felt it was contradictory to introduce a potentially confusing requirement for the proposed 0.25 g cut-off. Other comments stated it would be confusing to consumers if, because of the rounding requirements, a product containing either 0.4 g or 0.45 g total fat and 0.3 g saturated fat is declared as "0" g total fat and 0.5 g saturated fat.

The agency is persuaded that the level of 0.25 g as the cutoff for a zero declaration for saturated, polyunsaturated, and monounsaturated fat content implies unwarranted precision. The ability to distinguish 0.24 g as zero and 0.26 g as a 0.5 g increment is presently unsubstantiated. Therefore, FDA is amending § 101.9(c)(2)(i) through (c)(2)(iii), to require that when a serving contains less than 0.5 g of saturated fats, polyunsaturated fats, or monounsaturated fat, the content of the fatty acids will be expressed as zero.

5. Cholesterol

36. The majority of comments agreed with the proposal for the mandatory declaration of cholesterol content. A few comments disagreed stating that dietary cholesterol does not play a significant role in the etiology of atherosclerotic vascular disease. Some comments stated that the declaration of cholesterol would mislead consumers into believing that a food free of, or low in, cholesterol would be effective in lowering serum cholesterol levels no matter how much saturated fat or total fat it contained. These comments suggested that declarations of cholesterol content should be either voluntary or not permitted.

FDA disagrees that the declaration of cholesterol should be voluntary or not permitted. The declaration of cholesterol content is required by section 403(q)(1)(D) of the act. While section 403(q)(2)(B) of the act allows the Secretary to delete nutrient information that is not necessary to assist consumers in maintaining healthy dietary practices, FDA does not believe that this is the case for cholesterol. There is a strong scientific consensus that high dietary intakes of total fat, saturated fatty acids, and cholesterol are associated with an increased risk of atherosclerotic cardiovascular disease, most notably with elevations in blood LDL-cholesterol and increased risk of coronary heart disease (Refs. 2, 3, 4, and 30).

Further, numerous controlled experiments, in both animals and humans, verify that dietary saturated fats and cholesterol elevate blood LDL-cholesterol. For this reason, current recommendations suggest limiting cholesterol to 300 mg per day as a means of lowering blood LDL-cholesterol and thereby reducing the risk of atherosclerotic vascular disease (Refs. 2, 3, 30, and 48). Accordingly, the agency concludes that the declaration of cholesterol is warranted and will be beneficial to many individuals in the general population in the monitoring of their cholesterol intake. Therefore, no

changes have been made in § 101.9(c)(5), redesignated as § 101.9(c)(3).

37. A few comments requested the mandatory declaration of a cholesterol-saturated fat index. This index provides a single number for individual foods that describes their cholesterol and saturated fat content. The index indicates the potential of a given food, diet, or menu to raise blood cholesterol levels.

The agency is not persuaded that the declaration of a cholesterol-saturated fat index on the nutrition label is warranted. There currently exists no consensus on the efficacy of this index. Therefore, FDA believes that the declarations of cholesterol and saturated fat, as required by the 1990 amendments, are sufficient for those who wish to moderate their intake of these nutrients.

38. Several comments disagreed with the proposal to declare "not a significant source of cholesterol" if cholesterol is present at less than 2 mg per serving. One comment suggested that the label declare zero cholesterol only if the product is virtually devoid of cholesterol. The comments stated that it is misleading to have even minute quantities of a food component in a product when the label declares that the product is free of that component.

The agency is not persuaded by these arguments. As discussed in the July 19, 1990, tentative final rule on cholesterol (55 FR 29460 at 29461), FDA purposely selected a value, less than 2 mg of cholesterol per serving, that is dietarily insignificant yet that can be detected with reasonable analytical reliability. A quantitative declaration other than zero would not necessarily be more correct because methodological limitations do not generally permit precise quantification of cholesterol content within the 95 percent confidence level below 2 mg amounts. It is also extremely unlikely that sufficient quantities of foods containing less than 2 mg of cholesterol per serving would be consumed on a daily basis to represent a significant level of cholesterol intake.

39. A few comments requested that foods having less than 5 mg of cholesterol per serving be permitted to indicate "not a significant source of cholesterol" so that skim milk, at 4 mg cholesterol per cup, and similar foods could use the statement. Proposed § 101.9(c)(5) only allows its use on labels of foods containing less than 2 mg of cholesterol per serving.

FDA disagrees. The agency believes that the statement "not a significant source of cholesterol" is only appropriate on foods that contribute truly insignificant amounts of cholesterol to the diet. In the companion document on nutrient content claims published elsewhere in this issue of the **Federal Register**, the agency has determined that foods that contain less than 2 mg of cholesterol per serving are dietarily insignificant sources, and that foods that contain larger amounts, both individually and collectively, contribute significantly to a person's daily cholesterol intake. Therefore, FDA is taking no action on the basis of these comments.

D. Sodium

40. The majority of comments supported the proposal for the mandatory declaration of sodium. A few comments requested alternate methods of declaring sodium, such as a sodium to potassium ratio and a sodium balance system.

The agency has no data, nor were any submitted, that demonstrate that these alternative methods would more effectively present sodium content. Accordingly, FDA has not revised the provision for the declaration of sodium content.

41. A few comments questioned potential beneficial effects of sodium restriction in nonhypertensive populations. The comments suggested that there is still debate within the scientific community as to whether it is appropriate for the general population to reduce its overall sodium consumption. Further, these comments stated that control of sodium intake is only relevant for those segments of the population that are sodium sensitive. These comments requested that the agency not permit the declaration of sodium, or that it make the declaration of sodium voluntary.

The agency disagrees. Section 403(q)(1)(D) of the act requires the declaration of sodium. While section 403(q)(2)(B) of the act allows the Secretary to delete nutrient information that is not necessary to assist consumers in maintaining healthy dietary practices, the bulk of the accumulated evidence strongly supports the prevailing consensus that it would be prudent for the general population to reduce sodium consumption, even though not all people display increased blood pressure in response to high sodium intakes.

The Surgeon General's report (Ref. 2) asserts the need for moderation in sodium consumption, not only because there is a benefit to persons whose blood pressures do rise with sodium intake, but also because there is no biological marker for individual sodium sensitivity. Additionally, the report notes that there is no apparent harm from moderate sodium restrictions (Ref. 2). Accordingly, § 101.9(c)(9), redesignated as § 101.9(c)(4), will continue to require sodium declaration.

42. One comment from a national manufacturer of carbonated soft drink syrups explained that these syrups must be mixed with local water supplies, and that, therefore, the final products vary in sodium content. The comment suggested that the sodium in these products be declared as an average value, such as "less than 35 mg," even though the product contains slightly more, or slightly less, than that amount. Further, the comment suggested that the manufacturer be allowed to make a claim, such as "very low sodium," based on that range.

Data on the sodium content of the United States water supplies were previously submitted, reviewed, and discussed in the April 18, 1984, final rule on the declaration of sodium content (49 FR 15524). FDA's evaluation of these data revealed that a single label would accurately reflect the sodium content of all but 10 percent of soft drink products bottled in the United States, and that a second label could apply to the remainder without severely overstating the sodium content.

Further, the agency stated that the manufacturer had the option of using a single nationwide label with the highest possible sodium level declared. This approach would result in the sodium content being overstated by about 50 mg for a majority of products. While 50 mg is not an insignificant amount of sodium, it represents a relatively small portion of the daily sodium intake for all but those persons on extremely restricted sodium diets. Even if sodium were declared based on the highest level of sodium found in any source of water, all regular and diet soft drinks would fall into the "low sodium" category.

FDA is not persuaded by the comment to the July 19, 1990 or November 27, 1991, proposals that an average value representing a range of sodium levels, such as "less than 35 mg," is appropriate for these products. Sodium content may be underrepresented by this method.

Inasmuch as the declaration of sodium is required by section 403(q)(1)(D) of the act, and no new data were presented with the comment, the agency is denying the request that a range of sodium content be declared on the nutrition label or be allowed as a basis to support a nutritional claim.

E. Potassium

43. Several comments supported the proposal for the voluntary declaration of potassium. One comment, however,

requested that the agency not allow any declaration of potassium content. The comment suggested that the general population is unaware of the dietary role of potassium, and any declaration of potassium content would only serve to confuse the consumer. No data were provided to support this argument.

FDA is not persuaded that it should not permit the voluntary declaration of potassium content. As discussed in the mandatory nutrition labeling proposal (55 FR 29500 at 29501), beneficial effects of potassium intake relative to reducing mortality from stroke have been reported. Data from animal studies suggest that dietary potassium may lower blood pressure and the risk for heart disease and may also protect against vascular damage and stroke (Ref. 3).

In addition, epidemiological evidence for humans suggests that diets with high levels of potassium—but also low levels of sodium—may be beneficial in lowering blood pressure (Ref. 3). Moreover, the IOM report concluded that even though deficits or excesses of potassium intake do not pose public health concerns, the voluntary declaration of potassium would be beneficial to consumers (Ref. 1). Based on the foregoing evidence, FDA concludes that the declaration of potassium in nutrition labeling may assist in maintaining healthy dietary practices. Accordingly, in § 101.9(c)(10), redesignated as § 101.9(c)(5), FDA will allow potassium to be declared in nutrition labeling on a voluntary basis.

44. Comments from several health and professional associations, consumers, consumer groups, and universities supported mandatory declaration of potassium content. The comments stated that this information is potentially helpful to persons with kidney disease. Others referred to epidemiological evidence of a positive association among high potassium intake, low sodium intake, and lower blood pressure.

Although potassium has been acknowledged as a potential public health issue (Refs. 1 and 49), no specific, quantitative recommendations have been made by national consensus reports. Accordingly, potassium does not meet FDA's criteria for inclusion as a mandatory element of nutrition labeling, as discussed in FDA's mandatory nutrition labeling proposal (55 FR 29487 at 29493 and 29500).

Until such time as quantitative recommendations are made, the agency does not believe there are sufficient grounds to require labeling of potassium content. Therefore, FDA is continuing to permit potassium content labeling in nutrition labeling on a voluntary basis in § 101.9(c)(5).

45. One comment suggested that the declaration of potassium content should be mandatory only if magnesium is not required as a reference nutrient. The comment stated that potassium and magnesium are abundant in whole grain cereals, legumes, nuts, and other unprocessed foods. Further, the comment suggested that if magnesium is required, potassium should be voluntary.

The agency is not persuaded that the mandatory declaration of magnesium is warranted, or that the declaration of potassium should be mandatory because the declaration of magnesium is not required. Magnesium is not a nutrient for which there are significant public health concerns (Ref. 23).

Further, while magnesium and potassium are found together in many foods, using magnesium as a reference nutrient for potassium in food labeling is questionable because there are many fruits and some vegetables that are excellent sources of potassium but poor to moderate sources of magnesium (Ref. 23). The agency does not believe that a mandatory declaration of magnesium content is warranted at this time.

46. One comment suggested that information on potassium should be available from manufacturers' toll-free telephone numbers. The comment explained that consumers who must monitor their potassium intake, such as renal dialysis patients, often have difficulty determining how much potassium is in a product. The comment suggested that manufacturer's toll-free numbers would provide easy access to more detailed nutrient content information.

While FDA encourages manufacturers to make additional information available to consumers, this request is beyond the authority of the agency. Toll-free telephone numbers for product information may or may not be supplied according to the preference of the manufacturer.

F. Total Carbohydrate, Dietary Fiber, Sugars, Sugar Alcohol, and Other Carbohydrate

1. Total Carbohydrate

47. Comments from trade associations, manufacturers, professional societies, and another federal agency recommended that FDA reconsider proposed § 101.9(c)(6) which excludes dietary fiber from total carbohydrate. As noted in several comments, dietary fiber traditionally has been included as part of the carbohydrate content of food, is considered part of carbohydrate in current nutrition labeling regulations, is included within total carbohydrate for nutritional labeling by Canada, and is included in the Atwater method of determining "carbohydrate by difference." Other comments pointed out that excluding dietary fiber from total carbohydrate is consistent with definitions for labeling used by Codex Alimentarius Commission and the European Community (EC), which include only metabolized carbohydrate. A comment remarked that to exclude dietary fiber from total carbohydrate is inconsistent with all major data bases and U.S. publications on food composition and is different from the way carbohydrate has been presented to the consumer in nutrition labeling for the past two decades. This comment suggested that inconsistency in definitions will contribute to consumer confusion.

In the 1990 mandatory nutrition labeling proposal, FDA proposed mandatory declaration of total digestible carbohydrate, which excluded dietary fiber, the nondigestible portion of carbohydrate. Several comments noted that while the intent of this definition for total carbohydrate was to include only energy yielding components, in fact there is evidence that fermentation of dietary fiber yields available energy. Comments noted that dietary fiber content was accounted for in deriving both the general energy factor of 4 calories per g of carbohydrate and the specific Atwater factors for calculation of energy value of carbohydrate in foods. The comments stated that total carbohydrate (excluding dietary fiber) content as defined in proposed § 101.9(c)(6) is not appropriate for calculating calories from carbohydrate as proposed in § 101.9(c)(3). As a result, two different values for "total carbohydrate" would be required to comply with nutritional labeling: (1) Total carbohydrate (excluding dietary fiber) for the content declaration, and (2) total carbohydrate (including dietary fiber) for calorie calculation.

In the mandatory nutritional labeling proposal, FDA stated that the reason for declaration of carbohydrate content was, in part, to allow consumers to determine the percentage of calories from carbohydrate (55 FR 29487 at 29497). Several comments argued that departing from the established use of the term "carbohydrate" (i.e., including dietary fiber) used in determining carbohydrate calories by the Atwater method, will be confusing and thereby detract from the value to consumers of the caloric information. Several comments suggested that in separating dietary fiber

from "energy yielding" components of carbohydrate, FDA's logic was faulty for two reasons. First, carbohydrate fractions are not clearly delineated as digestible or nondigestible fractions. Rather, there exists a continuum of digestibility among carbohydrate substances. Second, dietary fiber is appropriately included in total carbohydrate for calculation of energy content with use of Atwater factors.

Many comments noted that, except for lignin, substances comprising dietary fiber are carbohydrates. Comments pointed out that dietary guidelines (Ref. 4) urge increased consumption of types of foods rich in both dietary fiber and complex carbohydrate and stated that separating these carbohydrate components in nutrition labeling will mislead consumers as to the nature of dietary fiber.

FDA is persuaded by the comments that the separation of dietary fiber from carbohydrate is inconsistent with established methods of reporting food composition and confuses the issue of calculating energy content. Further, the agency agrees that the separation of dietary fiber from carbohydrate will decrease consumer understanding of label information and its application to dietary recommendations that link dietary fiber and complex carbohydrate together in advising increased consumption of foods high in both. Accordingly, FDA is modifying § 101.9(c)(6) to include dietary fiber in the declaration of total carbohydrates. This action results in the inclusion of both digestible and nondigestible carbohydrates under total carbohydrates.

Section 101.9(c)(6) is also modified to state that total carbohydrate content is to be calculated by subtracting the sum of crude protein, total fat, moisture, and ash from the total weight of food. Additionally, since total carbohydrate now includes dietary fiber, the paragraphs relating to dietary fiber are redesignated under § 101.9(c)(6)(i) rather than under § 101.9(c)(7). Consequently, the remaining paragraphs within § 101.9(c) are renumbered.

2. Dietary Fiber

48. Comments from consumers, health professionals, health promotional organizations, and manufacturers agreed that declaration of dietary fiber should be mandatory. Other manufacturers, trade associations, and a university food science department disagreed and urged voluntary, rather than mandatory, declaration of dietary fiber. The arguments against required listing of dietary fiber included: (1) Analytical methods for dietary fiber in foods are not yet routine, are expensive, and lack precision in some types of foods; (2) mandatory declaration imposes an unnecessary analytical burden on producers of foods that are not significant sources of fiber; and (3) mandatory declaration will likely encourage fiber supplementation of foods.

The agency does not agree that the specified methods for fiber analysis are difficult and expensive. The operations involved and equipment required for the methods are standard in analytical laboratories. The agency recognizes that the official AOAC method for dietary fiber analysis is relatively recent. However, as a validated method, it should be included in current nutrition labeling regulations.

In regard to the analytical burden on producers of foods with insignificant amounts of fiber, the agency advises that if there is adequate and reliable reason to believe that fiber is not present, there is no need to analyze for it; it can be declared as "0". Additionally, § 101.9(c)(6)(i) provides for expression of dietary fiber in 1 g increments in recognition of the precision of analytical methods. For foods that contain less than 1 g of dietary fiber per serving, manufacturers may choose to state "contains less than 1 g" or to omit dietary fiber from the list of nutrients and to state at the bottom of the nutrition label "Not a significant source of dietary fiber."

There have always been concerns that nutrition labeling will encourage the supplementation (i.e., fortification) of foods. In part for this reason, FDA published a policy statement on the addition of nutrients to food on January 25, 1980 (45 FR 6314). The statement was issued to promote the rational addition of nutrients to foods to preserve a balance of nutrients in the diet of American consumers. In the statement, FDA established guidelines in § 104.20, which the agency urges manufacturers to follow if they elect to add nutrients to a food.

FDA intends to continue to monitor the marketplace through the Food Labeling and Packaging Survey, consumer and industry complaints, and other means to determine if inappropriate fortification is occurring. If the agency finds that there is a problem with inappropriate fortification of foods with dietary fiber or any other nutrients, it will take steps to ensure that overfortification does not result in the imbalance of essential nutrients in the diet of American consumers or the presence of excessive amounts of particular nutrients that have the potential for toxicity.

Thus the agency is not persuaded that there is a compelling cause not to require declaration of dietary fiber in nutrition labeling. Section 403(q)(1)(D) of the act requires dietary fiber to be included in nutrition labeling. Section 403(q)(2)(B) of the act allows a required nutrient to be deleted if the Secretary determines that the nutrient is not necessary to assist consumers in maintaining healthy dietary practices, but no information contained in the comments would lead to such a conclusion. In fact, most comments supported the usefulness of mandatory declaration of dietary fiber. Accordingly, § 101.9(c)(6)(i) will require the declaration of dietary fiber in nutrition labeling.

This action represents the final disposition of two petitions regarding label declaration of carbohydrates, including dietary fiber. One petition from the Kellogg Co. dated May 14, 1978 (Docket No. 78P–0091), requested, in part, permission to list under "carbohydrate" the amounts of "starches and related carbohydrates" and "sucrose and other sugars." The other petition from the Center for Science in the Public Interest dated June 1, 1987 (Docket No. 87P–0194/CP) requested that dietary fiber be a mandatory component of nutrition labeling, and that regulatory letters be sent to all manufacturers making misleading claims about fiber content.

49. Comments from nutritionists representing state cooperative extension services and from one manufacturer cautioned that declaration of soluble and insoluble subcomponents of dietary fiber should be prohibited because the methodology for separating soluble from insoluble fiber is inadequate, and because there is no scientific agreement as to the health effects of the subgroups of dietary fiber.

The agency advises that analytical methods for the measurement of soluble and insoluble dietary fiber are now part of an official AOAC method for dietary fiber (Ref. 50). While experience with these methods is limited, they will allow for accurate separation of these subcomponents.

In regard to scientific agreement as to the health effects of soluble or insoluble fiber, FDA has evaluated the health effects of the dietary fiber subgroups and has concluded that there is sufficient scientific agreement to issue a final rule permitting health claims relating to the effects of intake of soluble dietary fiber on heart disease. This decision is discussed in a companion document entitled "Food Labeling; Health Claims; Dietary Fiber and Cardiovascular Disease" published

elsewhere in this issue of the **Federal Register.**

Accordingly, § 101.9(c)(7)(i), redesignated as § 101.9(c)(6)(i)(A) and (c)(6)(i)(B), will continue to allow the voluntary declaration of soluble and insoluble dietary fiber in nutrition labeling, except that when a claim is made about either type of fiber, label declaration of that type of fiber will be required. To clarify that soluble and insoluble fiber are to be indented under dietary fiber rather than under total carbohydrate, FDA has modified § 101.9(c)(6)(i)(A) and (c)(6)(i)(B) to state "indented under dietary fiber." FDA has also modified these two sections to remove the requirement that whenever one type of fiber is declared, the other type must also be declared. Because total dietary fiber is a mandatory component of nutrition labeling, the amount of an undeclared subcomponent (i.e., soluble or unsoluble fiber) can be calculated simply by subtracting the amount of the declared subcomponent from the amount of dietary fiber. This change will minimize space requirements caused by the voluntary declaration of additional nutrients.

3. Sugars

a. *Definition of sugars.*

50. Comments from consumers, consumer interest groups, state governments, trade associations, food retailers, and a manufacturer concurred with the agency's proposed definition for sugars as the sum of all free mono- and oligo-saccharides through four saccharide units and their derivatives having similar sweetening, nutritional, and metabolic effects. Consumer interest in the sugars content of food, and concern that "sugars" should include all forms of carbohydrate sweeteners added to foods, were cited as reasons for support for the proposed definition. Comments from many consumers, state governments, and a health promotion association stated that information on content of both sugars and of sugar derivatives is important to assist consumers to moderate intake of sugars and to assist diabetics in maintaining healthy dietary practices. Consumer interest groups argued that underreporting of the sugars content in products rich in corn syrups is an appropriate justification for an expanded definition for sugars. A comment noted that the agency has a precedent for considering sugar alcohols as sugars in § 100.130(d)(4), which states that "sugar-free" type statements cannot be made on labels of diet beverages containing "sorbitol, mannitol, or other hexitols."

Other comments from a wide variety of manufacturers, trade associations, foreign and state governments, professional associations, and a Federal agency objected to the proposed sugars definition. Most of these comments recommended that the sugars definition be limited to monosaccharides and disaccharides. One argument for limiting the sugars definition to mono- and di-saccharides is that this is the traditional and widely accepted use of the term "sugars." They pointed out that it is also the definition of the term in the IOM report "Nutrition Labeling: Issues and Directions for the 1990s" (Ref. 1). Many comments noted that for conformity with international regulatory definitions for nutrition labeling (EC, Codex Alimentarius Commission, and Canada) sugars should be defined as mono- and di-saccharides.

Another argument, brought forth in comments, for limiting the sugars definition to mono- and di-saccharides is that there are no compelling health or nutritional reasons for including tri- and tetra-saccharides as "sugars." The comments pointed out that the 1986 "Report From FDA's Sugars Task Force" (Ref. 51) concluded that the only public health concern from sugars consumption in the United States is the promotion of dental caries. The IOM report (Ref. 1) concurred with this conclusion. The comments argued that, in the absence of a clear relationship between number of saccharide units and carcinogenicity, the proposal to include tri- and tetra-saccharides within sugars is not relevant to the public health concern of dental caries.

Several comments questioned the agency's logic in including tri- and tetra-saccharides with sugars. FDA had stated in the 1990 mandatory nutrition labeling proposal (55 FR 29487 at 29497) that the intent of including tri- and tetra-saccharides as sugars was to preclude potential underdeclaration of the sugars content of foods containing corn syrups. Several comments noted that mono- and di-saccharides are logically grouped in that they are sweet, naturally occurring, and rapidly absorbed, but that these characteristics are, for the most part, not in common with tri- and tetra-saccharides. Comments also noted that most corn syrup used in sweetening is in the form of high fructose corn syrup, which is composed of 95 percent monosaccharides, and that high fructose corn syrup accounts for two thirds of total U.S. corn syrup consumption. Comments noted that corn syrups with greater proportions of higher saccharides are used for technical purposes other than sweetness. Thus, the comments argued that underestimation of simple sugars from corn syrups is not of sufficient importance to warrant imposing a unique sugars definition for labeling purposes that would differ from common usage of the term.

Many comments objected to the proposed sugars definition on methodological grounds, in that they claimed that the proposed definition is not compatible with standardized analytical methods for measuring sugars. The comments acknowledged that validated methods for measuring mono- and di-saccharides in foods exist but argued that there are not collaboratively validated methods for the measurement of tri- and tetra-saccharides. The comments noted that measurement in foods of oligosaccharides larger than disaccharides is difficult, costly, and inaccurate. The comments asserted that the lack of validated analytical methodology appropriate for the definition would result in compliance difficulties and inaccurate information on the label.

FDA has evaluated all comments in favor of the proposed expanded sugars definition and those opposed to this definition. FDA is persuaded that compliance with nutrition labeling will be impeded by adopting a definition for sugars that is not supported by validated analytical methods. FDA is also persuaded that the usefulness of nutrition labeling will be hindered by adopting a definition that is inconsistent with commonly accepted use, and with the international use of the term.

FDA finds that these factors outweigh any public health benefit from including tri- and tetra-saccharides in the definition of "sugars" for nutrition labeling purposes. The public health concern associated with sugars consumption is the promotion of dental caries. While simple sugars are the most cariogenic carbohydrates, all fermentable carbohydrates, including starches, are capable of promoting dental caries. Factors such as the characteristics of the food that contains the sugar (e.g., stickiness), the frequency of consumption, and the sequence in a meal, appear to be as important in the etiology of dental caries as the sugars themselves (Refs. 2 and 3). As such, the inclusion of tri- and tetra-saccharides with sugars would not improve the ability of the label to assist consumers in maintaining healthy dietary practices with respect to dental health.

Therefore, the agency is modifying the definition of "sugars" in § 101.9(c)(6)(ii)(A), redesignated as

§ 101.9(c)(6)(ii), to include only free monosaccharides and disaccharides.

51. Several comments recommended that lactose be specifically excluded from the sugars definition for nutrition labeling. These comments asserted that the listing of lactose with sugars in nutrition labeling may mislead some consumers who may equate the lactose sugar content of dairy products with "empty calories" of products high in added sugar. The comments expressed a fear that dietary guidelines to moderate sugars consumption may lead some consumers to forego the important nutritional benefit of dairy products if lactose is included in sugars content. Comments also noted that intestinal digestion of lactose is inefficient. As such, the digestion and absorption of lactose more closely resembles complex carbohydrate than simple sugars. Furthermore, comments argued that lactose is not sweet nor used as a sweetener and could logically be separate from sugars used as sweeteners.

FDA disagrees with the comments. As discussed in the preceding comment, the agency has been persuaded of the need to define "sugars" for nutrition labeling purposes to be consistent with standard analytical methodologies and in conformity with the traditional usage of the term. Lactose, a di-saccharide, is clearly a sugar by conventional standards and is identified with all other mono- and di-saccharides in routine analytical procedures. The nutritional significance of the sugars content of certain types of foods, such as lactose in dairy products and natural sugars in fruit, and the importance of such foods as sources for other important nutrients, needs to be addressed through the consumer education program discussed below.

Accordingly, the agency is not making the recommended change to exclude lactose in the definition of sugars.

52. Several comments suggested alternative definitions for "sugars" based upon physiological characteristics rather than the number of saccharide units. Among these alternatives were suggestions for definitions based on digestibility, caloric value, glycemic index, and serum insulin response.

FDA finds that such alternative approaches are not feasible from a compliance standpoint because validated analytical methods to quantitate sugars defined in these ways do not exist. In addition, use of any of these definitions for sugars would be unique to U.S. nutrition labeling and would thus likely impede foreign trade. Moreover, because these definitions do not correspond to the commonly recognized meaning of the term, the resulting labeling information would be of limited usefulness.

53. FDA received comments that suggested alternative terminology for the "sugars" component of carbohydrate. The agency's longstanding use of "sugar" as synonymous with sucrose in ingredient labeling was cited as evidence of the need for an alternative term. Several comments felt that FDA's distinction between "sugar" and "sugars" would not be clearly understood by consumers. Alternative terms suggested included "sweeteners" and "simple carbohydrates."

FDA considered these comments but has concluded that it is best to maintain the proposed terminology. The agency advises that the term "sweeteners" would logically include the noncarbohydrate intense sweeteners, which would not be appropriately declared as a part of carbohydrate content. In addition, the term appears to apply more to added sugars than to total sugars and, therefore, would cause compliance problems because it is not possible, in most foods, to differentiate between added and naturally present sugars.

"Simple carbohydrates" may have been a good term for the originally proposed definition (i.e., mono-, di-, tri-, and tetra-saccharides). However, the agency finds it is too broad a term to encompass only the traditional sugars (i.e., mono- and di-saccharides).

b. *Total sugars versus added sugars.*

54. Some comments recommended mandating declaration of added sugars only rather than total sugars. The comments noted that consumers need to be made aware of added sugars because dietary recommendations urge use of sugars in moderation, while at the same time recommending increased consumption of fruits which are sources of naturally occurring sugars. Other comments recommended either mandatory or voluntary declaration of both added and naturally occurring sugars. One comment suggested that added sugars be required in addition to total sugars in foods containing more than 2 g of added sugar.

The agency is not persuaded that there is a need for mandatory disclosure of added sugars in place of, or in addition to, total sugars. There is no scientific evidence that the body makes any physiological distinction between added sugar molecules and those naturally occurring in a food. In addition, the agency believes that it should not promulgate regulations that it cannot enforce. When a product is sampled for compliance, laboratory analysis yields a value for total sugars. For most foods, as stated above, it is not possible to differentiate between added and naturally occurring sugars. Accordingly, the agency would not be able to determine the accuracy of a label declaration of added sugars.

Furthermore, declaration of only added sugars may significantly underrepresent the sugars content of many foods that are high in naturally occurring sugars. For example, in some fruits canned in heavy syrup, added sugars may represent only about 50 percent of total sugars. Disclosure of only the added sugars could be misleading to consumers who are concerned with total sugar intake. Therefore, the agency is retaining the provision of § 101.9(c)(ii)(A), redesignated as § 101.9(c)(ii), to declare total sugar content, e.g., that added as well as that naturally present.

While FDA is not distinguishing, on the nutrition label, between added and naturally present sugars, the agency does intend to include information about this distinction in the consumer education program that it is preparing. This information will help consumers: (1) Use the information on the nutrition label to differentiate between sugar-containing foods with high versus low levels of other important nutrients, (2) use the ingredient statement to distinguish foods with naturally occurring versus added sugars, and (3) appreciate the important role in the total daily diet of foods, such as fruits and dairy products, with naturally occurring sugars.

c. *Mandatory declaration of sugars.*

55. In the 1991 supplementary proposal, FDA requested specific comments as to the utility, appropriateness, and feasibility of requiring declaration of sugars content, particularly as such declaration relates to, and is supported by, public health goals (56 FR 60366 at 60369). Comments received were relatively evenly divided on the issue of whether the declaration of sugars should be mandatory in nutrition labeling. In general, consumers and health professionals and their associations supported mandatory declaration of sugars. Several state attorneys general and a few industry groups also agreed that consumers have a right to know the amount of sugars present. Comments argued that section 403(q)(2)(B) of the act only allows FDA to delete sugars as a mandatory component of nutrition labeling if such information "is not necessary to assist consumers in maintaining healthy dietary practices," and that such information is vital to this end. Comments from many consumers, state governments, and a health promotion

association stated that information on sugars content is important to diabetics in assisting them to maintain healthy dietary practices and to consumers in general in selecting diets that will moderate the intake of sugars. One comment urged mandatory declaration of sugars as a way to inform consumers of the content of new foods that are being marketed as "low fat" and "fat free" in which fats are being replaced by sugars.

Most industry groups as well as a few health professional associations and the IOM report (Ref. 1) recommended allowing sugars declaration to be voluntary. They argued that dietary guidance recommendations have not specified quantitative goals for sugar consumption, and that sugar declaration should not be required until a definition has been recognized by scientific communities that reflects physiological effects. They also pointed out that data bases do not generally contain information on sugars composition, so a substantial investment of time and money is needed for analysis and data base update. The comments argued that such an expenditure would be inappropriate for a nutrient of little public health concern. There was also a concern expressed that because total sugars would be declared rather than only added sugars, consumers would be confused by the amount of sugars in fruits and reduce their consumption of these foods. Despite these concerns, industry generally conceded that if sugars information is needed, requiring sugars declaration in the nutrition label is a better approach than mandating grouping of sweeteners in the ingredient statement, as the agency proposed in a document on ingredient labeling (56 FR 28593, June 21, 1991). Final action on the issue of grouping sweeteners in the ingredient statement is addressed in the final rule on declaration of ingredients published elsewhere in this issue of the **Federal Register.**

FDA is persuaded that mandatory declaration of sugars is of great interest to consumers, and that it will assist consumers in planning diets that conform to current dietary guidelines for Americans to avoid too much sugars (Ref. 4). As discussed above, FDA is modifying its proposed definition of "sugars" to be in conformity with general usage and international definitions for this term. The use of this definition will minimize the costs associated with necessary laboratory analyses and update of data bases.

Therefore, FDA is requiring in § 101.9(c)(6)(ii) that declaration of sugars be included in nutrition labeling.

4. Sugar Alcohol

56. Comments from a wide variety of manufacturers, trade associations, foreign and State governments, professional associations, and a Federal agency were opposed to inclusion of saccharide derivatives, specifically sugar alcohols, within the proposed "sugars" definition. The agency's proposed definition included in its coverage saccharide derivatives that have sweetening, nutritional, and metabolic effects similar to simple sugars. The comments stated that sugar alcohols are inappropriately included with sugars because sugar alcohols have many different chemical and physiological properties than sugars. Comments noted that it is these differences that motivated the development of uses for these substances and makes them useful as sugar substitutes. Comments pointed out that a salient distinction between sugar alcohols and sugars lies in their digestion and absorption, which is slower for sugar alcohols. Also, intestinal absorption of monosaccharide sugar alcohols occurs only by passive diffusion, not by active or facilitated monosaccharide absorptive mechanisms. As a result, significant portions of ingested sugar alcohols remain unabsorbed and pass into the colon, where they are fermented, similar to fiber and complex carbohydrate. Thus, the caloric value, insulin response, and glycemic index for some sugar alcohols are less than for sugars.

Several comments also claimed that sugar alcohols have reduced cariogenic potential compared to sucrose or other sugars. The comments noted that FDA proposed in § 101.13(o)(8) in the document on the general principles for nutrient content claims to permit chewing gums sweetened with sugar alcohols to be labeled as "sugar free" or "sugarless" as a means of indicating that these products do not promote tooth decay. The comments argued that declaring sugar alcohols as sugars would deny manufacturers the means to promote the reduced cariogenic potential of other sugar alcohol sweetened products relative to sugar containing products.

Comments also noted that international regulatory definitions for nutrition labeling (EC, Codex Alimentarius Commission, and Canada) exclude sugar alcohols and provide for a separate declaration of sugar alcohols under carbohydrates. As a result, the comments stated that a definition for sugars that includes sugar alcohols for U.S. nutrition labeling could be seen as an obstruction to international trade. The IOM report (Ref. 1) recommended that sugar alcohols not be grouped with sugars in ingredient labeling. Some comments argued that in the absence of any quantitative dietary guidelines concerning sugar alcohols, it is inappropriate to require any declaration of sugar alcohols in nutrition labeling.

FDA is persuaded that sugar alcohols have metabolic effects different than sugars, have a history of being considered to be sugar substitutes rather than as sugars, and have a role in contributing to dental health. FDA also acknowledges that the proposal to define sugar alcohols as sugars for nutrition labeling purposes is inconsistent with the nutrition labeling practices of other countries. Thus, FDA is modifying § 101.9(c)(6)(ii) to remove sugar alcohols from the definition of "sugars" for nutrition labeling. The agency is doing so in recognition of their usefulness as sugar substitutes in reducing the cariogenic potential of foods.

However, FDA continues to believe that the content of nutritive carbohydrate sweeteners used as sugar substitutes is of interest and importance to consumers. Therefore, FDA is retaining § 101.9(c)(6)(ii)(B), which provides for the voluntary declaration of sugar alcohols except when a claim is made on the label or in the labeling about sugar alcohol or sugars (e.g., "sugar free") and sugar alcohols are present in the food, in which case their declaration is mandatory. Because sugar alcohols will no longer be a subcomponent of sugars, FDA is redesignating § 101.9(c)(6)(ii)(B) as § 101.9(c)(6)(iii).

Removing sugar alcohol from the definition of sugars necessitates a change in the definition of sugar alcohol. The proposed definition included a criterion that sugar alcohols "meet the definition of sugars as described in paragraph (c)(6)(ii)(A)." Accordingly, FDA has revised the definition for sugar alcohol in § 101.9(c)(6)(iii) to use a chemical definition, namely that sugar alcohols be defined as "saccharide derivatives in which a ketone or aldehyde group is replaced by a hydroxyl group, and whose use in food is listed by FDA (e.g., mannitol) or is GRAS (e.g., xylitol, sorbitol)."

57. Comments from trade associations and manufacturers stated that the term "sugar alcohol" is potentially confusing in that consumers may assume such components contain a sugar and ethyl alcohol. The comments requested that the term "polyol," which has been recognized by the EC, be used in lieu of "sugar alcohol." Another comment from

the Canadian government included a copy of their nutrition labeling regulations which allow for declaration of the specific sugar alcohols by name (i.e., sorbitol, mannitol, and xylitol).

FDA advises that the term "polyol," a contraction of "polyalcohol" or of "polyhydric alcohol," is neither uniquely descriptive of the alcohol derivatives of saccharides used as sugar substitutes, nor is it a term that FDA expects consumers to recognize or understand. While the agency recognizes that it is a term that may be used voluntarily on labeling in the EC, it is unlikely that American consumers will have any concept of what it represents. As such, the agency considers the term "polyol" to be potentially more confusing to consumers than would be "sugar alcohol."

Despite this fact, FDA acknowledges that many consumers also may not be familiar with the term "sugar alcohol." Thus, FDA has decided to adopt the approach used by the Canadian Government, which allows manufacturers to use the specific name of the sugar alcohol in the nutrition label. The names of sugar alcohols that are listed or GRAS for use in food, (e.g., sorbitol § 184.1835, mannitol § 180.25, and xylitol § 172.395) are currently used in ingredient statements on labels of food packages and, hence, should be recognized by many consumers.

The primary disadvantage to this option is the introduction of the name of an ingredient into the nutrition label. While FDA is generally opposed to such a result, the agency concludes that the arguments opposed to the term "sugar alcohol" and the desire to harmonize with Canadian labeling regulations are more compelling in this instance than the need to maintain a clear separation between the nutrition label and ingredient list. However, to avoid cluttering the nutrition label and confusing consumers, if more than one sugar alcohol is used in a food, § 101.9(c)(6)(iii) provides that the term "sugar alcohol," and not the names of the ingredients, must be used in the nutrition label.

Accordingly, FDA is modifying § 101.9(c)(6)(iii) to specify the continued use of the term "sugar alcohol" or, alternatively, if only one sugar alcohol is present in the food, the name of the specific sugar alcohol present in the food may be used.

5. Other Carbohydrate

a. *Definition.*

58. In the supplementary proposal, FDA noted that the term "complex carbohydrate" has not been clearly or consistently defined, and that consensus reports that have associated increased consumption of dietary complex carbohydrate with health benefits have not attempted to define this food component. The agency solicited suggestions on appropriate chemical definitions and analytical methodology for complex carbohydrate (56 FR 60366 at 60369). Many comments from trade associations, food manufacturers, professional societies, and state and foreign governments expressed opposition to the agency's proposed definition for the term complex carbohydrate as the sum of dextrins and starches that contain ten or more saccharide units (56 FR 60366 at 60388). A majority of these comments also recommended as an alternative that "complex carbohydrate" be defined as the difference between total carbohydrate and sugars. Comments that argued for changing the definition pointed to the lack of existing analytical methodology to support the proposed definition. Thus, these comments raised concerns about the feasibility of compliance and the economic burden of developing methods and data bases. These comments also pointed out that complex carbohydrate content defined as the difference between total carbohydrate and sugars could readily be calculated.

Another criticism of the proposed complex carbohydrate definition was that the cutoff at 10 saccharide units is arbitrary. These comments noted that there are no known nutritional or physiological differences, nor a methodological justification, to make a distinction between polysaccharides smaller than 10 saccharide units and those with 10 or more saccharide units. Several comments were concerned that there is the potential for consumer confusion regarding total carbohydrate because neither of the subcomponents for total carbohydrate included the 5 to 9 saccharide unit polysaccharides.

Several comments suggested that the commonly accepted usage of "complex carbohydrate" includes all carbohydrates larger than disaccharides. Other comments suggested that complex carbohydrate should be defined as all digestible polysaccharides (e.g., dextrins, starch, and glycogen) rather than on the basis of the number of saccharide units. Comments emphasized that while there is not a consensus on a precise definition for "complex carbohydrate," the agency's proposed definition is not commonly recognized, nor is it consistent with the use of the term in the IOM report (Ref. 1).

One comment from a State government recommended that to avert undue emphasis on complex carbohydrate substances added to foods and to avoid the potential for misleading claims about complex carbohydrates, the term "other carbohydrate" should be used rather than "complex carbohydrate."

The agency noted in the supplementary proposal (56 FR 60366 at 60368) that identification of a specific benefit for complex carbohydrate is confounded by the fact that diets high in complex carbohydrate are usually mixed diets that contain significant amounts of cereal grains, fruits, and vegetables which are high in fiber, vitamins, and minerals and low in fats (Ref. 2). Thus the extent to which complex carbohydrate provides health benefits separate from those provided by fiber, vitamins, minerals, and reduced fat is unclear. FDA has evaluated comments concerning the complex carbohydrate definition and concludes that there is not sufficient consensus on the meaning of the term to justify adopting a specific definition for "complex carbohydrate."

In response to the comments that suggested defining this term as "digestible polysaccharides," FDA advises that carbohydrate digestibility is not clear cut. Some soluble dietary fiber is relatively digestible, whereas some oligosaccharides are relatively nondigestible. At this time there is not a consensus regarding the most reliable methods for determining carbohydrate digestibility nor for distinguishing energy derived from intestinal digestion from that derived from colonic fermentation. As a result, the agency feels that it is inappropriate to base a regulatory definition upon digestibility.

FDA, therefore, is modifying the definition it proposed for "complex carbohydrates"(§ 101.9(c)(6)(i), redesignated as § 101.9(c)(6)(iv)) to provide that it is the difference between total carbohydrate and the sum of dietary fiber and sugars or, if sugar alcohol is declared, the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol. This modified definition accommodates quantification of the remaining carbohydrates by calculation rather than by requiring additional laboratory analysis, and it resolves concerns that the defined components of total carbohydrate were not inclusive of all carbohydrates.

In addition, because there is no consensus on a clear definition for the term "complex carbohydrate" as it relates to physiological effects, health benefits, or dietary guidelines, the

agency concurs with the recommendation from a state government that the term "other carbohydrate" be used rather than "complex carbohydrate." The agency recognizes that the new definition will include many substances added to processed foods for technical purposes, such as for texture modification or as bulking agents. To declare these substances as complex carbohydrates would be misleading. The intent of dietary recommendations to increase the consumption of complex carbohydrates and dietary fiber is to select diets with plenty of fruits, vegetables, and grain products, not foods that have complex carbohydrates as added texturizers or bulking agents. Accordingly, FDA is modifying § 101.9(c)(6)(iv) to change the terminology from "complex carbohydrate" to "other carbohydrate." In addition, FDA is modifying § 101.9(g)(4) and (g)(6) to reflect this change in terminology.

Finally, because "other carbohydrate" will be calculated as that amount of carbohydrate remaining after subtraction of the amount of dietary fiber, sugars, and sugar alcohols (when declared) from total carbohydrate, it is logical to rearrange the subcomponents of total carbohydrate to place "other carbohydrate" at the bottom of the list. This reordering should help to reduce any potential confusion over the meaning of the term "other carbohydrate." Accordingly, dietary fiber is designated as § 101.9(c)(6)(i), sugars as § 101.9(c)(6)(ii), sugar alcohol as § 101.9(c)(6)(iii), and other carbohydrates as § 101.9(c)(6)(iv).

b. *Voluntary declaration of "other carbohydrate".*

59. In the supplementary proposal, FDA requested specific comment on the utility, appropriateness, and feasibility of mandatory declaration of complex carbohydrate content, particularly as it relates to, and is supported by, public health goals (56 FR 60366 at 60369). Based on the comments and information that it received in response to the supplementary proposal, the agency said it would decide, under section 403(q)(2) of the act, whether to include complex carbohydrate in the required list of nutrients in nutrition labeling. Several comments from consumers, health professionals, a manufacturer, and state governments supported mandatory listing of complex carbohydrates on the grounds that this information will be helpful to persons attempting to follow dietary recommendations. However, a much larger number of comments from health professional associations, academia, manufacturers, trade associations, and foreign governments supported voluntary listing of complex carbohydrates. The overriding factors cited in these comments were the lack of an accepted definition for "complex carbohydrates" and the lack of reliable analytical methods for determining amounts present. Comments also stated that dietary recommendations do not specify amounts of complex carbohydrates to be consumed; therefore quantitative information in nutrition labeling is not necessary to assist consumers in maintaining healthy dietary practices. Additionally, comments noted that the IOM report (Ref. 1) recommended voluntary listing of complex carbohydrate. Comments also pointed out that currently available data bases do not contain information on complex carbohydrates, and that there would be an inherent variability in amounts present in minimally processed foods.

In light of these comments, the agency's decision to drop the term "complex carbohydrate" because of the lack of a consensus on the meaning of the term, and the lack of methods for reliably determining the amounts present, FDA has reassessed the requirement in section 403(q)(1)(D) of the act to declare complex carbohydrates. Section 403(q)(2)(B) of the act allows the Secretary to determine whether information relating to nutrients specified in section 403(q)(1)(C), (q)(1)(D), (q)(1)(E), or (q)(2)(A) of the act is necessary to assist consumers in maintaining healthy dietary practices. If not, the Secretary may delete such nutrients from the list of those required to be included in nutrition labeling. FDA concludes that, without a specific definition for "complex carbohydrates," it is not possible to include quantitative information in the nutrition label that would assist consumers in maintaining healthy dietary practices. Therefore, under the provisions of section 403(q)(2)(B) of the act, FDA is deleting the requirement for the listing "complex carbohydrate" in the nutrition label and is allowing for declaration of "other carbohydrate" on a voluntary basis.

When "other carbohydrate" is omitted from the label, the declared subcomponents of total carbohydrate (i.e., dietary fiber and sugars) will not add up to the value for total carbohydrate in most foods. Consumer education programs should inform interested persons that other forms of carbohydrate beyond those declared on the label are in the food product. This situation is analogous to the fat category where the sum of saturated, polyunsaturated, and monounsaturated fatty acids often do not add up to 100 percent of the value for total fat because *trans* fatty acids are not included in the definition of the fatty acids but are included in the value for total fat.

G. Protein

1. Quantitative Protein Content

60. Several food manufacturers agreed with the proposed provision requiring that if the protein in foods represented or purported to be for adults and children 4 or more years of age has a protein digestibility-corrected amino acid score (PDCAAS) of less than 20 percent, and if foods represented or purported for children below 4 years have a protein quality value less than 40 percent of casein, the protein content statement must be modified by an adjacent statement, "not a significant source of protein," regardless of the actual amount of protein present. However, other food manufacturers objected to this provision of the proposal. These comments argued that the statement has little value in terms of the total dietary protein intake, and that there is no evidence of protein malnutrition in this country. These comments argued that, therefore, the statement is unnecessary. One food manufacturer stated that the statement should only be required if a claim is made. Another comment stated that the declaration of the percent of the RDI for protein should be required instead of the statement.

FDA disagrees with the comments that state the statement is unnecessary. Information on protein quantity alone can be misleading on foods that are of low protein quality. As stated in the supplementary proposal, dietary protein serves as a source of essential and nonessential amino acids, the building blocks of body protein. Because excess amino acids are not stored in the body, humans need a constant supply of good quality dietary protein to support growth and development. The determination of the quality of a protein is dependent upon the proportion and availability of essential amino acids (i.e., those amino acids that the human body cannot manufacture but must obtain through the diet) as well as the quantity of protein present. Foods that contain proteins that are low in one or more of the essential amino acids are known as incomplete proteins and are lower quality proteins than those that contain all the essential amino acids in sufficient quantities to support growth and development.

The agency believes that nutrition labeling must inform consumers when the quality of the protein is below

minimum specified levels. The majority of comments supported this position. Although the agency agrees that protein deficiency is not common in the United States, protein quality is still of concern for certain segments of the population, such as the very young and the elderly. Accordingly, the agency concludes that nutrition labeling must allow consumers to readily identify foods with particularly low quality protein to prevent them from being misled by information on only the amount of protein present.

Nonetheless, in the case of foods for adults and children over 1 year of age, the agency agrees with the comment that the percent of the reference value for protein (discussed below) is a satisfactory alternative to the statement, "not a significant source of protein," to allow consumers to readily identify foods of low protein quality. However, as discussed in the final rule entitled "Food Labeling; Reference Daily Intakes and Daily Reference Values" published elsewhere in this issue of the Federal Register, the label reference value for protein for adults and children 4 or more years of age has been established as a DRV rather than an RDI. As discussed in that document, this change to a DRV is necessary because the agency is no longer basing the label reference value for protein for this group on the Recommended Dietary Allowances for protein. Rather, they are now being based on percent of calories. However, because FDA did not propose DRV's for infants, children less than 4 years of age, pregnant women, and lactating women, the protein label reference values for these groups remain as RDI's.

Accordingly, the agency is amending § 101.9(c)(8), redesignated as § 101.9(c)(7), to permit the optional declaration of percent of the DRV or RDI for protein, as appropriate, expressed as "Percent Daily Value," in lieu of the statement "not a significant source of protein" when the food is represented or purported to be for use by adults and children 4 or more years of age and the protein quality value is a PDCAAS of less than 20 expressed as a percent, or when the food is represented or purported to be for use by children under 4 years of age and the protein quality value is a PDCAAS of less than 40 expressed as a percent.

FDA is not requiring declaration of percent DRV or RDI for protein instead of the subject statement, as requested in the comment, because of cost considerations. If a manufacturer is aware that the protein in a particular food product represented or purported to be for adults and children 4 or more years of age has a PDCAAS of less than 20 percent, or that the protein in a food represented or purported for children below 4 years has a protein quality value less than 40 percent of casein, and the manufacturer does not want to go to the expense of determining the precise percent of the label reference value present in the food, the agency has no objection to the use of the statement "not a significant source of protein."

In conjunction with this change, FDA is making a parallel modification in proposed § 101.9(c)(8)(i), redesignated as § 101.9(c)(7)(i), by deleting the prohibition on the declaration of percent of the RDI for protein on foods represented or purported to be for use by adults and children 4 or more years of age with a PDCAAS of less than 20 percent, or on foods represented or purported to be for use by children under 4 years of age with a protein quality value of less than 40 percent of the reference standard. That prohibition is no longer necessary because the PDCAAS method for assessing protein quality is more exact in measuring the protein quality for humans one year of age and above than the protein efficiency ratio (PER) which was previously used for all age groups. Because the PER is being retained to measure protein quality for infant foods, FDA has retained this prohibition for declarations on foods represented or purported to be for use by infants with a protein quality value of less than 40 percent of the reference standard of casein.

61. One comment requested that the food-specific conversion factors used by AOAC, and permitted in proposed § 101.9(c)(8), to convert amounts of nitrogen to protein content should be allowed in calculating the PDCAAS whenever such factors are available. The comment stated that in some cases (e.g., peanut butter) the amino acid score used in calculating the PDCAAS is artificially reduced when a conversion factor of 6.25 must to be used to calculate protein content rather than a food-specific conversion factor.

FDA agrees that there is an inconsistency in proposed § 101.9(c)(8) pertaining to the factors for converting g of nitrogen to g of protein when calculating protein content and when calculating the PDCAAS. While the method for calculating the PDCAAS described in the Report of the Joint Federation of Agriculture Organization and the World Health Organization (FAO/WHO) Consultation (Ref. 8) specifies a conversion factor of 6.25 (i.e., g of nitrogen x 6.25 = g of protein), the agency finds it appropriate to use more specific conversion factors for those foods where the official AOAC procedures require them. Therefore, to allow for consistent methods of calculating g of protein, the agency is modifying § 101.9(c)(7)(ii) to state that food-specific conversion factors required by the AOAC are to be used when calculating the PDCAAS.

2. Protein Content as a Percentage of the RDI/DRV

62. Several comments opposed the voluntary (in the absence of a claim) declaration of protein as percent of the RDI on the labels of foods intended for adults and children 4 or more years of age. The comments contended that mandatory declaration of protein as percent RDI for all groups would provide the consumer with information on how amino acid and protein needs are met and would assist consumers in appreciating that protein is an important part of the diet.

FDA disagrees with these comments. In the preamble of the mandatory nutrition labeling proposal, FDA stated that current evidence suggests that the diet typically consumed in the United States provides for an adequate protein intake of sufficiently high biological quality to meet the nutritional needs of adults and children 4 or more years of age (55 FR 29487 at 29499). Because protein intakes generally are adequate and not a public health concern for this population group, FDA finds that the additional costs associated with determination of the PDCAAS, which are necessary to calculate the percent of the DRV for protein, are not warranted on foods for this group unless protein claims are made. Therefore, while declaration of the quantitative amount of protein will continue to be required on all foods, § 101.9(c)(7)(i) allows voluntary declaration of the percent of the DRV for protein, expressed as "Percent Daily Value," for foods intended for adults and children 4 or more years of age unless a protein claim is made for the product.

63. Two baby food manufacturers suggested that the protein content expressed as percent of the RDI for protein should be voluntary for all foods, including those for infants and children less than four years of age, unless the food is infant formula or a protein claim is made. The comments stated that data show that breast or cow milk and formula are the main contributors of protein during the first 18 months, and that other foods are not sole sources of protein for infants above 4 months. One manufacturer provided survey data on the protein intake of children 2 to 18 months of age. The comments also stated that recent

evidence shows that the protein intake of children 1 to 4 years of age is 100 percent of the RDI, that nutrition information expressed as percent of the RDI would not be helpful to the parents, and that the requirement is burdensome. Other comments supported mandatory declaration of protein content expressed as percent of the RDI for children less than 4 years of age.

FDA rejects the suggestion that protein content expressed as the percent of the RDI should be voluntary for foods specifically intended for infants and children under 4 years of age. As noted in the preamble of the mandatory nutrition labeling proposal, mandatory declaration of the percent RDI is warranted for this age group because of the importance of protein quality in diets derived from a limited number of foods (55 FR 29487 at 29499). FDA acknowledges that breast or cow milk and formula are the major sources of protein during the first 18 months. However, as seen in the data provided in the comment, foods specifically intended for infants and young children, other than infant formula, do make a significant contribution to total protein intake. For example, at 6 to 7 months of age, infants are receiving approximately one-third of the total protein intake from baby foods (Ref. 52).

The agency recognizes that required declaration of the percent of the RDI for protein for foods for infants and children less than 4 years of age presents a burden to manufacturers. However, protein nutriture is critical during this period of life which is marked by rapid growth and development. Both protein quantity and quality are major factors in the utilization of protein. Because of the importance of adequate high quality protein in the diets of infants and young children, FDA considers the declaration of percent of the RDI for protein necessary. Moreover, with the information on digestibility the agency is providing in appendix B (see comment 66 in this document), declaring the percent of the RDI for protein should not be overly costly or difficult.

64. Several comments suggested the use of a system similar to the current approach of expressing the percent of the U.S. RDA for protein. Recommendations were made for the use of a single RDI or two RDI's (i.e., an RDI for proteins of high quality and another RDI for those of low quality) to calculate the percent RDI as long as the food is not intended for infants and toddlers. Three baby food manufacturers favored establishment of specific low and high protein quality-based RDI's to calculate the percent RDI for foods intended for infants.

FDA disagrees with the use of a system similar to the current approach of expressing protein as percent U.S. RDA. The use of breakpoints, as found in the existing regulation, creates artificial differences in apparent protein nutritive values of some foods when significant differences do not exist.

3. Protein Quality

65. One comment questioned FDA's authority to change the proposed protein quality methodology. The comment contended that the 1990 amendments did not require a change in methodology, and that the proposal must be reevaluated pursuant to President Bush's directive in his State of the Union address on January 28, 1992, and set forth in his memorandum on Reducing the Burden of Government Regulations (Ref. 53).

FDA stated in the supplementary proposal that while not directed to do so by the 1990 amendments, it was proposing to modify the approach for determination of protein quality in the mandatory nutrition labeling proposal. The agency did so in response to a citizen's petition submitted by Protein Technologies International Inc. (Docket No. 90P–0052), requesting that the agency accept an amino acid method that is corrected for digestibility as an alternative method for evaluating protein quality. FDA tentatively decided that the petition had merit, and that some of the concepts in the petition should be integrated into the rulemaking since protein quality is an important part of nutrition labeling. The agency has the authority under sections 201(n) of the act (21 U.S.C. 321(n), 403 (a) and (q) of the act, and 701(a) of the act (21 U.S.C. 371(a)) to modify the original proposed protein quality methodology to reflect expanding scientific knowledge. This final rule represents the final disposition of the subject petition.

66. Several comments commended the agency for acceptance of the PDCAAS method for assessing the protein quality of foods for regulatory purposes. Comments stated that the PDCAAS method was entirely appropriate and consistent with the FAO/WHO Consultation on protein quality evaluation (Ref. 8). Other comments from food manufacturers and a trade association conditionally supported the PDCAAS method. Several comments recommended that PDCAAS not be used as the sole method for measuring protein quality of foods intended for adults and children 4 or more years of age until more technical knowledge on the amino acid reference pattern and methodology is gained, and until manufacturers gain more practical experience in its application across a broad spectrum of foods. Two comments stated that compliance problems necessitate a transition period of 2 to 5 years to ease the logistical and economic burdens. Several comments supported the method but recommended that the current PER method also be permitted.

One manufacturer recommended: (1) Manufacturers be permitted to use calculated PDCAAS values for common foods and food ingredients; (2) that FDA issue a list of estimated digestibility values and PDCAAS values for major foodstuffs and ingredients before issuing the final regulation; and (3) that FDA convene an expert group to produce a data base on digestibilities and PDCAAS values and to make provision to update such a list.

Another manufacturer requested that FDA allow any valid methodology for determining protein quality for adults and children more than 1 year of age.

FDA disagrees with the recommendations that the PDCAAS method not be used as the sole method until more technical and practical knowledge is gained on its application to a broad spectrum of foods and disagrees that a transition period is needed. FDA advises that since most food products in the market place are intended for adults and children above 4 years of age, on which the declaration of percent DRV of protein is voluntary, a delay in the implementation of the PDCAAS as the sole method is not necessary.

The agency also rejects the recommendation that the PER method continue to be permitted for foods for adults and children 1 or more years of age as an option to the PDCAAS method for the following reasons: (1) The PDCAAS is based on human amino acid requirements and, therefore, is inherently more appropriate for evaluating the protein content of foods intended for human consumption than the PER which is based on the amino acid requirements of the rat (Ref. 8), (2) the PDCAAS method is recommended for regulatory purposes by a recognized international organization experienced in establishing such standards (Ref. 8), and (3) values obtained by the two methods differ so that their simultaneous use on different foods would not allow for comparison of food products.

FDA considered the recommendation that manufacturers be permitted to calculate PDCAAS values. The two pieces of information that are needed for

this calculation are the amino acid content and the digestibility of the food. FDA has concluded that current representative amino acid data bases on raw and processed food products are not sufficiently reliable to allow for calculated PDCAAS values. Current data bases often lack information on key essential amino acids, and the information that is there was often obtained using methodology that is now outdated. In addition, food processing, i.e., the chemical, biological, or physical treatment of foods, can reduce the amino acid content of the food, so that only data from a food that underwent similar processing or treatment should be utilized in calculating the PDCAAS. In time, the agency believes it will be possible to calculate PDCAAS values using representative amino acid data backed by periodic analytical spot checks, but, at the current time, more and better data are needed.

FDA does agree, however, that a data base on digestibility values could be of assistance in implementing the PDCAAS method and in reducing the expense of implementing this new methodology by eliminating the need for a bioassay. Therefore, FDA is providing a limited data base on published true digestibility values (determined using humans and rats) of commonly used foods and food ingredients, which manufacturers may use to calculate the PDCAAS for food products. The agency has decided not to publish the digestibility values in the Code of Federal Regulation at this time because the values are interim and subject to change on a frequent basis. The data base is being published in Appendix B to this document and is also available from the Division of Nutrition, Center for Food Safety and Applied Nutrition (HFF-260), Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

Appendix B lists foods from nine major food groups. In the development of this data base, the agency examined scientific data that included reports by national and international organizations, review articles and other scientific articles. In examining the data, FDA first considered true digestibility values of protein foods obtained using adult subjects, followed by data using the rat as an animal model. The agency did not consider digestibility data obtained using *in vitro* methods or other animal species. Comparative reviews of digestibility of some protein using humans and the rat model suggest that the true digestibility of a variety of foods is similar in humans and rats.

There are gaps in knowledge of the digestibility of protein in common food sources. Therefore, the data in Appendix B of this document are tentative. FDA believes that with the implementation of this regulation, better data will be forthcoming, and that, in due course, it will be able to revise the data base. The agency encourages industry to submit additional data to enable FDA to expand the assortment of foods included in the data base and to update current data.

FDA concludes that it would be premature to convene an expert group to develop a data base on digestibilities and PDCAAS values. There is a need to allow time for the compilation of reliable data based on digestibility and amino acid analyses obtained by the methods specified in this regulation. FDA will reconsider the idea of convening of an expert group on protein quality as such data become available.

The agency advises that manufacturers are not precluded from using other analytical methods for their own quality control purposes as long as they assure themselves that such unofficial methods compare adequately with the official methods. For compliance purposes the methods specified in the regulation will be used by FDA.

67. Several comments recommended that the proposed new method (PDCAAS) for the evaluation of protein quality be eliminated from the regulation. Some comments stated that the PDCAAS method will not provide flexibility and will be unnecessarily burdensome and expensive, because it requires that digestibility and amino acid analysis be performed on every product for which a declaration of the percent of the RDI for protein is made. One comment stated that foods are often reformulated, creating an ongoing cost. Several comments expressed concern that, because of the costs, the PDCAAS could have unintended negative effects on the competitive position of smaller companies and on the willingness of manufacturers to provide complete nutrition information to the consumer.

A few comments argued that for some foods, the PDCAAS will result in lower values being declared for the percent of the RDI than current methodologies using the PER, and that this will effect the ability of the foods to make claims about protein content. Another manufacturer opposed the change to new methodology and commented that the PDCAAS methodology should be reviewed and scrutinized by the AOAC before application.

FDA does not agree that the PDCAAS should be eliminated. FDA wishes to clarify that declaration of the percent DRV for protein (which uses the PDCAAS method) is voluntary for foods intended for adults and children 4 or more years of age unless a protein claim is made for the product. Therefore, for this age group, the burden and expense of the PDCAAS method are voluntarily assumed by the manufacturer.

FDA acknowledged in the preceding comment that values obtained for percent of label reference value differ when calculated using the PDCAAS rather than the PER. However, the PDCAAS, based on human requirements, is inherently more appropriate for assessing protein quality of foods intended for human consumption than the PER which is based on the amino acid requirements of the rat (Ref. 8). Accordingly, label claims based on these values will more accurately describe the role of the protein product in meeting human nutrition requirements.

FDA advises that the analytical methodologies for amino acid analyses involved in the calculation of the PDCAAS method have undergone collaborative studies and have been published in the Journal of the Association of Official Analytical Chemists.

68. One comment expressed uncertainty about the proposed amino acid scoring pattern used in calculating the PDCAAS and stated that the WHO/FAO recommended further research to confirm the currently accepted values of preschool children.

FDA acknowledges that the WHO/FAO Consultation (Ref. 8) recommended further research on the proposed scoring pattern to confirm and reinforce the existing information. The Consultation concluded, however, that the proposed scoring pattern is robust and represents the best available estimate of indispensable amino acids for this age group. Because of the high protein requirements of the preschool age group for adequate growth and development, protein foods and diets with an amino acid pattern that effectively meets the needs of the preschool child will adequately meet the needs of older children and adults whereas the reverse may not be true (Ref. 10). Therefore, FDA concludes that the proposed amino acid scoring pattern for preschool age children is at present the most suitable pattern for use in the evaluation of dietary protein quality for all age groups, except infants.

69. Comments agreed that the amino acid pattern for 1 to 4 year old children should be the same as the amino acid reference pattern for 2 to 5 year old children when calculating the PDCAAS. According to the data presented in the comments: (1) There is little difference

in the portion of protein and amino acids needed for maintenance and growth between the two age groups; (2) there is no sound nutrition rationale for using 70 percent of casein as the reference standard for 1 to 3 year old children as recommended by the Codex Committee on Nutrition and Foods for Special Dietary Uses (Ref. 10a); and (3) there is no evidence that the pattern of intake of amino acids for 1 to 3 year old children differs from, or that the pattern is inadequate compared to, the pattern for 2 to 5 year old children. The comments also confirmed that there is sufficient overlap between the age groups to render one standard adequate.

In the preamble to the supplementary proposal, FDA specifically requested comments on the inconsistency between the FAO/WHO and the Codex Committee on Nutrition and Foods for Special Dietary Uses standards for the protein quality of foods intended for children 1 to 3 years old. The data presented in the comments (Refs. 54 and 55) supported the agency's tentative conclusion to use the amino acid scoring pattern for preschool 2 to 5 year old children for determining the PDCAAS of foods intended for children over 1 year of age. Therefore, the agency is maintaining the requirement in § 101.9(c)(7) that the PDCAAS be used to measure protein quality in foods for children above 1 year of age.

However, the agency inappropriately left a parenthetical notation in proposed § 101.9(c)(8) that indicated that casein was to be used as the reference standard for determining the PDCAAS for children greater than 1 but less than 4 years of age. Because by definition the PDCAAS uses an amino acid scoring pattern based on human requirements as the standard, the agency has modified proposed § 101.9(c)(8), redesignated as § 101.9(c)(7), to remove the reference to casein for that age group.

70. Two comments disagreed with retaining the PER method and the casein standard for assessing protein quality for infants. The comments asserted that the requirement was not consistent with the FAO/WHO Consultation recommendation for the use of the amino acid pattern of breast milk for this age group.

FDA acknowledges that the FAO/WHO Consultation (Ref. 8) recommended that the amino acid composition of human breast milk should be the basis of the scoring pattern to evaluate protein quality in foods for infants under the age of one. However, in the same document, the Consultation stated that further data on the amino acid profile of human breast milk using standardized methods of analysis are required to confirm the pattern for calculating the chemical score of infant formulas (Ref. 8).

Because of the uncertainties expressed in the FAO/WHO report (Ref. 8) and the inconsistencies in reported amino acid patterns of human breast milk (Ref. 56), the agency finds that it is premature to use the FAO/WHO reference pattern for infants, especially since this population group relies on relatively few foods for nutrients. Until further data become available, the safer course is to continue to use the current PER method using casein as a standard. When more data become available, FDA would be willing to reconsider this position in response to a petition.

71. A few comments stated that the use of the PDCAAS will understate the biological quality of vegetable proteins consumed in a mixed diet. Another comment requested that FDA provide manufacturers with ways to communicate the complementary nature of different proteins from different sources.

FDA agrees that use of the PDCAAS does not indicate the value of individual proteins consumed as part of a mixed diet. However, this is true with any method used to measure quality of proteins in individual foods. The calculation of the corrected amount of protein of a food does not take into account the complementary potential of the food in a mixed diet, i.e., how a food rich in a particular essential amino acid can "complement" a food low in that amino acid to result in a total diet that provides sufficient amounts of the amino acid. What the method does is allow for a greater awareness of the value of protein sources when consumed alone.

While FDA acknowledges that more consumer education would be helpful on the complementary effects of individual foods in mixed diets, providing such information is beyond the scope of nutrition labeling. Space limitations within the nutrition label generally prevent the addition of information to communicate the complementary nature of different proteins. However, FDA advises that the regulation does provide in § 101.9(e) for the voluntary inclusion of a second column to declare the nutrient content of common combinations of foods (e.g., milk and cereal, peanut butter and bread). It would be possible to declare in this column the percent of the DRV or RDI for protein, as appropriate, for the combination of foods. Also, the manufacturer may include nonmisleading statements about the complementary nature of protein sources in materials outside the nutrition label.

72. Several comments expressed concern over the amino acid analytical methodology and urged that high performance liquid chromatography (HPLC) technology be incorporated into the methodology, and that hydrolysis time be tailored for specific foods. One comment suggested that FDA appraise the use of plasma aminograms as indicators of protein quality.

FDA agrees that the HPLC technology should be incorporated into the suitable methodology for amino acid analyses. In the preamble of the supplementary proposal, the agency stated that the analytical methodology for PDCAAS is described in the Report of the Joint FAO/WHO Consultation, section 5.4.1 (Ref. 8). The analytical methodology includes HPLC and provides flexibility in the hydrolysis of specific foods.

The agency has evaluated the merits of using plasma aminograms for protein quality evaluation. FDA believes that the method is not appropriate for this purpose. Current methodologies using plasma amino acids for predicting the protein quality of foods are highly variable, nonstandardized, and expensive. Consequently, it is not practical on a routine basis to conduct tests using plasma amino acid changes in humans as a basis for estimating protein quality.

73. One comment requested information on how to implement the PDCAAS method and on whether commercial testing laboratories have the necessary capabilities to determine the PDCAAS value.

FDA advises that the methods for determining a food product's PDCAAS is found in "Protein Quality Evaluation, Report of a Joint FAO/WHO Expert Consultation" which is being incorporated by reference into the final rule. As stated in § 101.9(c)(7)(ii), this report is available from the Division of Nutrition, Center for Food Safety and Applied Nutrition (HFF-260), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or is available for inspection at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC. To assist persons in using this report, FDA has modified § 101.9(c)(7)(ii) to add the specific sections of the FAO/WHO report in which the methodology is found. These sections are 5.4.1, 7.2.1, and 8.00.

For those foods for which the digestibility factors are known and found in FDA's interim data base, commercial testing laboratories will be able to calculate the PDCAAS after running an amino acid analysis as

described in the FAO/WHO report, section 8.00 (Ref. 8). The equipment necessary for amino acid analyses is commonly used by commercial laboratories and should be widely available.

For those foods for which the digestibility factor is not known, digestibility values must be determined in laboratories according to methods in the FAO/WHO Report, sections 7.2.1 and 8.00 (Ref. 8).

74. A comment noted that the agency had not specified increments for reporting the "Percent Daily Value" for protein as had been done in proposed § 101.9(c)(11)(iii) for reporting the "Percent Daily Value" for vitamins and minerals.

FDA acknowledges the oversight and is modifying § 101.9(c)(7)(i) by specifying that the "Percent Daily Value" for protein is to be declared to the nearest whole percent as it is for fat and carbohydrate in § 101.9(d)(7)(ii).

4. Conclusion

In all other respects, § 101.9(c)(8), redesignated as § 101.9(c)(7), remains unchanged except that § 101.9(c)(7)(iii) has been reserved in this document. That paragraph is included in the companion document entitled "Food Labeling; Reference Daily Intakes and Daily Reference Values" published elsewhere in this issue of the **Federal Register** in which the DRV for protein for adults and children over 4 years of age and the RDI for protein for infants, children less than 4 years of age, pregnant women, and lactating women are established.

H. Vitamins and Minerals

75. Retaining the requirement for mandatory listing of vitamin A, vitamin C, calcium, and iron on the food label was supported by a large number of comments representing a broad spectrum of consumers and consumer organizations, public health organizations, health care professionals, industry representatives, and trade associations. These comments agreed with the rationale stated in the proposal for continuing the mandatory declaration of these nutrients in nutrition labeling.

There were, however, some comments that did not support the mandatory listing of these nutrients. Some comments suggested that vitamin A and vitamin C should not be mandatory but should be allowed on the food label on a voluntary basis. One comment questioned whether inadequate intake of these vitamins is a public health issue, noting that some milk is fortified with vitamin A and stating the belief that consumers are aware that citrus fruits are sources of vitamin C. One comment noted that the IOM report (Ref. 1) recommends that vitamin A and vitamin C should be allowed on the food label rather than required. Additionally, a few comments recommended voluntary rather than mandatory declaration of calcium and iron.

In view of the strong support for the mandatory listing of vitamin A, vitamin C, calcium, and iron on the food label, and in the absence of strong opposition to the agency's proposal to require the listing of these nutrients on the label, FDA is not persuaded that voluntary listing of these nutrients is desirable and in the interest of the public health. While the IOM report does suggest that vitamin A and vitamin C could be allowed, rather than required, on the food label, it identifies vitamin A and vitamin C as potential public health issues and states that certain subpopulations are still at risk for deficiencies of these vitamins (Ref. 1). The report states that inadequate dietary intake of vitamin A is found in children under 5 years of age, and that two segments of the population are at risk for vitamin C deficiency (infants fed cow's milk exclusively and elderly individuals on inadequate diets).

FDA continues to believe that public health concerns exist for vitamin A in these at-risk groups and for the general public. While fortification of certain foods, such as low fat and skim milk, has helped to improve intakes of this vitamin among healthy persons consuming a balanced diet, the inclusion of adequate vitamin A in the diet still requires care and effort on the part of a consumer in selecting good food sources of this vitamin. Vitamin A is found in a relatively limited number of foods within the food supply, and these foods must be selectively chosen by consumers on a regular basis to ensure adequate intake.

FDA also continues to believe, as supported by numerous comments, that vitamin C is a nutrient with public health significance, in that, even with fortification efforts and greater year-round availability of citrus fruits and dark green vegetables, certain subpopulations are considered at risk (see 55 FR 29487 at 29501).

In the case of calcium and iron, these minerals are identified as public health issues in the IOM report (Ref. 1) and by numerous other sources, including the Surgeon General's report (Ref. 2), Diet and Health (Ref. 3), and the report on "Nutrition Monitoring in the United States" (Ref. 49).

Therefore, § 101.9(c)(11)(ii), redesignated as § 101.9(c)(8)(ii), requires vitamin A, vitamin C, calcium, and iron as mandatory elements of nutrition labeling.

76. Many comments were received from persons at risk of iron overload, particularly hemochromatotics, supporting mandatory labeling of iron and requesting that the food label declare both added and naturally occurring iron.

FDA has carefully considered these comments. The agency recognizes that a segment of the population is at risk of iron overload. In deciding whether the declaration of a nutrient or component on the food label should be mandatory, however, the agency must consider the broad public health significance of its action. Inadequate intakes of dietary iron are responsible for the most prevalent form of iron deficiency in the United States. Iron deficiency remains a risk for certain segments of the U.S. population, notably young children, adolescents, women of childbearing age, and pregnant women, especially those with low incomes (Refs. 2, 3, 23, and 49). Thus, public health concerns relative to iron, as stated in the National Nutrition Goals for the Year 2000 (Ref. 47), center on the prevention of iron deficiency and support increased dietary intake of iron among children 1 to 2 years of age, women 20 to 44 years of age, and low-income pregnant women. The agency believes that the listing of iron on the food label aids the consumer in making individual food selections in structuring the total diet, and that this total diet has significant effects on health.

However, as discussed in comment 54 of this document concerning added sugars, the agency has taken the position that it should not attempt to regulate actions that it cannot enforce. Because available laboratory analytical methods do not differentiate between added and naturally occurring iron, the agency would not be able to determine compliance with declared amounts of added iron.

Therefore, the agency is denying the request that manufacturers declare on their labels separate quantitative amounts of added and naturally occurring iron.

For the segment of the U.S. population at risk of iron overload, the agency notes that the food label will provide quantitative declaration of iron and vitamin C content of a food, as well as a listing of ingredients (including iron compounds if iron is added to the food). As absorption of nonheme iron may be enhanced by consumption of vitamin C containing foods, those at risk

of iron overload can decrease their simultaneous consumption of foods containing iron and vitamin C by using the information on the iron and vitamin C content of foods found on the food label.

77. The majority of comments that the agency received from consumers, health care professionals, public health agencies, universities, industry, and trade associations agreed with FDA's proposal to allow thiamin, riboflavin, and niacin to be listed voluntarily unless a claim is made, or unless these nutrients are added to a food. Most comments based their position on the decline of public health concern for deficiencies of these vitamins over the past 20 years.

On the other hand, there were some comments that advocated continued mandatory listing of these vitamins on the food label. Several comments expressed the opinion that mandatory inclusion of thiamin, riboflavin, and niacin within nutrition labeling contributed to the reduction of the incidence of deficiencies of these vitamins in the United States. One comment stated that these vitamins continue to be important to a significant portion of the U.S. population, that listing these vitamins on the label provides information on the nutritional properties of a food, and that the 1990 amendments direct FDA to mandate declaration of any vitamin that the agency deems to be important for the maintenance of healthy dietary practices.

FDA does not agree that the listing of thiamin, riboflavin, and niacin on the food label has been the major cause of the declining incidence of deficiencies of these vitamins. Rather, the agency believes that the variety and abundance of the food supply and the enrichment of many standardized foods with these vitamins are the primary factors responsible for reducing the occurrence of deficiencies of these vitamins (Ref. 57).

FDA acknowledges that these vitamins continue to be important nutrients, and that listing these vitamins on the label provides information on the nutritional properties of a food. However, the agency notes that while the 1990 amendments direct the agency to include in the nutrition label information that will assist consumers in maintaining healthy dietary practices, not all information related to maintaining healthy dietary practices can be included on the food label. If all such information were included, all essential nutrients would be declared on the nutrition label. Not only would space constraints not allow for this, but the large amount of information would interfere with consumers' abilities to use the information of the greatest public health significance (see discussion in response to comment 3 of this document). Such a result would be contrary to the intent of Congress (Ref. 16).

For this reason, FDA developed criteria in its mandatory nutrition labeling proposal to assist it in determining which nutrients to require in nutrition labeling (55 FR 29487 at 29493). These criteria specify that nutrients should be required when quantitative intake recommendations have been made in scientific consensus documents, and when the nutrient is of particular public health significance. Based on the preponderance of comments that agreed with FDA's assessment that thiamin, riboflavin, and niacin are no longer of particular public health significance, FDA has decided to provide in § 101.9(c)(11)(ii), redesignated as § 101.9(c)(8)(ii), for the voluntary declaration of thiamin, riboflavin, and niacin.

78. Several comments requested that FDA clarify whether thiamin, riboflavin, and niacin are required to be listed on the nutrition label of a product made with enriched flour, a standardized food, if no claim is made about these enrichment nutrients other than their listing in the ingredient statement as part of enriched flour. Similarly, another comment suggested that FDA explicitly state, as in current § 101.9(h)(7), that labeling of voluntary nutrients will not become mandatory if present in a food product as part of an enriched ingredient that has a standard of identity. The comment also requested that nutrients added strictly for a technological effect not be required to be declared in nutrition labeling, in a similar fashion to current § 101.9(h)(6).

Proposed § 101.9(c)(11)(ii) stated that vitamins and minerals (other than vitamin A, vitamin C, calcium, and iron which must be declared) need only be declared in the nutrition label when they are added as a nutrient supplement, or when a claim is made about them. FDA's intent in this section, which is redesignated as § 101.9(c)(8)(ii), was that when a food product is made with enriched flour as an ingredient, but the label does not make an "enriched" claim or use "enriched" in the name of the food, the nutrition label need not declare the enrichment nutrients. If, however, the product is made with unenriched flour and supplemented with nutrients as ingredients to achieve the equivalent of a product made with enriched flour, the product's label must list the enrichment nutrients in the nutrition label. Information on the amount of the enrichment nutrients is also required if an "enriched" claim is made on the label; or if "enriched" is used in the name of the food. Section 101.9(c)(8)(ii) is modified to clarify this requirement.

FDA agrees with the comment that nutrients that are not required to be declared in the nutrition label and are added to a food strictly for a technological effect need not be declared if the nutrient is declared solely in the ingredient statement and is otherwise not referred to on the label or in labeling or advertising. This provision, similar to current § 101.9(h)(6), is added to § 101.9(c)(8)(ii).

79. Several comments stated that listing of other vitamins and minerals should be required, even without a claim, such as vitamin D, magnesium, and phosphorus. One comment supported the listing of all vitamins (even those absent from the food or food product).

FDA notes from these comments consumer interest in a variety of nutrients but points out that not all nutrient information related to maintaining healthy dietary practices can be included on the food label. As discussed in comment 3 of this document, the agency must be selective with regard to the information that it requires to be listed on the label. Thus, it emphasizes nutrients or components of particular public health significance. FDA does not believe that all vitamins and minerals are of equal public health significance, a view that is supported by the IOM and Nutrition Monitoring reports (Refs. 1 and 49). The agency is also aware that space limitations on the food label require that it use discretion in deciding which nutrients it requires to be listed there.

FDA does not agree that vitamin D, magnesium, or phosphorus are of particular public health significance in the United States. Because the human requirement for vitamin D can be met with sufficient exposure to sunlight, and because milk and other foods are fortified with vitamin D, deficiencies in this vitamin are very rare (Ref. 23). Magnesium and phosphorus are cited in both the Nutrition Monitoring and IOM reports as food components that are not currently public health issues (Refs. 1 and 49). FDA, therefore, is not requiring mandatory listing of vitamin D, magnesium, or phosphorus in the nutrition label.

80. Some comments suggested not requiring any vitamins or minerals on the food label unless claims are made, or the nutrient is added to the food, in

order to minimize the space requirements of nutrition labeling.

As discussed in the supplementary proposal (56 FR 60366 at 60368), FDA interprets section 403(q)(1)(E) of the act to require the inclusion of vitamins and minerals currently required in § 101.9(c)(7)(iii) if the Secretary (or FDA, by delegation) determines that such information will assist consumers in maintaining healthy dietary practices. For the reasons discussed above, FDA, has determined that vitamin A, vitamin C, calcium, and iron meet the criterion in section 403(q)(1)(E) of the act and, therefore, must continue to be required elements of nutrition labels. The 1990 amendments did not provide for nutrients to be omitted to save space. Therefore, § 101.9(c)(8)(ii) continues to require declaration of vitamin A, vitamin C, calcium, and iron.

81. One comment requested that the final regulations allow for the voluntary identification of foods that are important sources of beta-carotene, either as a subset of vitamin A or through an independent designation. The comment stated that beta-carotene may reduce the risk of chronic diseases and appears to have its own independent biological functions in addition to serving as a source of vitamin A. The comment also noted that "Recommended Dietary Allowances" (10th ed.) states that "For food products containing large quantities of carotenoids, it would be advisable in nutrition labeling to distinguish between retinol, which in large amounts is toxic, and carotenoids, which are not" (Ref. 23).

The agency has carefully reviewed the relationship of beta-carotene to cancer in the companion document entitled "Food Labeling; Health Claims and Label Statements; Antioxidant Vitamins and Cancer," published elsewhere in this issue of the **Federal Register**. Based on that review and the stated recommendations in "Recommended Dietary Allowances," FDA has concluded that there should be a method within nutrition labeling to voluntarily distinguish the amount of beta-carotene present in food products. Accordingly, FDA is adding § 101.9(c)(8)(vi), which states that the percent of vitamin A that is present as beta-carotene may be declared to the nearest 10-percent increment immediately adjacent to or beneath the nutrient name (e.g., "Vitamin A (90 percent as beta-carotene)," see example in appendix C).

82. A few comments objected to FDA's proposed deletion of the synonyms vitamin B1 and B2 for thiamin and riboflavin, respectively. The comments argued that many consumers continue to use these terms and understand them better than the "scary-sounding chemical" names. Similar comments were received in response to proposed § 101.36 *Nutrition labeling of dietary supplements of vitamins and minerals.*

Based on the comments, the agency has reassessed its position on this issue. FDA believes that for consistency the chemical name of the nutrient (i.e., thiamin and riboflavin) must always be given when the nutrient is declared in nutrition labeling, or when claims are made (e.g., "high in thiamin"). However, the agency will not object to the voluntary parenthetical listing of "vitamin B1" or "B1" following "thiamin" and "vitamin B2" or "B2" following "riboflavin." Accordingly, FDA has modified § 101.9(c)(11)(v), redesignated as § 101.9(c)(8)(v), by adding vitamin B1 and vitamin B2 as synonyms for thiamin and riboflavin, respectively. While FDA believes a similar change is appropriate in proposed § 101.36, given the requirements of the DS Act, FDA is taking no action with respect to dietary supplements, and thus is not acting on proposed § 101.36, at this time.

83. One comment suggested that other synonyms be allowed, namely "pyridoxine" as a synonym for vitamin B6 and beta-carotene for vitamin A when the vitamin A is solely beta-carotene.

FDA rejects this comment. Pyridoxine is only one of three different forms of vitamin B6 (Ref. 23). In addition, the agency believes that it would be a more difficult term for consumers to use and understand. In regard to vitamin A, FDA believes new § 101.9(c)(8)(vi) (see comment 81 of this document) is a preferable course because in most foods, beta-carotene is only a fraction of the total vitamin A content.

84. FDA received a few comments that addressed increments for those nutrients that are expressed as a percent of a reference standard. One comment proposed a more complex incremental scheme than that in the proposed rules, suggesting 1-percent increments up to and including the 5-percent level, 2-percent increments from 6 percent up to and including the 12-percent level, 5-percent increments from 15 percent up to and including 50 percent, and 10-percent increments above the 50 percent level. Another comment suggested increments of 5 percent up to the 50-percent level and 10-percent increments thereafter. This comment suggested that FDA not permit the use of 2-percent increments because the necessary measurements are not accurate enough to allow for such small increments.

FDA proposed to maintain the current increments for vitamins and minerals, i.e., percentages are expressed in 2-percent increments up to and including the 10-percent level, 5-percent increments above 10 percent and up to and including the 50-percent level, and 10-percent increments above the 50-percent level. FDA considered both the comment suggesting a more complex incremental system and the comment suggesting omission of the 2-percent increments. Neither suggestion provided sufficient justification for the change. One appears to believe that an accuracy of 1 percent of the RDI is necessary, the other that an accuracy at 5 percent of the RDI is sufficient. Inasmuch as the agency has experienced no problems with the increments that have been in use since the early 1970's, and given that so few comments addressed this issue, the agency sees no need to modify the incremental scheme in proposed § 101.9(c)(11)(iii), redesignated as § 101.9(c)(8)(iii).

85. One comment noted that regulations specified that all nutrients except vitamins and minerals were to be expressed to the "nearest" unit or increment (e.g., total carbohydrates are to be expressed to the nearest g, and sodium to the nearest 5-mg increment between 5 and 140 mg of sodium and to the nearest 10-mg increment above 140 mg of sodium). The comment asked for direction on reporting amounts of vitamins and minerals.

To clarify the regulations and promote consistency, FDA is modifying § 101.9(c)(8)(iii) to specify that vitamins and minerals are to be expressed to the nearest 2-percent increment up to and including the 10-percent level, the nearest 5-percent increment above 10 percent and up to and including the 50-percent level, and the nearest 10-percent increment above the 50-percent level.

86. A comment objected to the provision in proposed § 101.9(c)(11)(iii) that allows vitamins and minerals that are not present to be represented by an asterisk that refers to a statement "Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients)." The comment stated that consumers might be misled into thinking that small amounts of the vitamin or mineral are present when they are not.

FDA considered this comment and has concluded that the flexibility the use of the asterisk provides in allowing manufacturers to reduce the space needed for nutrition labeling outweighs any slight misunderstanding about the amount of a vitamin or mineral present

in a food that might result. Amounts of either zero or less than 2 percent of the RDI (declared as Percent Daily Value) for these nutrients are physiologically insignificant.

The RDI's are provided in § 101.9(c)(8)(iv) which has been reserved in this document. That paragraph is included in the companion document entitled "Food Labeling; Reference Daily Intakes and Daily Reference Values" (hereinafter referred to as the RDI/DRV final rule) published elsewhere in this issue of the **Federal Register**. In accordance with section 203 of the DS Act that prohibits FDA from promulgating regulations based upon recommended daily allowances of vitamins and minerals other than the U.S. RDA's currently specified in § 101.9(c)(7)(iv) until November 8, 1993, § 101.9(c)(8)(iv) includes values for only one age group (i.e., adults and children 4 or more years of age) rather than the 5 proposed groups (i.e., adults and children 4 or more years of age, children less than 4 years of age, infants, pregnant women, and lactating women). FDA intends to adopt in accordance with section 203 of the DS Act, appropriate RDI's for all groups. Therefore, FDA has adopted the references to such groups in §§ 101.9 (a)(4), (c)(8)(i), (e), and (1) of this final rule, even though such values do not exist at this time. In the meantime, suggested RDI values for other age groups, which, to be consistent with the DS Act, are based on the 1968 RDA's are presented as guidance in the preamble of the RDI/DRV final rule.

IV. Analytical Procedures

A. General Issues

87. Several comments asserted that FDA should explicitly state the methods to be used for the analysis of various nutrients. Some comments expressed the opinion that the agency should not mandate listing of any nutrient when there are serious issues with the reliability of the analytical method. Dietary fiber was specifically cited as one example. One comment added that FDA must specify the method of analysis for analytes not available in the AOAC.

The agency acknowledges the concern expressed in the comments. In the mandatory nutrition labeling proposal (55 FR 29487 at 29498), FDA discussed the analytical methodologies for sugars and dietary fiber. The agency noted that in the 17 years since the promulgation of § 101.9, it had acquired substantial experience under the regulation, and techniques for analyzing foods for their nutrient content have greatly improved. The agency considers it is inadvisable to explicitly state a method for a particular nutrient. The applicability of a specific method to products of different matrices varies. As noted in several comments, values for some nutrients, such as fat, are dependent upon the procedure used. If a specific method is cited, it may give the erroneous impression that other methods that are more appropriate to the matrix or that utilize newer techniques could not, or would not, be acceptable. It is FDA's policy and practice that any method used to support a nutrient declaration value requires appropriate validation if it has not been collaborated for that nutrient in a specific matrix. Validation procedures are a necessary component of sound analytical technique and are frequently used even with official, collaborated methods.

The agency agrees that no nutrient should be a required component in nutrition labeling if there is no satisfactory analytical method for determining its level in a food. In fact, this view was a major factor in the agency's decision not to require declaration of complex carbohydrates. FDA believes that there is adequate methodology to assay for the nutrients that it has made mandatory elements of the nutrition label, even, as explained below, for dietary fiber.

Analysis is not needed for nutrients, however, where reliable databases or scientific knowledge establish that a nutrient is not present in the product. For example, there is no need to analyze for cholesterol in fruits and vegetables or for dietary fiber in seafood. Costs associated with nutrition labeling will be contained by not analyzing for a nutrient where there is no reasonable expectation that the nutrient occurs in the food.

88. Some comments noted that analytical variability—which ranges from 1 percent to as high as 20 percent according to one comment—may be a function of the method selected and its inherent variability, the laboratory performing the analysis, the level of nutrient in the food, and the ability to obtain a homogeneous sample composite. A few comments specifically cited the difficulty in measuring levels of complex carbohydrates or vitamin C in potatoes. These comments observed that the nutrient levels may differ between the time of harvesting and processing, as well as after a period of storage. One comment recommended that FDA allow flexibility in selecting analytical methodology such that there would be a broadened range of methods used to generate nutritional information.

FDA advises that manufacturers are free to use methods of their choice for ascertaining the quantity to declare on the label as well as for screening purposes as part of their quality control procedures. However, when questions arise as to the validity of the data, the agency will utilize the methods of the AOAC or other validated procedures.

Given the analytical problems in determining values for complex carbohydrates, the agency has deleted the requirement for declaring complex carbohydrates and is eliminating the term "complex carbohydrate" from the nutrition label. As discussed above, it is using instead the term "other carbohydrate." The term "other carbohydrate" is defined as the difference between total carbohydrates and the sum of dietary fiber, sugars, and sugar alcohols (when declared). Because a specific method of analysis is no longer required for complex carbohydrates, the concern about measuring this food component in potatoes has been addressed. In regard to the concern about the analysis for vitamin C in potatoes, FDA advises that in this situation vitamin C is a naturally occurring, or Class II, nutrient. Thus, the declaration is in compliance if the nutrient is present at a level of 80 percent or more of the declared label value. It should be noted that current regulations and § 101.9(g)(6) permit reasonable excesses within current good manufacturing practice for both vitamin C and other carbohydrate.

As more nutritional analyses are performed in support of label values, more methodologies will be validated. As a result, the number of methods that manufacturers may use in determining the amount of a nutrient will increase. Moreover, products that heretofore had not been labeled with nutrition information will now be subjected to testing. These new matrices will create new challenges for both the food industry and the agency. However, these challenges should not impede the development of full, accurate nutrition information on food labels. The agency is committed to working with industry to provide valid nutrition label information that will promote selection of healthier diets by U.S. consumers.

89. Some comments suggested that FDA work with trade associations and industry on the analytical techniques required to prepare nutrition labels. One comment recommended that designations be made as to which food matrices are appropriate for existing methods and which ones are not.

FDA agrees it should be actively involved in the review of suitable methods to be used in the

implementation of mandatory nutrition labeling. The AOAC Task Force on Nutrient Labeling Methods was established early in 1992 by AOAC for the purpose of assisting its membership in meeting the requirements of the agency's regulations. The agency worked closely with the Task Force, participating in meetings as well as in evaluating appropriate methods for various matrices. The Nutrient Labeling Task Force Report on Analytes for Nutritional Labeling is available from the agency or AOAC. The report lists the methods that are adequate for various nutrients and various matrices. As pointed out in the official AOAC publication, The Referee (Ref. 58), not all analyte/matrix combinations in the report have been fully collaboratively studied, however.

In this context, it should also be noted that § 101.9(g)(2) of these final rules allows for the use of other reliable and appropriate analytical procedures if no AOAC method is available or appropriate. Sources of such methods include FDA's "Lipid Manual" (Ref. 59) and FDA's Food Additive Analytical Manual, vol. I and vol. II (Ref. 60). Additional methods may be found in "Approved Methods of the American Association of Cereal Chemists" and "Official Methods and Recommended Practices of the American Oil Chemists Society."

The method of analysis used must be suitable to achieve the purpose for which it is used. For example, the method used to quantify vitamin C for nutrition labeling must be able to determine whether ascorbic acid or isoascorbic acid is present in the food. Isoascorbic acid and sometimes ascorbic acid are used as antioxidants in food processing. Only ascorbic acid, however, is an active form of vitamin C and considered in the determination of vitamin C content of the food. Thus, the method must be able to distinguish ascorbic acid from isoascorbic acid.

90. FDA received several comments regarding the use of the Official Methods of Analysis of the AOAC. One comment stated that the latest edition of this reference should be cited to avoid obsolescence when new editions are issued.

FDA does not have authority to not reference a particular edition of the Official Methods. The Office of the Federal Register requires that each statement of incorporation by reference into the Code of Federal Regulations contain specific information, including the date and edition of the publication. Accordingly, FDA has not modified § 101.9(g)(2).

91. A comment supported a policy whereby FDA would verify laboratory analysis results on file at a firm to substantiate the nutrition label information in lieu of doing nutrient analysis from a limited sample of products. The comment expressed the opinion that FDA should be required to perform additional sampling and testing and to consider the statistical variation inherent in test procedures before initiating a legal action, such as a seizure.

The agency disagrees with the comment. FDA is a law enforcement agency, and its mission is consumer protection. To support a misbranding charge for inaccurate nutrient content information, FDA must have accurate, reliable, and objective data to present in a court of law. To obtain that information, FDA relies upon the work performed by its trained employees because it does not have legal authority in most instances to inspect a food manufacturing firm's records.

The practice of performing nutrient analysis from a composite of 12 subsamples is well established. Compositing the contents of the twelve containers yields a numerical result essentially equivalent to what would be obtained if each container were analyzed, and the results averaged. Thus, the composite value is considered to be the same as the average of a sample of twelve containers. As noted in § 101.9(g)(4) and (g)(5), FDA will not take regulatory action based on a determination of a nutrient value that fails to meet appropriate levels by a factor inherent in the variability generally recognized for the analytical method used on that food at the level involved.

B. Calories

92. Comments stated that the regulations should clarify how calories are to be calculated. Several comments recommended adding "caloric content may be determined by the Atwater method" to proposed § 101.9(c)(3). Some comments objected to the use of the specific Atwater food factors published in "USDA Handbook 74" which have not been updated since 1955. Another comment noted that if a food item is a commodity-type product for which a specific Atwater factor is available, the caloric content for these products should be required to be calculated using the specific Atwater factors.

Several comments disagreed with the proposal to subtract dietary fiber from the amount of carbohydrate before applying the general factor of 4 (i.e., 4 calories per g of carbohydrate). These comments contended that the general factor is intended to apply to total carbohydrate including fiber. Because the gastrointestinal effects of dietary fiber were taken into account in the derivation of the general factors, these comments did not consider it to be legitimate to exclude fiber from carbohydrate content when calculating caloric content.

One comment suggested that calories be calculated from carbohydrate-plus-dietary fiber if the general factor of 4 calories per g of carbohydrate is used. Alternatively, the comment suggested that calories be calculated from available carbohydrate if the general factor of 3.75 calories per g of carbohydrate is used. The factor of 3.75 calories per g for carbohydrate is used by the United Kingdom for calculation of available carbohydrate energy (Ref. 61).

One comment suggested that both total dietary fiber and other nondigestible carbohydrate should be subtracted from the total carbohydrate content before calculating calories contributed by carbohydrates. As noted in the comments, many new food ingredients such as reduced-calorie fats, fat substitutes, and modified carbohydrates have been developed in recent years. Some of these ingredients have caloric values substantially less than the general factors of 4, 4, and 9 for protein, carbohydrate, and fat, respectively. Comments requested specific allowances for ingredients used as reduced calorie replacements for conventional ingredients to permit methods for calculating the available calories other than use of the general factors.

The agency recognizes that confusion may exist about methods for calculating caloric content because of the proposed changes in how total carbohydrate content has been defined in § 101.9(c)(6) and because of the changes in the treatment of dietary fiber. Therefore, the agency is modifying § 101.9(c)(1) to clarify how caloric content is calculated by providing five options for calculating the energy value of foods in § 101.9(c)(1)(i).

The first option, which is set forth in § 101.9(c)(1)(i)(A), is the use of specific Atwater factors that are found in Table 13 in "Energy Value of Foods—Basis and Derivation" by A. L. Merrill and B. K. Watt, USDA Handbook No. 74 (1955). FDA disagrees with the comment that suggested requiring the use of specific Atwater food factors for those foods for which such factors exist. The agency does not believe that there is any need to limit a manufacturer's flexibility in selecting a method for determining

caloric content Current regulations do not require the use of specific Atwater food factors, and no data were presented to support a change in current practices.

The second and third options utilize the general factors of 4, 4, and 9 calories per g for protein, carbohydrate, and fat, respectively. In § 101.9(c)(1)(i)(B), which provides for calculating calories by general factors, dietary fiber is included in total carbohydrate. FDA also recognizes, however, that doing so can result in significant error for the caloric value of some foods because of the relatively low energy value of dietary fiber. Adjustments for dietary fiber content are therefore appropriate for nutrition labeling of some foods.

However, because some soluble dietary fiber can make a significant contribution to a food's energy value (Ref. 61), FDA does not consider it appropriate to allow an absolute exclusion of all dietary fiber from caloric calculation. Recognizing that there can be significant levels of available energy in some soluble fiber, and that official AOAC methods for dietary fiber now provide for separation of soluble and insoluble fiber, the agency considers it appropriate to permit exclusion of the insoluble component of dietary fiber alone from calculation of carbohydrate calories. Accordingly, FDA has added § 101.9(c)(1)(i)(C) in the final rule to permit calculation of caloric contribution from the carbohydrate portion of food by multiplying carbohydrate content minus insoluble dietary fiber content by the general factor of 4 calories per g.

In addition, § 101.9(c)(1)(i)(D) permits manufacturers or users of soluble dietary fiber additives or other food additive substances with reduced available energy to petition for use of alternative energy factors in nutrition labeling through established procedures for food additive or GRAS petitions. Soluble dietary fiber substances are frequently added to foods to replace fully caloric nutrients in formulating reduced calorie foods. In such cases, the burden for establishing the actual energy value of the food is appropriately with the manufacturer.

The calculation of the caloric contribution of novel fats and carbohydrates has been discussed in section III. of this document. The agency has stated that it will consider digestibility of new products on a case-by-case basis as requested. In support of this action, the agency requests that manufacturers who wish to declare adjusted values for the energy contribution of a substance, based on reduced digestibility, submit information on digestibility of the substance, analytical assay procedures for the substance, and data on interference with required methods of analysis. As stated in section III. of this document, this information should be included in a food additive petition or a petition for affirmation that the use of a substance is GRAS. The agency will then publish the specific digestibility coefficients in 21 CFR part 172 for food additives and in 21 CFR part 184 for GRAS substances. These coefficients can be utilized in determining the caloric value of specific food ingredients.

Other procedures may be required for particular foods and will be addressed by other appropriate means. FDA is allowing for this contingency in § 101.9(c)(1)(i)(D) by adding "or other means, as appropriate." For example, in the voluntary nutrition labeling program for raw fish, data were presented to FDA supporting a value of fat and calories for the fish "orange roughy" that omits a portion of the total fat since more than 90 percent of the fat in the product is in a wax ester that is not metabolized (Ref. 62). FDA published these corrected values for available fat and calories in Appendix B "Nutrition Labeling Provided by FDA for the 20 Most Frequently Consumed Fish" (57 FR 8175; March 6, 1992).

To afford even more flexibility in determining caloric content, FDA is including § 101.9(c)(1)(i)(E), to provide for the use of bomb calorimetry. The agency notes that the caloric value so obtained must be corrected for nonmetabolizable protein by subtracting 1.25 calories per g of protein to correct for incomplete digestibility, as discussed in Energy Value of Foods, Basis and Derivation, "USDA Handbook No. 74" (Ref. 63). The caloric value determined by bomb calorimetry may give a higher value than the other allowed methods. However, because it would produce an over-estimation of the caloric content of the food, FDA would not consider it to be disadvantageous to the consumer. A primary consideration in selecting which method to use must be the accuracy of the declaration of the caloric content in light of the agency's compliance criteria in § 101.9(g).

The agency is aware that some manufacturers have developed their own specific factors for conventional food ingredients that they use in calculating the caloric content of their products. FDA views this practice as analogous to using data bases to determine nutrient label values, in that the manufacturer assumes the responsibility for ensuring that the values obtained are consistent with those obtained analytically by FDA. As such, the agency does not believe it needs to provide for this option in § 101.9(c)(1)(i).

In summary, the agency is amending § 101.9(c)(1) to permit five optional methods for calculation of caloric content of foods: (1) Specific Atwater food factors (i.e., the Atwater method) given in Table 13, "Energy Value of Foods—Basis and Derivation," A.L. Merrill and B.K. Watt, USDA Handbook No. 74 (1955), (2) general factors of 4, 4, and 9 calories per g of protein, total carbohydrate including dietary fiber, and total fat, respectively, as described in USDA Handbook No. 74, (3) general factors of 4, 4, and 9 calories per g for protein, total carbohydrate, and total fat, respectively, as discussed in USDA Handbook No. 74, except that insoluble dietary fiber content may be subtracted from total carbohydrate content before calculating the caloric contribution of the carbohydrate portion of the food; (4) specific factors for particular food ingredients approved by FDA through incorporation in 21 CFR parts 172 or 184 or other means, as appropriate, or (5) bomb calorimetry data after subtraction of 1.25 calories per g protein to correct for incomplete digestibility, as described in USDA Handbook No. 74, p. 10.

By providing for these varied means of calculating caloric content, FDA is giving manufacturers flexibility in how they determine calorie content in a variety of foods, both conventional foods and new foods developed to meet changing marketing strategies.

93. A recommendation was made in one comment that products with a negligible amount of dietary fiber (suggested as less than 2.5 percent) should not be required to have dietary fiber analysis for determination of caloric content.

The agency advises that because revised § 101.9(c)(6) now includes dietary fiber in total carbohydrate content, separate analysis for dietary fiber is no longer required for calculation of either carbohydrate content or calories from carbohydrate. Therefore, the concern expressed in this comment has been addressed.

94. Several comments asked for clarification on the discussion in the mandatory nutrition labeling proposal (55 FR 29487 at 29493 and 29503) of the possible caloric contribution of macronutrient substitutes or other ingredients such as certain types of soluble fibers or gums. While one comment agreed with the agency's position that manufacturers of these ingredients should be asked to provide

evidence that these substances do not contribute to the energy value of food, another comment found the concern unwarranted and opposed the use of any correction factors for calories from soluble fibers (e.g., gums). One comment noted that more research is needed in this area.

In the mandatory nutrition labeling proposal, the agency expressed concern that available energy of soluble dietary fiber food additives (e.g., gums) would not be included under the agency's proposed method for caloric calculation, which excluded energy contribution of all dietary fiber. Innovations in food technology have resulted in reduced calorie foods that utilize various soluble dietary fibers and other modified carbohydrates, proteins, and fats for technical effects that allow reduction of total fat content. The agency considered it inappropriate to automatically assign a zero energy value to all soluble dietary fiber additives when some of these substances may have available energy. Likewise, some modified carbohydrate additives may have less available energy than the 4 calorie per g assigned by the general energy factor for carbohydrate but still have available energy. The agency has determined that petitions regarding specific caloric values for these types of food ingredients are appropriate. FDA's new policy is discussed in comment 92 of this document.

C. Fats, Fatty Acids, and Cholesterol

95. As discussed in section III. C. of this document, comments raised many questions about analytical procedures to be used to measure fat and their reliability. In addition, several comments expressed concern regarding the adequacy of methods for measuring cholesterol. One comment cited a published article on a method for measuring cholesterol that is undergoing collaborative study under the auspices of the AOAC.

The agency believes that its new definition for total fat in § 101.9(c)(2) (i.e., total lipid fatty acids expressed as triglycerides) will help to clarify what analytical procedures are to be used by clarifying what compounds are to be included in the declaration of total fat. As with all nutrient analyses, consideration must be given to the analyte and matrix when selecting a method to determine total fat content. To that end, the AOAC has established methods for analyzing for total lipid fatty acids in a variety of product matrices. A recent publication of the AOAC, The Referee (Ref. 32), contains a compilation of these methods. Other reliable and appropriate methods are also cited in comment 89 of this document.

FDA notes that issues exist about the reliability of methods for measuring low levels of fat. As discussed in a recent article, fat determinations are reliable down to concentrations of 1 to 5 g per 100 g, provided a large enough test portion is taken to obtain at least 50 mg of weighable residue (Ref. 64). The premise is that accuracy generally increases when larger amounts are used for analysis so that there is always a minimum quantity of extracted fat available for weighing.

Although official analytical methodologies for determining cholesterol content are somewhat limited at the present time, the agency is pleased to note that comments indicate that this is an area of active research. FDA, as a member of the AOAC Task Force on Nutrient Labeling Methods, looks forward to the development of additional collaborated methods for a range of matrices.

D. Dietary Fiber

In proposed § 101.9(c)(3) of the mandatory nutrition labeling proposal and proposed § 101.9(c)(7)(ii) of the supplementary nutrition labeling proposal, FDA specified that total, soluble, and insoluble dietary fiber content are to be determined by the method "Total Dietary Fiber in Foods, Enzymatic Gravimetric Method."

96. One comment noted that satisfactory analytical procedures for measuring dietary fiber are available and cited the American Association of Cereal Chemists Method No. 32–21 and the proposed AOAC method. This comment stated these methodologies were at least as accurate as certain other sanctioned procedures. It acknowledged that research should continue, however, to improve the utility and standardization of analytical methods for fiber. Another comment noted that the precision of the proposed method may cause difficulties at low levels, typical of that found in some fruits and vegetables (more than 1 percent to 5 percent) and especially when fat is present in the sample. The comment stated that because of questions concerning the accuracy of methods for measuring dietary fiber, companies may elect not to declare low levels of fiber in their products. The comment stated that there is a more accurate method for use in these situations.

Two comments from the meat industry expressed concern that the proposed method for fiber had only been evaluated on cereals, grains, and breads. They questioned the applicability of the method to other types of products. According to another industry comment, currently approved methods for analyzing dietary fiber seriously underestimate dietary fiber content of high moisture foods, which leads to inaccurate and misleading label information. This comment said that a current analytical method for high moisture products is unavailable. A comment expressed the hope that the tests adopted to measure dietary fiber would not falsely exclude low molecular weight bulking agents, such as polydextrose.

The few comments that addressed analytical methods for soluble and insoluble fibers were split on whether available methods are adequate or inadequate. One comment to the supplementary proposal noted that the agency's cited method does not measure soluble fiber directly. The comment said that the method measures total dietary fiber and insoluble dietary fiber, then calculates soluble dietary fiber as the difference between the two.

With the currently available AOAC methods for dietary fiber and its components, FDA believes that suitable methodology exists for the analysis of dietary fiber for nutrition labeling purposes. Since the issuance of the supplementary proposal, two additional methods for dietary fiber have been accepted by the AOAC, based upon the collaborative data. One new method (AOAC 15, 991.43) permits the discrete analysis of total dietary fiber and of each subcomponent, i.e., soluble and insoluble dietary fiber. The concern expressed by the comments as to the availability of validated methods for measuring dietary fiber is therefore alleviated. Because methods for measuring dietary fiber are now included in the Official Methods of Analysis of the AOAC, § 101.9(c)(7)(ii) of the supplementary proposal, which described dietary fiber methodology, and § 101.9(g)(2), which directs compliance by official AOAC methods, are redundant. As such, § 101.9(c)(7)(ii) has not been included in the final rule.

The enzymatic-gravimetric method (AOAC 15, 985.29) cited in proposed § 101.9(c)(7)(ii), is valid for high-moisture foods and those with fat present in the product. The method specifies drying conditions, as well as defatting procedures, that are to be performed before analysis for total dietary fiber. If drying conditions are a part of the analysis, analytical results must incorporate the loss on drying to obtain the total dietary fiber content of the "as received" product. Likewise, any loss of weight from fat or sugar removal must also be compensated for in the calculations.

Regarding the comment on the appropriateness of including low molecular weight bulking agents in dietary fiber, in the absence of a consensus on a chemical definition for dietary fiber, the available analytical methods dictate classification of such ingredients. Some manufactured low molecular weight, carbohydrate based, bulking agents, such as polydextrose, do not analyze as dietary fiber in the official AOAC methods for measuring dietary fiber. Such food ingredients, while not reported as dietary fiber in nutrition labeling, would be included in total carbohydrate and reported as "other carbohydrate."

97. A few comments recommended that dietary fiber be listed in 0.5-g increments, believing it to be a meaningful quantity to declare. Other comments concurred with the agency's proposal of whole-g declaration for dietary fiber on the basis that 0.5 g requires greater analytical precision than is possible for measuring dietary fiber.

The agency disagrees with the first comment. No data were presented to support a change to 0.5-g increments. Therefore, FDA continues to believe that the precision of the analytical methodology for determining quantitative amounts of dietary fiber does not allow for accuracy to the 0.5 g level. Accordingly, § 101.9(c)(6)(i) will require that dietary fiber be expressed to the nearest g.

98. One comment recommended use of the word "fiber" in lieu of "dietary fiber." The comment stated that consistency with the 1990 amendments was not needed and was far less important than using terms that consumers understood. The comment also contended that insertion of the word "dietary" into each term of fiber content would clutter the label.

The agency disagrees with the comment. No data were presented to support the contention that the term "dietary fiber" would confuse consumers. FDA believes that it is important to distinguish between dietary fiber and crude fiber to ensure that there is no question as to what fiber components are declared.

99. One comment took exception to the agency's citation of USDA Handbook 74 (1955) as the reference for the subtraction of dietary fiber in the calculation of total carbohydrate at § 101.9(c)(6) of the supplementary nutrition labeling proposal. In the cited reference, dietary fiber is not a part of the calculation. The comment noted that, as a defined, analyzable entity, dietary fiber was unknown in 1955.

FDA acknowledges the accuracy of the comment in regard to the concept of what dietary fiber was in 1955. As noted previously, the agency has modified § 101.9(c)(6) so that dietary fiber is no longer subtracted from the weight of the total food in the calculation of total carbohydrate content for nutrition labeling purposes. Therefore, the concern expressed by this comment has been addressed.

E. Sugars and Other Carbohydrate

In the mandatory nutrition labeling proposal, FDA discussed the analytical methodologies for sugars and dietary fiber (55 FR 29487 at 29498). The agency acknowledged in the supplementary proposal (56 FR 60366 at 60369) that analytical problems were a concern for the mandatory declaration of sugars and complex carbohydrate.

100. Essentially all of the comments stated that current methodology is inadequate to determine the levels of sugars and complex carbohydrate, as defined. Other comments described the methodology as unavailable, costly, difficult, and imprecise. One comment noted that there are no current analytical standards for measuring complex carbohydrates as defined in FDA's proposed rule. There were no comments that provided references for available, validated analytical methodology for these food components. Another comment noted that assay techniques for the quantitative determination of polysaccharides of 10 and higher saccharide units are beyond the reasonable capabilities of many in the food industry.

One comment included an evaluation of two liquid chromatographic procedures for monosaccharides through pentasaccharides and delineated disadvantages of each. The technique of high performance ion chromatography was identified by the comment as the technique that could provide the most accurate values for sugars. This technique has not however, been studied collaboratively by the AOAC.

Concerns expressed in regard to the analytical determination of sugars and complex carbohydrates have been alleviated by the revision of the definition of "sugars" to include only the sum of mono- and disaccharides and of "other carbohydrate" as the difference between total carbohydrates and the sum of dietary fiber, sugars, and sugar alcohols (when declared). There is established methodology in the Official Methods of Analysis of the AOAC for the determination of mono- and disaccharides in several food groups with a high degree of confidence. Continued analytical work will be necessary to validate methodology for a wider, more diverse food supply.

The agency will use the technique of HPLC in monitoring compliance with label statements concerning sugars content. The agency's use of this technique will not preclude the use of emerging technologies such as high performance ion chromatography or supercritical fluid chromatography as they are developed and validated.

F. Vitamins

101. A comment stated that the agency should list those carotene fractions that can be included in the declaration of vitamin A for labeling purposes. It noted that a variety of HPLC methods for vitamin A and carotene are available and currently in use by industry and FDA. The comment also stated that analytical reagents required for AOAC official methods for determining vitamin A content are no longer available.

In its RDI/DRV proposal, the agency proposed that vitamin A content is to be expressed in retinol equivalents (55 FR 29476 at 29485). One retinol equivalent was established to be equivalent to 1 microgram (μg) retinol or 6 μg beta-carotene. The nomenclature for vitamin A as retinol equivalents was carried forward in the supplementary proposal at § 101.9(c)(11)(iv). FDA is aware of literature data where alpha-carotene is present in some carrots in significant amounts. To account for this and other carotene fractions, the agency also recognizes the National Academy of Sciences' definition of retinol equivalents as 12 μg of provitamin A carotenoids other than beta-carotene (Ref. 23).

As noted above, the agency worked closely and actively with the AOAC Task Force on Nutrient Labeling Methods to judge the adequacy of AOAC methods to meet nutrition labeling needs. The decreased availability of the analytical reagents for some methods for determining vitamin A content has caused both industry and the agency to rely more on HPLC procedures. For example, the yellow OB dye (formerly FD&C Yellow No. 4) used for standardizing the alumina column in the AOAC method for determining the vitamin A content in margarine is no longer readily available. However, FDA advises that the Nutrient Surveillance Branch (HFF-266), Center for Food Safety and Applied Nutrition, FDA, can provide limited quantities of the dye upon request to the address listed at the beginning of this document.

V. Format

A. Legal Authority for an Improved Nutrition Label Format

Congress clearly intended that nutrition information be presented to the public in a manner that facilitates understanding of the information and that assists consumers in maintaining healthy dietary practices. This fact is evidenced by at least two provisions of the 1990 amendments. Section 403(q)(1) of the act, which was added by the 1990 amendments, states:

> The Secretary may by regulation require any information required to be placed on the label or labeling by this subparagraph or subparagraph (2)(A) (section 403(q)(1) or (2)(A)) to be highlighted on the label or labeling by larger type, bold type, or contrasting color if the Secretary determines that such highlighting will assist consumers in maintaining healthy dietary practices.

In addition, section 2(b)(1)(A) of the 1990 amendments states that the implementing regulations shall:

> * * * require the required information to be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet.

Consistent with the authority vested in the Secretary (and FDA, by delegation) to determine if specific label information will assist consumers in maintaining healthy dietary practices, the House report accompanying the 1990 amendments directs FDA to consider a variety of format options, including: "information about the recommended daily intake, the use of descriptive terms such as 'high,' 'medium,' and 'low' or use of universal symbols to indicate desirable or undesirable levels of particular nutrients." The report goes on to state: "While the bill does not mandate any particular approach, it does require the Secretary to specify requirements that would permit the consumer to understand the nutrition information pertaining to a particular food in relation to recommended dietary information" (Ref. 16).

B. The Role of the Nutrition Label

The 1990 amendments provide several descriptions of the role of the nutrition label. Section 403(q)(1) of the act, which was added by the 1990 amendments, uses the language "assist consumers in maintaining healthy dietary practices." Section 2(b)(1)(A) of the 1990 amendments uses the language "enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet." In the format proposal, FDA requested comment about how the nutrition label can best assume the information role mandated by the 1990 amendments.

102. A number of comments from food manufacturers, trade associations, health promotion organizations, and consumer groups identified more than one role for the nutrition label in assisting consumers in maintaining healthy dietary practices. One illustrative comment from a health professional organization described two different roles of the food label as: (1) Helping consumers choose appropriate foods and (2) helping consumers to understand the "importance of diet and proper dietary behaviors to a healthy life." Similarly, a comment from a trade association made the distinction between the food label "contributing to the consumer's understanding of the relative significance of the food in the context of a total daily diet" and providing "guidance on how to use information in the food label to make appropriate food choices." Many comments made similar distinctions between the food label helping to place the particular product in the context of a daily diet and the food label providing guidance on how to maintain healthy dietary practices. A number of comments from industry questioned whether the act mandated an explicit educational role for the nutrition label to provide guidance to consumers on how to maintain healthy dietary practices.

Many comments argued that the nutrition label cannot by itself provide all the information important to maintaining healthy dietary practices but reached different conclusions about the relevance of this limitation for the nutrition label format. A number of comments, particularly from industry, pointed out that because of the limited space available on the food label, the nutrition label cannot be expected to adequately convey all the information consumers need to understand the importance of nutrition information in maintaining healthy dietary practices. These comments concluded that the role of the nutrition label should be limited to providing factual, product-specific information, and that the broader dietary guidance role should be reserved to off-label activities of public and private nutrition education programs. These comments asserted that these programs will have sufficient time and space to inform consumers about the concepts of flexibility and personal choice necessary to maintain healthy dietary practices.

Other comments, primarily from consumer organizations and health professional groups, acknowledged the necessity of off-label consumer education to help consumers understand how to use the nutrition information to maintain healthy dietary practices but saw the nutrition label as a useful food selection tool that needs to be integrated with off-label educational programs.

FDA agrees that the nutrition label can and should help consumers make informed food choices, and that it can also contribute to helping consumers maintain healthy dietary practices. The two roles are by no means inconsistent. To help consumers make appropriate food choices contributes undoubtedly to maintaining healthy dietary practices. Among those choices are choices that will assist the consumer in maintaining healthy dietary practices. Maintaining healthy dietary practices, however, is a larger and more complex goal than informing food choices, and one that requires motivation and knowledge of how to combine and balance the many different kinds of foods and eating occasions that constitute a total diet. The 1990 amendments require the agency to take both senses of the possible role of the nutrition label into account in evaluating alternative formats for the nutrition label. However, the agency also agrees that the mandated role of the nutrition label to assist consumers in maintaining healthy dietary practices does not encompass an explicit educational role for the nutrition label to provide dietary guidance to consumers.

The agency believes that the nutrition label format needs to give first consideration to helping consumers make informed food choices by enabling them to both comprehend the nutritional value of the food and to understand its relative significance in the context of the total daily diet as called for in section 2(b)(1)(A) of the 1990 amendments.

The agency's view is that the basic format elements that best serve the mandated role of the nutrition label must be identified and justified on the basis of consumer research. Therefore, the implications of format elements for the use of the nutrition label in assisting consumers to understand the nutritional value of the food and to understand the food in the context of the total daily diet were extensively examined in the agency's format research.

C. Need for Consumer Research

Section 2(b)(1)(A) of the 1990 amendments specifies criteria for an acceptable format for nutrition label information. The operative terms in this section, "readily observe and

comprehend" and "understand its relative significance in the context of a total daily diet," are goals stated in terms of consumer perception and understanding. The consequences of various formats and format elements on consumer perception and understanding can only be measured objectively in terms of behavior (i.e., in terms of how well consumers use a format for a specific task). Formats and format elements can be assessed subjectively by asking consumers or experts to judge the usefulness of various formats. Behavior-based performance measures, however, rather than subjective judgment, are generally accepted as the more reliable and valid way to evaluate the consequences of information displays on consumer perception and understanding.

Major scientific groups (Refs. 1, 65, and 66) urged FDA to subject possible nutrition label formats to consumer testing to objectively determine which formats can be used most effectively by consumers. FDA has placed considerable emphasis on the importance of consumer research in developing a new format for the nutrition label because of this advice and because the techniques of consumer research (surveys, focus groups, experiments, and preference polls) provide the best and perhaps the only possible bases for evaluating alternative nutrition label formats against the consumer perception and understanding criteria specified in the 1990 amendments.

103. A number of comments argued that virtually any nutrition label format, even the current format, can serve to help consumers put foods in the context of a total daily diet depending on the knowledge and understanding of the person reading the label. To the same point, many comments recommended nutrition education activities to supplement the public's understanding of label information. Some comments suggested that nutrition education activities can be an alternative to including one or more information elements, such as a listing of DRV's for certain macronutrients, on the nutrition label.

FDA agrees that each person's knowledge is the necessary context for understanding label information, and that nutrition education activities can be an important complement to the public's understanding of label information. FDA disagrees with the implication sometimes drawn from these facts that FDA is thereby relieved from the burden of adopting a format based in part on the available evidence about what kind of format does the best job at achieving the objectives of the 1990 amendments. Although various considerations bear on the selection of a final nutrition label format, FDA believes that an essential criterion is how well a format conveys information that Congress expected would be provided by the nutrition label. Congress expected that such information would allow people to decide whether, based on the nutrition content of the food, they would want to buy the food (Refs. 67 and 68) and to understand the relative significance of the food in the context of the daily diet (section 2(b)(1)(A) of the 1990 amendments). FDA has sought to measure, and has sought other information that measures, the ability of various formats to achieve these objectives.

D. Consumer Research Submitted as Comments or Referenced in Comments to the Format Proposal

1. Background

The agency reviewed a number of qualitative studies (i.e., five focus groups, seven preference polls) and quantitative studies (i.e., five surveys, seven experiments,) that were submitted as comments or referenced in comments to the format proposal. Consumer research studies about format issues were conducted by FDA, food industry groups, individual food companies, consumer groups, public health organizations, health professionals, and academic researchers.

Much of this work was done in response to FDA requests for additional information, and became available only in comments submitted in response to such requests. For example, FDA published an advance notice of proposed rulemaking in the **Federal Register** of August 8, 1989 (54 FR 32610), soliciting public comment on a wide range of food labeling issues, including: (1) Whether to revise requirements for nutrition labeling and (2) whether to change the nutrition label format. FDA subsequently held four public hearings on food labeling, the last of which was held in Atlanta, Georgia on December 13, 1989. This last public hearing focused on the nutrition label format.

Additionally, in the **Federal Register** of May 20, 1991 (56 FR 23072), FDA published a notice announcing the availability of a report on research on alternative nutrition label formats that had been conducted by the agency and inviting comments on the report. The comments on this notice were used in the design and execution of subsequent consumer research conducted by the agency. In the **Federal Register** of July 1, 1991 (56 FR 29963), FDA announced a plan for a cooperative pilot program with industry to test alternative nutrition label formats that led to several industry sponsored nutrition label format studies. In the **Federal Register** of April 2, 1992 (57 FR 11277), FDA gave notice of a meeting for industry, including small businesses, at which the agency presented the results of its research studies related to the format and design of the nutrition label, so that comments to the proposed format rule (57 FR 32058) could be as informed as possible.

In a number of instances, FDA staff provided materials, information, support, and consultation on technical aspects of study design and label format to researchers. In addition, FDA received many comments from the general public in response to articles in newspapers and newsletters that solicited consumer opinions in the form of informal polls based on examples of possible nutrition label formats provided by FDA. Table 1 presents a summary of the various research studies received in response to the format proposal and the format research conducted by FDA.

Table 1.—Research Studies Submitted as Comments or Referenced in Comments to Docket Number 91N-0162: Food Labeling: Format of Nutrition Label; Proposal

A. Experimental Studies Submitted

1. Frito-Lay Study (Ref. 74)

a. Design: Between subjects; five format cells.

b. Subjects: Central location test; adults, age 18+ who purchased and/or ate salty snacks in the past 4 weeks, one site, N=750.

c. Formats tested: Same as FDA Study 1 on actual product.

d. Key dependent measures: (1) Scale based on seven questions, three number-of-serving type and four dietary-judgment type; (2) rating of single format based on helpfulness, ease of use and adequacy of information.

e. Assessment/comments: All subjects saw same product. Well controlled study.

2. GMA/NFPA Industry Study (Ref. 71)

a. Design: Between subjects; seven format cells.

b. Subjects: Shopping mall intercept/central location test; adults 18+ who did at least half of household food shopping, quota controls on age, income, education and race; 36 sites, N=5,600.

c. Formats tested: Same as FDA Study 2 on realistic product mockups.

d. Key dependent measures: (1) Product comparison task identical to FDA task, (2) four-product comparison task with specific nutrient probes, (3) dietary judgment task with specific nutrient probes, "if you were trying to get more/limit (NUTRIENT) in your diet, how would you feel about eating this

(FOOD)?"; (4) rating of single format based on adequacy of information and ease of use, (5) self-report of whether subjects knew how to use the DRV information.

e. Assessment/comments: Each subject worked with only one format executed in a variety of ways. Products are confounded with tasks. Format executions are inconsistent across products. Percent DRV formats are sometimes executed with 1, 3, or 4 column displays depending on product, while other formats have either one- or two-column displays. This complex execution for Percent DRV formats may explain why they show poor product comparison performance and are rated more negatively than other formats. Exposure to formats on early tasks may affect responses on later tasks.

3. FDA Format Study 1 (Ref. 69)

a. Design: Repeated measures within subjects; subjects assigned to one row of a 5(formats) X 5(products) Greco-Latin Square.

b. Subjects: Shopping mall intercept/central location test, adults 18+ who did at least half of household food shopping, quota controls on age, income, education and race; eight sites in seven states, N=1,560.

c. Formats tested: Five formats (see format proposal (57 FR 32058)).

d. Key dependent measures: (1) Product comparison task, measured both accuracy and time; (2) preference rating for most liked/least liked format among the five seen in the study, and reasons for choices.

e. Assessment/comments: Formats presented as two dimensional nutrition labels of realistic size but not on packages.

4. FDA Format Study 2 (Ref. 70)

a. Design: Repeated measures within subjects; subjects assigned to one row of one of three 4(formats) X 4(products) Greco-Latin Squares.

b. Subjects: Shopping mall intercept/central location test, adults 18 + who did at least half of household food shopping, no quota controls; 8 sites, N=1,232.

c. Formats tested: seven formats (see format proposal (57 FR 32058)).

d. Key dependent measures: (1) Product comparison task, measured both accuracy and time; (2) judgments of front panel nutrition claims; (3) judgments of nutrients that need to be balanced in the diet after eating product; (4) product healthfulness ratings before and after seeing nutrition label; (5) estimate of how many servings of product needed to meet daily requirement; (6) preference for most liked/least liked format out of the four seen, with stated reasons for choices.

e. Assessment/comments: Formats presented as two dimensional nutrition labels of realistic size but not on packages. All formats not tested on product comparison task. FDA Study 1 data used to impute product comparison performance for Control and Adjective formats. Percent DV/With DRV used as proxy for Percent DV/Without DRV on product comparison task.

5. Geiger Study (Ref. 72)

a. Design: Repeated measures within subject; subjects assigned to one of two format sets of either five or six formats.

b. Subjects: Shopping mall intercept/central location test, one site, eligibility requirements not specified, N=243.

c. Formats Tested: 11 formats including versions of Control, Control/DRV, Percent DV/With DRV, Percent DV/Without DRV and versions with adjectives, bar graphs and various combinations of these design features.

d. Dependent measures: (1) Reading accuracy; (2) number-of-serving type questions; (3) perceived usefulness of various formats based on a conjoint measurement procedure-equivalent to preference for large choice set.

e. Assessment/comments: All formats executed on same product. Learning effects across repeated measures may confound format effects on performance measures—the same information is available on all formats. Correct answers to number-of-serving type questions are not clearly defined.

6. Byrd-Bredbenner (Ref. 73)

a. Design: Repeated measures within subject; seven format cells.

b. Subjects: Supermarket intercept, 15 sites in same geographic area, food shoppers 18+, age and education quota controls, health and nutrition-related workers excluded, N=300.

c. Formats tested: seven formats including versions of Percent DV, Adjective, DRV Listing and Control in various combinations.

d. Key dependent measures: (1) Hybrid scale consisting of number-of-serving type questions and product comparison questions; (2) scale consisting of product comparison questions; (3) preference ratings of most helpful/least helpful with stated reasons.

e. Assessment/comments: Products confounded with formats. Order of format presentation partially confounded with amount of information in format.

7. Burton (Ref. 75)

a. Design: Between subjects, 4(formats) X 3(reference values: none/daily/meal) X 2(high/low nutrient values).

b. Subjects: Recruited for a university sponsored project by letter, cross-section of adults, n=500.

c. Formats tested: Versions of Control, Adjective and Percent DV with and without different versions of a DRV listing.

d. Key dependent measures: (1) Product ratings: bad-good, not nutritious/very nutritious, purchase intentions; (2) number-or-serving type measure; (3) rank ordering of formats on quantity and quality of information.

e. Assessment/comments: Well controlled study.

B. Survey Studies Submitted

1. AHA Quantitative Study (Ref. 87)

a. Design: Central location test, details unspecified.

b. Subjects: N=405.

c. Relevant format topics: Frequency of reading back of food labels, magnitude estimation of amount of fat in product, awareness of calorie base for fat, knowledge of how to adjust Fat DRV if person eats less than 2,350, likelihood of using information on food label to help reduce fat intake.

d. Assessment/comments: Most of the survey is devoted to issues related to use of the word "healthy" on food labels.

2. CSPI Study (Ref. 95)

a. Design: National probability sample of telephone households.

b. Subjects: N=2,008 adults, assigned to one of eight versions of magnitude estimation question.

c. Relevant format topics: Magnitude estimation of fat amounts in product.

d. Assessment/comments: Fat is the only nutrient considered.

3. American Meat Institute/Roper Study (Ref. 96)

a. Design: Multistage, stratified national probability sample of households, in home interviews.

b. Subjects: N=2,000, males who shared food shopping responsibility equally with other people in the household were selected when possible, otherwise any food shopper available from household was selected.

c. Relevant format topics: Attitudes and behavior regarding food labels, understanding of "RDA" and "DRV."

d. Assessment/comments: A comprehensive survey on food labeling issues.

4. Kellogg Study (Ref. 97)

a. Design: Not a probability sample, subjects call toll-free number for some product-specific reason.

b. Subjects: N=272, unknown characteristics.

c. Relevant format topics: Understanding of DRV, knowledge of how to adjust DRV for varying calorie needs, rated helpfulness of DRV information.

d. Assessment/comments: Sample characteristics are unknown.

5. GMA/NFPA Industry Study (Ref. 71)

a. Design: Central location test (see description above). Questions that were asked before subjects saw any food label formats or questions that did not involve use of formats are considered survey questions.

b. Subjects: See description above.

c. Relevant format topics: Frequency of reading food labels, frequency of various uses of food label information, understanding of DRV concept.

d. Assessment/comments: Large sample, detailed questions about possible label uses, DRV questions are asked after respondents have been exposed to particular food label formats, subjects exposed to Control formats are not asked DRV questions, only 4,790 respondents are asked the DRV questions.

6. National Consumers League (Ref. 98)

a. Design: National probability sample of telephone households.

b. Subjects: N=1,139, 1,007 who read nutrition labels at least sometimes completed full questionnaire.

c. Relevant format topics: Frequency of reading food labels, reasons for reading food labels.

d. Assessment/comments: Most of the survey is devoted to issues related to use of the word "healthy" on food labels.

C. Focus Group Studies Submitted

1. FDA Study 1 (Ref. 85).
2. FDA Study 2 (Ref. 86)
3. Geiger (Ref. 72).

4. AHA Study 1 (Ref. 87).
5. AHA Study 2 (Ref. 87).

D. Informal Preference Polls

1. COSTCO Newsletter (Ref. 88).
2. Washington Post (Ref. 89).
3. Nutrition Action Newsletter (Ref. 90).
4. USA Today (Ref. 91).
5. Daily Herald (Ref. 92).
6. Atlanta Constitution (Ref. 92).
7. New York Times (Ref. 94).

The studies vary greatly in the issues addressed, methodology, sampling, types of nutrition formats studied, types of evaluation measures used to assess formats, and degree of control used in the research. Many of the consumer studies submitted or referenced in comments about nutrition label formats were based on recently conducted research studies and on interpretations that had not yet appeared in the scientific literature.

FDA considers the findings of research studies submitted in comments to constitute an important separate class of comments for purposes of evaluating various nutrition label formats. Research findings based on specific measures need to be considered as distinct from conclusions based on combining findings across several different measures. Research findings also need to be considered in the context of a body of similar research to evaluate consistency in the pattern of effects across studies (e.g., reliability) and consistency in the identification of important controlling factors (e.g., validity). Comments offering conclusions based on research findings are discussed below in the relevant sections. In this section, the research findings themselves are discussed in terms of methodologies used, types of evaluation measures, consistency of effects across studies, the strength of effects, and implications for the design of the nutrition label format. The agency believes that to clarify its reasons for decisions about the nutrition label format that rely on research findings, it is necessary to articulate its understanding of the relevance, reliability, and relative significance of the various research findings.

To facilitate discussion of research findings, FDA considers it useful to distinguish among three primary types of evaluation measures used to assess nutrition label formats: Performance measures based on label use tasks, consumer preference judgments of various formats, and questions about consumer understanding of selected elements of possible nutrition labels, such as Daily Values (DV's) (called in the format proposal DRV's). Each type of evaluation measure has a different relevance to the selection of an improved format for the nutrition label.

2. Performance Measures Based on Specific Label Use Tasks

As a rule, different tasks and performance measures have been used to evaluate how well a format meets the different primary performance objectives specified in the 1990 amendments. These objectives as discussed in section V.B. of this document are: (1) To enable consumers to readily observe the nutrition information, (2) to enable consumers to comprehend the nutrition content of the particular product, and (3) to enable consumers to understand the relative significance of product nutrition information in the context of a total daily diet. (Objectives (1) and (2) are closely linked for testing purposes and will be frequently discussed together in this document). In the research reviewed by FDA, measures to evaluate formats in relation to these objectives have appeared only in experimental studies, probably because this type of measure requires a substantial degree of control over the conditions under which such measurements are taken.

For performance measures based on specific label use tasks, respondents are asked to perform a task using the information from a nutrition label. The task is constructed so that a performance measure can be defined (e.g., speed, accuracy, likelihood of giving appropriate response), indicating the degree to which the respondent can readily observe and comprehend product label nutrition information or "understand its relative significance in the context of a total daily diet."

a. *Product comparison tasks.* The type of tasks most commonly used to evaluate formats with respect to the objective of enabling consumers to readily observe and comprehend product nutrition information were product comparison tasks. These tasks presented respondents with two or more product labels simultaneously and asked them to engage in a relatively simple information search (e.g., find differences between the products, identify which product is higher or lower in a certain nutrient) where answers were scored correct/ incorrect and timed.

104. The product comparison type of task was employed by the two FDA format studies (Refs. 69 and 70) and by three other studies submitted in comments to the format proposal (Refs. 71, 72, and 73). One study (Ref. 72) simply asked respondents to read certain information from a product label and scored whether they gave the correct answer.

Performance levels on product comparison tasks were high, with most of these studies finding accuracy levels of 70–90 percent correct.

The product comparison type of task tended to produce consistent format effects. The most consistent finding, replicated in all studies, was that simple formats that have clean, nonredundant displays of nutrient information per serving worked best in this kind of task. Because it has the least amount of information, the current format performed well on product comparison tasks. But several studies (Refs. 70, 72, and 73) found that other ways to display nutrient information per serving, using either g/mg amounts or percent DV declarations, were equally effective when the format was executed with a clean and uncluttered appearance.

Multiple column nutrient information per serving displays were much more difficult than single column displays for consumers to use for product comparisons. Several studies (Refs. 69, 70, and 71) found that product comparison performance dropped sharply for labels using the "as packaged/as prepared" dual declaration format. Both the major industry format study and FDA's first experimental format study found that declaring nutrient amounts per serving in adjacent columns of g/mg amounts and percent DV led consumers to make more mistakes and to take longer on the product comparison type of task. FDA's second experimental study, however, showed that when g/mg nutrient amount information was placed immediately next to the nutrient name in an unordered array, and percents were placed in a column array, the adverse effects on product comparison performance disappeared.

Most studies found that the addition to the label of a listing of the DV's for some or all nutrients did not greatly affect the ability of consumers to use the nutrition label for product comparison purposes. Similarly, the use of a highlighting or grouping scheme on the nutrition label neither impaired or improved respondents' performance of product comparison tasks.

The use of adjectives on the nutrition label did appear to cause respondents to miss nutrient differences between products when the adjectives used to describe the nutrient for each product were the same. Several studies (Refs. 69, 71, and 73) found that formats using adjectives did not perform as well as formats without adjectives on product comparison tasks.

FDA considers this product comparison type of performance measure to be a valid and reliable indicator of how well a given format's information can be readily observed and comprehended. The major conclusions that FDA drew from this research are that: (1) Clean, uncluttered nutrition label formats work best, (2) dual column declarations of nutrition information per serving make it harder for consumers to readily observe and comprehend nutrition information, and (3) adjective formats lead consumers to miss quantitative differences between products when different nutrient levels are characterized by the same adjective. The formats that FDA tested (Refs. 69 and 70) that were effective on product comparison tasks included the CONTROL, CONTROL/DRV, PERCENT, PERCENT/DRV, GROUPING, and HIGHLIGHTING.

b. *Dietary judgment tasks.* A different type of task was used to evaluate formats with respect to the second performance criterion, enabling consumers to understand the relative significance of product nutrition information in the context of a total daily diet. Most of the dietary judgment tasks presented respondents with one product label at a time and asked them to make a dietary judgment about the product (e.g., how likely they would be to eat the product if they were trying to limit/increase a specific nutrient in their diet; what nutrients they should try to cut back on/get more of in other foods they eat that day after eating three servings of the product; whether they consider a high/low nutrient claim for the product to be correct/incorrect). Respondent dietary judgments were then scored as correct/incorrect or appropriate/ inappropriate.

105. This type of dietary judgment task was used in the second FDA format study (Ref. 70) and two industry studies (Refs. 71 and 74). Measures based on dietary judgment tasks produced consistent format effects. The most consistent finding, replicated by all these studies, was that providing adjectives to describe nutrient levels per serving or declaring nutrient levels per serving as percentages of the nutrient DV helped respondents to make correct and appropriate dietary judgments relative to formats where nutrient levels were declared in g/mg amounts. These studies found that other nutrition label format design elements, such as inclusion of a listing of DV's, highlighting, or grouping nutrients on the label, did not improve performance on these types of dietary judgment tasks.

A consistent finding across two studies (Refs. 70 and 71) was that percent DV declaration had a moderating effect on dietary judgments relative to formats without percent DV declaration. Respondents were less likely to consider a given nutrient level unacceptably high or to say that they would avoid the food entirely because of its nutrient levels when the amount per serving information was presented as percent DV.

Performance levels on this type of dietary judgment task ranged from 45 to 80 percent correct across studies.

FDA considers that how well consumers are able to judge the magnitude of specific nutrient levels as measured by this type of dietary judgment task is a valid and reliable indicator of how effectively a given format helps consumers to understand the significance of product nutrition information in the context of a total daily diet. The major conclusions that FDA drew from this research are that: (1) The declaration of nutrient amount information as percentages of DV or the placement of adjectival descriptors next to the nutrient amount information are both effective ways to help consumers understand the significance of product nutrition information in the context of a total daily diet, (2) percent DV declarations moderate dietary judgments about a food, and (3) other format elements, such as a list of DRV's for important macronutrients, highlighting, or grouping nutrients according to dietary guidelines, do not help consumers make better dietary judgments. The formats that FDA tested that were effective on this kind of task were the PERCENT DV, PERCENT DV/ DRV, and ADJECTIVE.

106. Several comments on the format proposal recognized that the ADJECTIVE and PERCENT DV formats have benefits to consumers for dietary judgment types of tasks. They argued that both of these format design elements correct a common tendency to misjudge the magnitude of specific nutrient levels when they are given in g/mg amounts. The comments asserted that consumers make such errors because they tend to use a single numeric standard to estimate magnitude.

The comments stated that when nutrient amounts per serving are declared in g/mg amounts, the numbers appearing on the label cannot be used as guides to estimate the relative magnitude of nutrient levels in the product. These comments continued: A reasonable reference standard for one nutrient is quite different from the reasonable reference standard for another nutrient. For example, 5 g is a high level for saturated fat, but 100 mg is a low level for sodium. Because the nutrients on the label vary greatly in terms of reference standards, the common tendency of consumers to use a single numeric standard when nutrient amounts are declared in g/mg units leads to flawed dietary judgments.

Percent DV declarations, by contrast, display nutrient amounts per serving in comparable units, and this type of display facilitates the appropriate use of a common numeric reference standard for all nutrients. Adjectival descriptors also serve to translate nutrient levels into comparable units by describing disparate nutrient amounts per serving in easily understood ordinary language terms.

FDA agrees that this reasoning provides a plausible explanation of the research finding that percent DV declarations and adjectives help consumers make more appropriate magnitude estimates of nutrient levels in a product.

c. *Number-of-servings calculation tasks.* Some studies employed a one-product task where respondents were asked to estimate how many servings of the product were needed to meet a daily requirement for a certain nutrient. FDA considers this number-of-servings type task to be relevant to consumers' abilities to use product information for meal planning and quantitative dietary management purposes that are properly considered part of placing the product in the context of a total daily diet.

107. This type of performance measure was used in the second FDA format study (Ref. 70) and in four other studies submitted in comments to the format proposal (Refs. 71, 72, 73, and 75). The number-of-servings type of performance measure did not show consistent format effects across studies, possibly because of variations in stimuli and procedures between studies.

One well controlled study (Ref. 70) found that the current nutrition label format was the worst format on this type of performance task, but a less well-controlled study (Ref. 72) found that the current nutrition label was among the best formats on the number-of-servings type of task. One study (Ref. 70) that asked for a numerical answer found that PERCENT DV formats performed almost as well as the best formats on this measure, but another study (Ref. 71) that asked the respondent to articulate the computation process found that PERCENT DV formats were much worse than the best performing formats.

In all studies, performance levels on the number-of-servings calculation task were noticeably lower than for the kinds of tasks discussed above. Performance levels ranged from 10 to 50 percent

correct across studies. All studies found that this type of task was highly sensitive to respondents' education levels and arithmetic sophistication.

FDA considers this type of performance measure to be relevant to how well a given format serves to place product information into the context of the total daily diet, particularly with respect to the role played by including a listing of the DV's on the label. However, a lack of consistent results across studies and low levels of consumer competence to perform the required computations suggests that this measure be considered of secondary importance for evaluating nutrition label formats.

d. *Single product rating tasks.* Some studies showed respondents a product label in a given format and asked them to rate the product on healthfulness or to rate purchase intentions toward the product. The measure compared ratings made after seeing front panel information consisting of nutrient or health claims and ratings made after being exposed to product information on the nutrition label.

108. This type of measure was used in the second FDA format study (Ref. 70) and in one other study submitted as a comment (Ref. 75). Both studies showed a consistent effect: Consumers relied more heavily on back panel than front panel nutrition information when making general judgments about a product. They become more negative toward the product after seeing the back panel nutrition information relative to an initial impression based on front panel information alone. Neither study found that the format of the nutrition label had much effect on this type of measure.

Because it appeared insensitive to format effects, FDA does not consider this type of single product rating comparison to be an important consideration for evaluating how well a format meets the criteria specified by the 1990 amendments.

e. *Measures based on two or more types of tasks.* Some studies defined scales that combined more than one type of performance measure, such as product comparison questions and number-of-servings questions. Where possible, FDA considered these scales to represent only one of the composite measures, the one they most resembled, so that they could be discussed in the appropriate sections above. Such measures were evaluated by comparing results with other measures from the same study and with measures from other studies which utilized similar elements.

109. One study (Ref. 73) submitted as a comment to the format proposal reported results for a scale based on product comparison questions and number-of-servings questions (discussed in section V.D.2.a. and V.D.2.c. of this document). In this instance, the results showed that format effects on the scale were quite different from format effects on a different scale in the same study which was clearly made up of product comparison questions. Therefore, FDA considered this scale to be an example of the number-of-servings type of performance measure.

110. Another study (Ref. 74) reported results for a scale based both on number-of-servings type questions and dietary judgment type questions. Examination of the results for this scale showed that the performance findings most resembled findings from other studies based on dietary judgment questions. Therefore, FDA considered this scale to be an example of a dietary judgment performance measure.

3. Preference Judgment Measures

In the research reviewed by FDA, consumer preference judgments of various formats were primarily choice measures based on a direct or implied question to respondents about which of some given set of possible examples of nutrition label formats would be most helpful, most useful, or would work best for consumers. Measures of this type occurred in all research modalities and were often the principal measures in focus group and informal preference poll research. Because respondents were typically asked to express a relative preference, the set of choices presented to respondents influenced the selection process and thereby constitutes an important limitation on the validity of this type of measure.

Preference measures are not of the same order as behavioral measures, which address how well a given format performs in a given label use situation. Stated preferences for formats reflect a respondent's implicit theory about what kind of format generally works best. Judgment in these instances is abstracted from any particular product or any particular label use situation.

An extensive scientific literature review suggests that untested theories about the amount and type of information that are most useful to consumers are sometimes wrong (Refs. 76, 77, 78, 79, and 80). In particular, studies of preference for nutrition information have generally shown that consumers prefer the largest amount of information offered (Refs. 81, 82, and 83) but perform best with limited amounts of information specifically related to the task (Ref. 84).

a. *Experimental studies.* 111. Both FDA format studies and three other studies submitted as comments on the format proposal employed relative choice measures of format preference based on choosing a most preferred or least preferred format from the set of formats being evaluated in the study (Refs. 69, 70, 72, 73, and 75). Direct comparisons between studies are difficult because no two studies used exactly the same choice set of formats.

Despite differences between studies, there were basic consistencies in the pattern of preference results across studies. In every case, respondents tended to prefer the format with the most information in the choice set and tended to dislike formats with the least information in the choice set. The addition of a listing of DV's to the nutrition label for some or all of the nutrients was seen as more informative, and was always highly preferred, over alternatives lacking a listing of DV's. All of the studies that asked respondents to give reasons for their selection of a certain format (Refs. 69, 70, and 73) found that providing more information was one of the most common reasons given.

Other format features in addition to a DV list that were viewed positively relative to formats without such features were adjectives, bar graphs, highlighting, and, to a lesser extent, grouping and declaring nutrient amount per serving as percent of a DV.

All studies that included both performance and relative preference measures (Refs. 69, 70, 72, 73, and 75) found little or no consistency in the pattern of format results across performance and preference measures. For studies that included performance measures of the product comparison type (Refs. 69, 70, 72, and 73), the common finding was an inverse ordering between formats that were preferred and formats that performed well on this type of task.

Two experimental studies (Refs. 71 and 74) varied formats between subjects such that each subject saw a single format and rated only that format. One study (Ref. 74) asked respondents to rate the helpfulness, ease of use, and adequacy of information of the single format. The other study (Ref. 71) asked respondents to rate ease of use and adequacy of information. Neither study found that respondents gave the highest ratings to the format with the most information. A format similar to the current format that did not include a listing of DV's for some nutrients was

among the highest rated formats in both studies.

In one study, respondents expressed suspicion toward formats using adjectives (which provided relatively more information), apparently because they felt the company was deciding how and when the adjectives were used. In the other study, respondents were more negative toward formats using percent DV declarations. However, in the latter study, the PERCENT DV formats were executed with extra columns of information, so that a single nutrition label had as many as four numeric columns. Respondents in this study considered the PERCENT DV with DV list format to provide more information than was desirable.

FDA is convinced by these results that consumer preferences for various nutrition label formats were very sensitive both to the set of formats the respondent was asked to compare and to the particular methodology used to measure preference. Moreover, preferences did not correspond to objective measures of format performance. This lack of correspondence raises serious questions about the underlying validity of such measures, even though respondents were asked to base preferences on which formats they thought would work best. Given these methodological problems and the apparent lack of validity, FDA considers preference measures to be of secondary importance for decisions about the nutrition label format.

b. *Focus group studies.* Research using focus group discussions about nutrition label issues elicited preferences for various kinds of format design elements by showing the group examples of different formats and asking them to discuss their reactions.

112. The two FDA focus group studies and three other focus group studies submitted as comments on the format proposal discussed the groups' reactions to various format elements (Refs. 72, 85, 86, and 87). In every study, respondents indicated strongly that they would like more information on the nutrition label, particularly with respect to helping them understand whether given nutrient levels could be considered high or low. A listing of DV's for some or all nutrients was always among the most preferred additions to the nutrition label. Other format design features favorably mentioned in some or all of the focus group studies were bar graphs, percent DV declarations, and percent of calorie declaration for macronutrients. Other features, such as adjectives or pie charts, received some favorable mentions, but fewer than the above features.

Respondents in focus group discussions often stated they would like to see a simpler and easier to use label than the current nutrition label. One focus group study (Ref. 85) asked respondents to consider in detail how they might use certain format features and found that pie charts and bar graphs were seen to be hard to use. Formats using adjectives were sometimes criticized because of suspicion about who decided how and when the adjectives were to be used.

FDA considers the focus group preference results to be consistent with the preference results of experimental studies.

c. *Informal preference polls.* Many comments from the general public were generated by articles in newspapers and newsletters that solicited consumer opinions in the form of informal polls based on examples of possible nutrition label formats. FDA considers such articles to be informal preference polls and therefore a form of research. FDA recognizes limitations on the validity of such research: respondents are highly self selected, no background information about respondents is available, responses are influenced by the accompanying news article, and responses depend on the choice set of formats given in the article. FDA has tried to identify the actual articles and the choice sets of formats presented to readers in interpreting these comments.

113. FDA identified seven informal preference polls that generated comments on the format proposal (Refs. 88, 89, 90, 91, 92, 93, and 94). One informal preference poll conducted by a consumer buying club in its newsletter (Ref. 88) asked consumers to rate their preferences toward three formats taken from FDA's research formats: ADJECTIVE, HIGHLIGHTING, and GROUPING. Over 400 responses were received. Seventy percent of the responses favored the ADJECTIVE format.

A midwest newspaper (Ref. 92) published examples of all seven formats used in FDA's format study 2 and asked readers to indicate which one they preferred. Approximately 100 responses were received. Sixty-five percent of the responses favored the ADJECTIVE format.

A consumer group newsletter (Ref. 90) published an example of a recommended format that included adjectives and a listing of DV's for macronutrients and asked readers to respond to FDA in support of the recommended format. Approximately 130 responses were received in support of such a format.

A nationally distributed newspaper and a regional newspaper (Refs. 91 and 93) published an example of a graphically enhanced PERCENT DV with DRV format (Appendix C from the format proposal). Approximately 40 responses were received. Sixty-five percent of the responses disapproved of the published format.

A major eastern newspaper (Ref. 89) published examples of four formats taken from the format proposal; PERCENT DV with DRV (Appendix C), CONTROL with DRV Ranges (Appendix E), CONTROL with Sex-Specific DRV (Appendix E), and CONTROL with Dietary Guidance (Appendix F). It asked readers to respond to FDA with their preferences, and approximately 450 responses were received. Two formats (CONTROL with DRV ranges and CONTROL with Sex-Specific DRV) were most preferred overall, each by approximately 35 percent of respondents.

FDA considers the results of informal opinion polls to be consistent with the preference results observed in experimental studies and focus groups. Most consumers say they prefer the format with the most information out of the set of formats they are asked to evaluate. However, FDA is not convinced that formats that have more information are necessarily the formats that best meet the criteria specified in section 2(b)(1)(A) of the 1990 amendments.

4. *Measures of consumer understanding.* Some of the research submitted or referenced in comments to the nutrition label format proposal consisted of survey questions about consumer understanding of various elements of proposed nutrition labels (Refs. 71, 87, 95, 96, 97, and 98). Some of these questions addressed topics such as whether consumers use nutrition labels and, if so, for what purposes. Other questions addressed the concept of a DV: how consumers understand it, whether they can use it, how they might use it, or whether they are aware of it. A third type of question about consumer use of format elements was how consumers assign magnitude estimates to nutrient levels.

FDA considers this kind of research about format elements to provide an important context for the decision about an improved nutrition label format. Although it does not directly address the format objectives specified by the 1990 amendments, this research does provide some insight on how consumers understand and use the nutrition label.

a. *Survey questions about consumer use of nutrition labels.* 114. Four surveys submitted as comments on the format proposal (Refs. 71, 87, 96, and 98) asked questions about how often respondents read nutrition labels and ingredient information on food packages. These studies consistently found that approximately 70 to 80 percent of consumers report that they read this information almost always, often, or sometimes. These figures are consistent with a number of other surveys (Refs. 99 and 100) that asked similar questions.

In several studies submitted as comments, consumers were asked about specific purposes for reading nutrition labels. One study (Ref. 71), which asked 5,600 respondents detailed questions about possible label uses, found that the most common purposes for reading nutrition labels were: To calculate how high or low the product is in certain nutrients, to get a general idea of nutritional content, to compare different types of food products, and to help determine brand choices. The least common purposes for reading nutrition labels were to help in meal planning or to figure out how much of the product you should eat.

Other submitted studies reported results consistent with these findings. Specifically, one study (Ref. 96) found that only 7 percent of those who read nutrition labels did so "to help in planning a specific meal." Another study (Ref. 87) found that 83 percent of respondents would be very or somewhat likely to use information on the food label to help reduce fat intake.

FDA considers the results of these questions about consumer uses of nutrition labels to show that consumers are already using nutrition labels for purposes that are consistent with the format objectives of the 1990 amendments. Indeed, the two most common types of reported uses: (1) To evaluate nutrition characteristics of single products and (2) to assist in making choices between products, correspond well to the two primary criteria specified for formats in the 1990 amendments. The agency believes that the introduction of a revised nutrition label and accompanying educational activities will have a significant impact on use of the nutrition label for these purposes in the future.

b. *Questions about Daily Values.* 115. FDA received a number of studies as comments on the format proposal that asked questions related to consumer understanding of the concept of DV's. One study (Ref. 96) reported that 22 percent of respondents said that they were familiar with the term "Daily Reference Value" or "DRV" compared with 65 percent who said they were familiar with the term "Recommended Daily Allowance" or "RDA". Two studies (Refs. 87 and 97) found that only about half of respondents could correctly identify (i.e., read from the label) the DRV for a specific nutrient.

One study (Ref. 71) found that approximately two-thirds of all respondents considered the DRV to be appropriate for "everyone" or "most people." The same study found that 71 percent of respondents considered the DRV to apply to them personally. However, two other studies (Refs. 87 and 97) found that approximately two-thirds of all respondents stated that they understood that a DRV based on 2,350 calories would be high for a person who ate less than a 2,350 calorie diet.

One study (Ref. 87) showed respondents a label with a listing of DRV information and a footnote stating that DRV's were based on a 2,350 calorie diet. It found that more than half of all respondents could not correctly answer a question about the number of calories on which the DRV was based.

FDA considers results of questions about consumer use and understanding of DRV's to be tentative and likely to change because the public's exposure to the concept has been very limited, and educational activities to explain the concept have not been undertaken. The experimental format research (see section V.D.2. of this document) did not find that listing the DRV's on the nutrition label had much effect in a positive or negative direction on label uses that required evaluation or comparison of specific products, although it did improve calculation of number of servings needed to meet a daily requirement. None of this research, however, evaluated the impact of listing the DRV's on the food label on consumers' overall dietary management behavior, either alone or in conjunction with possible education initiatives.

FDA concludes that in the absence of reliable guidance from research findings, it has to rely on other comments to evaluate the potential value of listing the DRV's on the food label as a guide to better overall dietary management behavior.

c. *Magnitude estimation of specific nutrient amounts.* 116. Two studies submitted as comments addressed the issue of consumers' ability to make correct magnitude judgments about the level of a nutrient when told the amount. One study (Ref. 87) found that over one-half of all respondents considered 13 g of fat to be a large amount of fat.

A more detailed study (Ref. 95) asked respondents to estimate whether a given amount of fat in a product would be considered a low, medium, or high amount of fat. The amount of fat was systematically manipulated to determine how respondents assigned magnitudes across a range of values (7, 13, 20, and 33 g of fat). At the lowest level (7 g of fat per serving), approximately 20 percent of respondents considered the product to be high in fat. At the highest level (33 g of fat per serving), approximately 50 percent of respondents considered the product to be high in fat. The same magnitude estimation results were found when the amount of fat was expressed as a percentage of the DRV for fat. When amount of fat was expressed as a percentage of the DRV for fat, however, respondents were slightly less likely to give a "don't know/can't tell" answer than they were when fat amounts were expressed in g. Also, respondents were more likely to give a "medium" answer when the level of fat was expressed as 50 percent of the DRV instead of 33 g.

FDA considers these findings to show that consumers estimate nutrient level magnitudes of fat in a reasonable manner. However, the agency also concludes that a tendency exists for some consumers to see low fat levels as too high and other consumers to see high fat levels as less than high. More research is necessary to determine whether these results might be due to response biases inherent in the particular kinds of questions being used, or whether they reflect the different attitudes toward fat in the general population. FDA considers these findings to be consistent with the results of magnitude estimation measures used in experimental studies (see section V.D.2. of this document). FDA is convinced that an important consideration for decisions about the nutrition label format is whether the format helps consumers make appropriate magnitude estimations of nutrient levels in the product.

E. Criteria to Use in Judging Nutrition Labeling Format

Section 2(b)(1)(A) of the 1990 amendments specifies the requirements that an appropriate nutrition label format must meet (see Section V.C. of this document), but it does not specify how to weight these requirements with respect to various possible label uses or how to weight the various measures intended to evaluate alternate formats against the requirements. The 1990 amendments also do not specify how to balance the benefits of a revised

nutrition label against the practical limitations of small package sizes and the interests of many consumers, particularly older and less educated consumers, to have a highly legible label. In the format proposal, FDA requested comment on the criteria to use in judging nutrition label formats.

117. Most comments strongly supported the view expressed in the format proposal that a simple, uncluttered nutrition label is highly desirable. Comments from consumer groups and health professional organizations emphasized the benefits of a simple and uncluttered label for older and less educated consumers. Comments from food manufacturers and industry associations emphasized in addition that a simple, uncluttered format would allow greater flexibility to accommodate packaging constraints. Consumer research conducted by industry and by FDA demonstrated that simpler, less cluttered label formats help consumers to make comparisons between products.

FDA is convinced by the research results and these comments that a simple and uncluttered format is the best way for information on the nutrition label to be "readily observed and comprehended," as called for by the 1990 amendments. Accordingly, FDA is taking the steps discussed below to minimize the amount of information and the number of columns used on the nutrition label.

118. A number of comments from food manufacturers, consumer groups and health professional groups called for consistent label formats for both FDA and USDA regulated food products. The comments identified many benefits of having a uniform format for all food products including: (1) Making it easier for consumers to compare different kinds of products, (2) making it easier for consumers to become familiar with, and to learn how to use, the new labels, and (3) reducing the likelihood of consumer confusion because of apparent inconsistencies between different food labels.

FDA agrees that consistency between FDA and USDA regulated food labels should be an important consideration in decisions about the nutrition label format.

119. A number of comments from food manufacturers, consumer groups, and health professional groups argued that decisions about the nutrition label format should be informed by consumer testing, and that the agency should not propose formats that have not been tested. For the most part, these comments were directed at three label formats included in the format proposal that presented more elaborate listings of DRV's and more extensive educational footnotes than any of the formats included in FDA's previous nutrition label format research.

The agency agrees with the comments that emphasized the importance of consumer research in informing decisions about the nutrition label format. However, the agency is satisfied that most of the format elements that have been suggested for a revised nutrition label format have been sufficiently tested to permit research-based conclusions about their effects on consumer comprehension and label use behavior. The agency's view is that format elements that were less well tested, such as those suggested by the three formats described above, do not introduce sufficiently novel elements to the nutrition label to require independent testing. Information about the performance characteristics of more cluttered labels, listings of DV's, and elaborate footnotes is already available from extant research and can be extrapolated to estimate the performance characteristics of these particular formats as well.

120. The agency received a number of comments about the relative importance that should be assigned to product comparison versus dietary judgment measures of format performance in making decisions about nutrition label format. Many comments, primarily from food manufacturers and trade associations, argued that enabling consumers to compare the nutritional characteristics of food products is the fundamental use for the nutrition label and concluded that label formats should be evaluated mainly on this basis. Other comments, primarily from consumer groups and health professional organizations, gave more emphasis to the importance of the food label for helping consumers to make dietary judgments about the nutritional value of the food product that involve placing the product in the context of a total daily diet. These comments concluded that decisions about a nutrition label format need to take account of both product comparison measures and dietary judgment measures. The research on the reported frequency of different kinds of nutrition label uses showed that comparing products and assessing nutritional value are the two most important consumer uses of the nutrition label and are considered about equally important by consumers.

FDA is convinced by the research and by these comments that decisions about a nutrition label format should consider both types of label uses and evaluation measures rather than only one. Use of the nutrition label to compare products is dependent on the consumer's ability to comprehend the nutrition information, and use of the nutrition label to assess nutritional value is dependent on the consumer's ability both to comprehend the information and to understand its significance in the context of the total daily diet. Accordingly, FDA has considered these primary nutrition label uses in making decisions about the nutrition label format.

121. One comment from a health professional argued that consumer preferences for nutrition label formats should be considered as important as the ability of a format to achieve the format objectives specified in the 1990 amendments because a format that is more preferred will be more likely to be used by consumers.

FDA is not aware of any data that support the assertion that a more preferred label format will be more likely to be read. The agency's view is that people read the nutrition label because they are interested in what it says, not because they have an impulse to read the label based on its appearance. Actual ease of use, that is, the ease with which a consumer can extract needed information from the nutrition label, rather than preference for a format, is likely to influence the probability of reading a nutrition label. The consumer research shows that consumer preference for different label formats is, if anything, negatively related to actual ease of use (see sections V.D.2. and V.D.3. of this document). Therefore, FDA does not agree that preference should be considered as important as performance criteria for decisions about nutrition label formats.

122. One comment from a consumer organization argued that label uses should be weighted according to the likelihood that consumers engage in such uses. The comment recommended that less importance be given to label uses that assume that consumers will add up their daily totals of fat, saturated fat, or other nutrients because relatively few consumers are likely to engage in such difficult and burdensome monitoring. The comment suggested that many more people are interested in making qualitative judgments about individual foods, such as "is this food high or low in fat?" and recommended that dietary judgment measures assessing this aspect of label use be given the most weight in decisions about the nutrition label format.

Consistent with the comment, the consumer research did not show quantitative monitoring of dietary intake to be a common label use behavior.

However, it also did not show that making qualitative judgments about a food is the only important use of the nutrition label (see comment 114 of this document). FDA is convinced by the research that helping consumers to make qualitative judgments should be an important, but not overriding, consideration in making a decision about the nutrition label format. Other evidence shows that consumers use the nutrition label to compare products and to assess a product's nutritional value. Accordingly, FDA has considered facilitating qualitative judgments as one of the dietary judgment factors important for evaluating the various proposed formats.

F. FDA's Tentative View

In the format proposal, FDA presented its tentative conclusions about the elements that it will include in the final nutrition format and requested comments about them. The agency listed the following four elements as those that were likely to be included in the final nutrition format:

(1) The information must be presented in a manner that is simple and minimizes clutter.

(2) The information must be presented in tabular fashion, although perhaps enhanced by other graphic devices to provide rapid access to, and greater visibility of, key nutrition information.

(3) The nutrition information display must include either a listing of the quantitative amount of each nutrient, in absolute terms (e.g., g), or a listing of the amount as a percent of the proposed RDI or DRV, or both.

(4) Nutrient information must be linked to the dietary guidance that is considered important to public health.

123. Comments mentioning the first three elements were unanimously supportive. Comments mentioning the fourth element were generally supportive, although a number of comments argued either that the nutrition label cannot or should not be the primary vehicle for providing general dietary recommendations, or that educational materials should not appear on the food label at all.

The agency disagrees with statements that the nutrition label should not play a role in educating consumers. FDA is convinced that the nutrition label is an important source of basic information for consumers, and that the 1990 amendments require that the label facilitate consumer education. The agency's view of the educational role of the nutrition label is elaborated in section V.B. of this document.

However, the agency does agree that the nutrition label cannot be the primary vehicle for providing general dietary recommendations. Accordingly, as discussed later in this document, FDA, USDA, health professional organizations, and the food industry are developing a comprehensive consumer education program that will ease the transition to the revised nutrition label and help consumers to use the label to make well-informed dietary choices.

FDA points out that under the act, the requirement that nutrition information be linked to dietary recommendations need not require presentation of dietary guidance on the label. The House report that accompanied the 1990 amendments states, "While the bill does not mandate any particular approach, it does require the Secretary to specify requirements that would permit the consumer to understand the nutrition information pertaining to a particular food in relation to recommended dietary information" (Ref. 16). The declaration of nutrient amounts as percent DV provides such information. For the nutrient in the food for which a DV has been established, the percent DV advises the consumer how much of the recommended intake of that nutrient is provided by the food. Seen in this way, a requirement that nutrition information be linked to dietary guidance plays a greater role in describing the food than in presenting educational material.

G. The Format and Format Elements

FDA received approximately 1,000 responses to the format proposal and to a public meeting, notice of which was given in the *Federal Register* of July 23, 1992. Responses were received from consumers, health professionals, trade and retail associations, State and local governments, foreign governments, professional societies, consumer advocacy organizations, industry, and universities. Many of the comments selectively responded to issues of particular concern to the individual or organization commenting, but a large number included a reference to the specific formats favored or opposed.

1. Titles and Terminology

a. *Title for the nutrition label.* 124. A number of comments addressed the issue of the title for the nutrition label. The majority of comments supported retaining the current label heading "Nutrition Information per Serving." Comments suggested that consumers are familiar with this heading, and that the title is descriptive of the information that follows. One comment opposed the introduction of any new title because new terms are confusing. Another comment expressed concern that new titles have not been proposed or tested. Other comments suggested such terms as "Nutrition Information," "Nutrient Information," and "Nutrient Facts."

FDA acknowledges that the current title is descriptive and familiar to consumers. However, the agency also notes that the current title requires more space than several alternatives that are equally descriptive. The agency has concluded that modifying one of the suggested alternatives to "Nutrition Facts" yields a term that will clearly describe the information declared on the nutrition label. This more succinct term also allows the title of the nutrition label to use a larger typeface in the same space so that the nutrition label will be more readily noticed, and thus, more readily observed by consumers. Accordingly, in § 101.9(d), the agency is requiring that the term "Nutrition Facts" instead of "Nutrition Information per Serving," be presented as the heading of the nutrition information.

b. *Terminology for subcomponents of nutrients.* In its format proposal (57 FR 32070 at 32071), FDA solicited comment on certain format elements not addressed by research studies. The agency requested comment on what terminology and graphic elements would most effectively distinguish subcomponents of nutrients from the declaration of the total amount of the nutrient and improve their visibility in the nutrition label display.

i. Subcomponents of fat and of carbohydrate. 125. The majority of comments supported the use of the terms "total fat" and "total carbohydrate." Many comments suggested using indentation of subcomponents as a graphic means to further distinguish subcomponents because it is a commonly used technique that would be easily understood by most consumers. A few comments suggested bolding and highlighting of the broader classification to further distinguish subcomponents of fat and carbohydrate. Other comments suggested using such terms as "includes," "including," "of which," and "which includes" before the subcomponent to further establish that the subcomponent is a part of a broader classification.

Section 403(q)(1) of the act specifies that nutrition labeling shall include information on several nutrients, including total fat and total carbohydrates. In order to be consistent with the terminology used in the 1990 amendments, the supplementary proposal (56 FR 60366 at 60387 and 60388) included provision for listing "total fat" and "total carbohydrate" as mandatory elements of the nutrition label. Given the statutory derivation of

this terminology, the support for its use in the comments, the fact that the terminology reflects the broad category of nutrient, and the lack of opposition to the use of this terminology, the agency is retaining the provisions for the declaration of total fat and total carbohydrate based in § 101.9(c)(2) and (c)(6) and, by reference, in § 101.9(d)(7).

The agency agrees that indentation of subcomponents along with the use of the term "total" before the major classification provides effective means of establishing separate and recognizable subcomponent status. The agency is not providing for the use of terms such as "including" and "of which." While these terms may add clarity, they will also introduce additional words to the label, contributing to label clutter. The agency is persuaded by the comments that the use of indentation of subcomponents is sufficient to clearly distinguish the subcomponents of total fat and total carbohydrate because it is a commonly used and well understood graphic device. Therefore, the agency is requiring the indentation of saturated, polyunsaturated, and monounsaturated fatty acids in § 101.9(c)(2)(i) through (c)(2)(iii), respectively, and the indentation of dietary fiber, sugars, sugar alcohol, and other carbohydrates in § 101.9(c)(6)(i) through (c)(6)(iv), respectively, when such nutrients are declared. In addition, as explained in section V.H.1. of this preamble, the broader classifications must be highlighted by boldface print as provided in § 101.9(d)(1)(iv).

ii. Calories and calories from fat. 126. The plurality of comments supported using the term "total" preceding or following "calories" to denote that it includes the calories from fat (i.e., "total calories" or "calories, total"). Some comments suggested that a potential for confusion exists because "calories from fat" must be declared on the nutrition label, and consumers may be unaware that they are included in the larger category "calories." These comments expressed concern that consumers would mistakenly add calories from fat to the larger classification declared simply as "calories." Additionally, several comments suggested indenting "calories from fat" to further distinguish it from "total calories."

The agency is persuaded by the comments that the term "total" preceding or following "calories" will better enable consumers to understand that it is the larger classification of which the subcategory "calories from fat" is a part. The agency notes that it is requiring the term "total" for the other larger classifications, total fat and total carbohydrate. A label that has the term "total" preceding two of the three larger classifications may have the potential to confuse consumers with regard to the third. However, the agency also notes that the term "calories" has fewer words, and therefore requires less space and minimizes clutter. Furthermore, consumers have been seeing the term "calories" on labels to designate total calories, and, unlike the other nutrient subcomponents, the subcomponent "calories from fat" designates subcomponent status by its structure. Therefore, in § 101.9(c)(1), FDA is providing for the use of the terms "total calories;" "calories, total;" or "calories." In addition, in § 101.9(c)(1)(ii), the agency is requiring that the subcategory "calories from fat" be indented for consistency with other nutrient subcomponents when it is listed in a column under the total calorie information.

c. *Terminology for Daily Reference Value.* In its mandatory nutrition labeling proposal (55 FR 29487) FDA asked for comments concerning an appropriate single new term to be used to refer to all the reference values in the nutrition label. On its own, FDA arrived at "Daily Value (DV)" as a possibility for use as this single term. FDA used this term in the research that it conducted on formats. Most consumers correctly interpreted the general meaning of the term. However, during probing in focus group discussions conducted by the agency, several consumers commented that the word "value" may connote something of worth and suggested that another term might be appropriate for food labeling purposes. In its supplementary proposal published November 27, 1991 (56 FR 60366 at 60371), the agency reiterated its request for comment on, and suggestions for, appropriate terminology to be used to refer to the entire set of reference values.

127. A number of comments responded to the issue of terminology for a single term to denote all label reference values. Two comments stated that the word "value" may give the impression that these levels are goals to be achieved rather than points of reference. A wide range of alternative terms were offered, including "Human Daily Need," "Recommended Daily Standard," "Reference Value," "Daily Amount," "Reference Daily Intake," and "Recommended Daily Intake." However, no general agreement emerged from the comments, and no research data were submitted in support of suggested alternatives for the term "Daily Value."

One comment stated that the term "reference" has little meaning for most consumers, while a few others said that the use of the term precludes persons assuming that the value is a goal. Another comment stated that the term "standard" avoids the confusion of having to differentiate between minimum and maximum intakes. One comment suggested that the term "U.S. RDA" be retained to denote all label reference values. Many other comments requested retention of the U.S. RDA's; however, those comments appeared to be referring to retention of the current numerical values for the U.S. RDA, not the terminology to be used on the label.

FDA disagrees that the term "U.S. RDA" should be retained. The term was developed in 1972 when label reference values for all nutrients listed on the label were derived from the Recommended Dietary Allowances (Ref. 23). The term was developed to suggest the link between the Recommended Dietary Allowance and the label reference values developed by the agency. However, the reference values for a number of the nutrients that are to be included in the nutrition label, under the final rule on DRV's and RDI's, published elsewhere in this issue of the Federal Register, are not based on a Recommended Dietary Allowance value because the National Academy of Sciences has not established Recommended Dietary Allowances for these nutrients. It therefore would be inaccurate and misleading to retain the term "U.S. RDA."

Further, the agency believes that terms that use the words "recommended," "requirement," or "need" would be misleading to consumers and would complicate nutrition education efforts. Some of the reference values that FDA is adopting are intended to guide consumers relative to maximum intakes (for example, saturated fat), while others are intended to serve as a basis for planning general diets to meet nutrient requirements (for example, vitamin C) or as minimum intakes (for example, potassium). It would be incorrect to imply that FDA "recommends" that consumers consume the maximum intake level for total fats, or that such levels are "required" or "needed." Also, FDA cannot agree that the term "standard" is appropriate. While the comment argued that this term does not suggest a minimum or a maximum, the agency believes that it commonly implies a level to be achieved or surpassed, and for which it is undesirable to fall below. Thus, it may connote a minimum level for many consumers.

Moreover, the term "daily intake" suggests a requirement or prescriptive

need for individuals, rather than a general reference point. Furthermore, the agency is concerned that if the term were used, it could become a source of confusion in information and educational materials on nutrition because "daily intake" for nutrients is used to mean current consumption levels, rather than reference intakes based on dietary recommendations. For example, the current daily intake of fat is estimated to be 95 g per day based on food consumption surveys. However, the agency's DRV for fat is 65 g for a 2,000 calorie diet and is based on dietary guidance.

After reviewing the comments carefully, the agency concludes that it is appropriate to retain the proposed term "Daily Value." FDA research has shown that the term is generally understood by consumers as a point of reference, and no appropriate or well-supported alternatives have been suggested to the agency. FDA acknowledges that two comments suggested that the word "value" may be indicative of a goal. However, no data were submitted to support this suggestion, and no other comments objected to the term on these grounds. Therefore, FDA will use "Daily Value" as the single term to refer to all reference values on the nutrition label and is providing for its inclusion in § 101.9(d)(6).

To preclude any confusion, the agency points out that the Daily Values are a specific, regulatorily established set of reference values that have been derived based on dietary guidance and, for certain nutrients, on the assumption of a 2,000 calorie per day diet (see the document on RDI's and DRV's published elsewhere in this issue of the **Federal Register**). FDA recognizes that alternate daily caloric requirements (e.g., 2,500 calories) produce alternate recommended values for those nutrients with dietary recommendations that are based on calorie requirements, and that these alternate values can be considered "daily values" for people consuming the given calorie level. However, the recommended values for various calorie intake levels other than 2,000 calories per day should not be confused with the Daily Values, specifically the DRV's that FDA is establishing by regulation (see § 101.9(c)(7)(iii)) and that are referenced in several of the regulations that FDA is adopting today (see, e.g., § 101.13).

2. PERCENT DV Format

The majority of comments that supported the PERCENT DV or PERCENT DV with DRV format were from consumer groups and health promotion organizations, although several industry and other types of organizations also supported the proposed format. The majority of comments that opposed the PERCENT DV format were from industry.

128. The major argument given in support of the PERCENT DV format was that the percent formats are easy to use and provide clear information about how a food fits into a total daily diet. FDA's research showing that the percent formats have superior performance characteristics, particularly with regard to label tasks related to dietary judgments, was sometimes cited. Some comments argued that consumers are mainly interested in using the nutrition label to make qualitative judgments about specific foods, such as whether the food is low or high in a nutrient of interest. Many fewer people, it was argued, keep running lists of nutrient amounts throughout the day. The comments argued that the percent format facilitates this type of qualitative judgment.

Many of the comments opposed to the PERCENT DV format also addressed the issue of consumers' ability to use the PERCENT DV information, arguing that consumers would not be able to use percent displays effectively. Specific arguments included that the percent formats did not perform well in the Grocery Manufacturers of America and the National Food Processors Association (GMA/NFPA) industry study (Ref. 71), and that consumers do not understand percents.

FDA has carefully considered the arguments regarding percent displays but finds no basis not to conclude that consumers will be able to use PERCENT DV declarations more effectively than they would any other format tested. The consumer research (see section V.D.2. of this document) supports the assertion that the PERCENT DV format, with or without a listing of the seven macronutrient reference DV's, improves consumers' abilities to make correct dietary judgments about a food in the context of a total daily diet. This result was replicated in three separate studies (Refs. 70, 71, and 74), two of them industry-sponsored, and on three different dietary judgment tasks: judging the correctness of nutrient claims about the product, identifying the nutrients in the product that needed to be counterbalanced by changes in the daily diet, and judging how much to eat of the given food if you want to reduce intake of certain nutrients. In one industry-sponsored study (Ref. 71), the PERCENT DV format helped consumers judge how much to eat of a given food despite the fact that PERCENT DV formats were executed with extra columns of nutrient information per serving.

As noted in section V.D.2. of this document, the percent DV format element is one of only two format elements that have been shown to improve consumer performance on dietary judgment tasks (the other format element is the use of adjectives). In addition, the PERCENT DV format, when executed without additional columns, scored as well or better than any other format on all of the other tasks measured in FDA's study. No evidence was submitted to FDA showing that consumers cannot effectively use a PERCENT DV format when it is appropriately executed.

FDA studies (Refs. 69 and 70) found that for label use tasks involving simple comparisons between products, PERCENT DV declaration formats were best executed as single column displays with g/mg amounts next to the nutrient name and not in a column. Executed in this manner, no difference was found between PERCENT DV formats and the CONTROL format on product comparison tasks.

The GMA/NFPA industry study (Ref. 71) found that when the format was executed as two adjacent columns of numbers with different units (g/mg amounts and percent DV declarations), performance on simple comparison tasks was adversely affected. This result is likely attributable to the additional columns added to the format, particularly since the units differed, and is not an inherent weakness of the PERCENT DV declaration formats (see section V.D.2. of this document). FDA considers the placement of g/mg amounts in an unordered array next to nutrient names to be a necessary feature of the PERCENT DV format because it improves consumers' abilities to readily observe and comprehend the percent information on the nutrition label as demonstrated by FDA format studies. Thus, use of this format is consistent with section 2(b)(1)(A) of the 1990 amendments.

The argument that people have difficulty in understanding percents is not borne out by the consumer research. In the nutrition label situation, a consistent system of percents is used such that virtually all the nutrients on the label can be declared in equivalent units, in this instance percent DV. A list of nutrients declared in equivalent units has the unique property that the list of values is self-anchoring, that is, values in the list can serve as references for each other. A low value on the list is likely to be a "true" low value, a high value on the list is likely to be a "true" high value. This consistency is not possible when the list contains nutrients declared in very different units. Five g

of saturated fat may be a "true" high value and 115 mg of sodium may be a "true" low value, but few consumers see the number 5 as high and the number 115 as low according to FDA research. Percent DV declarations help consumers because they overcome the problems associated with declaring nutrients in nonequivalent units (see comment 106 of this document).

Gram/milligram formats with a list of DV's give consumers the numbers they would need to calculate percentages and thus to transform the amounts to equivalent numbers. However, research, including FDA's format research, has consistently shown that most consumers are unwilling or unable to transform data provided on labels (Refs. 70 and 101). Available evidence shows that providing consumers with raw data is not effective. Providing them with data in the form needed to make judgments, e.g., in consistent percentages, is effective.

Consumers have been seeing vitamin and mineral levels expressed as percent of U.S. RDA on food products for about 20 years. Few know what the U.S. RDA's are for specific nutrients or even know what units the U.S. RDA's are in. No arguments have been raised that percents in this context are difficult to use or hard to understand. The presentation of macronutrient data in percents is a logical extension of the system that consumers have been using with apparent success for years.

Therefore, FDA is requiring in § 101.9(d)(7)(ii) that nutrition information per serving be declared as percent of the DV in the primary columnar display on the nutrition label.

129. Many of the industry supporters of the PERCENT DV format cited the relatively small space requirements for the format, particularly if the DV listing is not required.

FDA agrees that the PERCENT DV format without a DV listing requires little additional space relative to the CONTROL format. A strength of the PERCENT DV format not shared by any other format except ADJECTIVE is that consumers can use it equally well for most label use tasks with or without the reference DV listing. For this reason, the agency is not requiring that the reference DV list be displayed as such. Rather, it is displayed as part of an example of recommended nutrient amounts for different calorie intake levels, and the normal placement is not beside the Percent DV information but beneath it.

In addition, the calorie-specific daily value list may be omitted in simplified formats and on small and intermediate sized packages (§ 101.9(f)(5) and (j)(13), respectively). In contrast, labels declaring amounts of nutrients only in g/mg units require consumers to compare the reference DV list with the amount declarations in order to make dietary judgments. Thus, for such labels, the presentation of the reference DV list adjacent to the declaration of amounts is necessary for most label use tasks.

Accordingly, § 101.9(d)(9) provides that daily values for 2,000 and 2,500 calorie diets be placed in columns beneath the vitamin and mineral information. However, if space is not adequate beneath the vitamin and mineral information, § 101.9(d)(11) provides that the calorie-specific daily value information may be placed to the right of the Percent DV information. In addition, § 101.9(f)(5) allows the calorie specific daily value information to be omitted from labels of products that qualify for the simplified format, and § 101.9(j)(13)(ii)(C) allows it to be omitted from packages with 40 or less square inches of label surface available to bear labeling.

130. A number of comments argued against the PERCENT DV format because of poor legibility of the basic format. They argued that legibility will be lower because the absolute amount declarations are hidden and are likely to be hard for consumers to find and because two numbers are required for each nutrient.

FDA disagrees that the basic format has poor legibility. The agency's research showed that consumers are easily able to use the PERCENT DV format displayed with amounts by weight in parentheses next to the nutrient name (see section V.D.2. of this document). Most consumers will not need to use the amounts by weight. The format prominently and clearly displays the one piece of nutrient information that will be most easily used and understood by the general population. The amounts by weight are provided for consumers who find it easier to use them, such as individuals who manage their diets using g/mg amounts.

131. Other comments argued that consumers will be confused because they will have to learn a new type of declaration, and those consumers used to the amount by weight declarations may mistakenly use the percentages as absolute amounts.

FDA disagrees with this argument. Evidence from consumer research shows that consumers generally are not able to effectively use the current format for some important label uses, such as placing a food in the context of their total daily diet (see section V.D.2.b. of this document). In contrast, research shows that consumers are able to use percent displays for all of the label uses tested, including those tasks related to dietary judgments, such as placing the food in the context of the total daily diet. As consumer education reaches more people, and as consumers become more familiar with the percent display format, its effective use will increase. In addition, under § 101.9(d)(7)(ii), as explained in section V.H.1. of this document, the symbol for percent (i.e., "%") must be used after each number. Therefore, consumers are not likely to use the percentages as absolute weight amounts.

Many of the comments opposed to the use of the PERCENT DV formats did not acknowledge that these formats provide g/mg amount information on the nutrition label. FDA included amounts by weight to meet the needs of consumers who had come to rely on such information. An appropriate balance must be achieved between how much and how prominently information can be presented on the label. The relative numbers of people likely to use different information is an important consideration in achieving this balance. Few people currently engage in the kind of dietary management that requires keeping daily running sums of particular nutrients, such as assumed by some of the comments opposed to PERCENT DV formats.

132. Several comments stated that PERCENT DV formats are misleading because they provide inappropriate dietary guidance or offer no guidance to those consumers whose daily requirements differ from the DV. Concern was expressed that consumers will believe the numbers apply to them personally.

The agency disagrees that PERCENT DV declarations are misleading because they provide inappropriate dietary guidance. A major advantage of a percent unit is that it communicates the relative magnitude of the nutrient level in a food without the consumer having to be concerned about the absolute level or units of the underlying scale being used. Knowledge of quantitative dietary goals for specific nutrients is not inherent in, or necessary for, accurate magnitude assessments of the nutrient levels in the food. The DV base of the percent does not have to exactly fit each individual's needs in order for the percent to accurately reflect the relative magnitude of the nutrient level in the product.

FDA considers estimation of the relative magnitude of nutrient levels in the food to be central to the placement of a food in the context of the total daily diet. FDA's research and other research submitted as comments to the format

proposal showed that consumers were able to use PERCENT DV formats to assess high/low levels of nutrients more effectively than any other format (see section V.D.2.b. of this document).Therefore, for purposes of placing the food in the context of a total daily diet, a label use for which consumers have no need to adjust the scale for individual variations, the declaration of nutrient amounts as percent DV cannot be considered misleading or inappropriate dietary guidance.

Although, for the reasons described above, detailed knowledge of the DV's and their relation to an individual's diet is not necessary for using a PERCENT DV format to make product comparisons or dietary judgments about the product, it is useful for other dietary management purposes. Information about how daily values vary by calorie needs will help those people who so desire to estimate their own personal daily values and will help them to differentiate the concept of a reference Daily Value used for labeling and regulatory purposed from personally appropriate dietary guidance.

Therefore, to decrease the likelihood of consumer misunderstanding, the agency is requiring in § 101.9(d)(9)(i) that a footnote accompany the percent DV declarations stating that these declarations are based on a 2,000 calorie diet, and that personal needs vary depending on an individual's calorie intake. In addition, to assist consumers in estimating their own quantitative dietary needs relative to the reference DV's, the footnote will display daily values of total fat, saturated fat, cholesterol, sodium, total carbohydrate, and dietary fiber based on 2,000 calories and 2,500 calories. By providing a concrete example of how individual dietary needs may vary depending on calorie intake level, the footnote will help people to place their personal dietary needs with respect to the reference Daily Values and to avoid any misunderstanding as to whether the reference DV's are dietary guidance relevant for them.

133. Several comments argued that PERCENT DV formats are mathematically misleading because they are calculated against an implied range if the terms "or less" and "or more" are used, or because consumers will not be able to reconstruct the percents from the absolute amounts and the DV numbers because of the rounding rules for percents of macronutrients.

FDA disagrees that consumers will see qualifying terms such as "or less" and "or more" as constituting a range from which a percent cannot be calculated. These terms were included on the PERCENT DV/DRV format in the second FDA label format study, and no subject expressed confusion resulting from their presence (Ref. 70).

FDA agrees that the rounding rules for percents for macronutrients and sodium in proposed § 101.9(c)(12) (56 FR 60366 at 60390) have the potential to cause consumer confusion when used with the PERCENT DV format. The agency notes that the amount by weight declarations for these nutrients have already been rounded, and that additional rounding of the percents may lead to an undesirable degree of inaccuracy, depending on the specific percent.

Therefore, the agency is requiring in § 101.9(d)(7)(ii) that percent declarations for macronutrients, sodium, and potassium in the PERCENT DV/DV format be calculated by using as the numerator the actual amount of the specified nutrient before rounding for label declaration. The resulting proportion will be transformed to a percentage and rounded to the nearest whole percent.

134. Some comments argued that the PERCENT DV format should not be selected because the lack of DRV's for some nutrients will result in blanks in the principal numeric column. The comments argued that such blanks will leave consumers with no information about the level of some nutrients and will be confusing to them. However, none of the comments that supported the PERCENT DV format suggested that the lack of DV values for some nutrients was a disadvantage of the format.

Several of the comments that discussed the lack of reference values in the context of whether the DV list should be required on the label provided arguments that apply to all uses of the DV information and thus also apply to the PERCENT DV format. These comments argued that it is more beneficial for consumers to have the values for some nutrients than to have the values for no nutrients.

The agency disagrees that blanks in the principal numeric column resulting from the lack of DV's for some nutrients is sufficient reason to reject the PERCENT DV format. The g/mg amounts will be listed for nutrients that have no DV, so that some information will be presented for these nutrients. Since a reference value has not been set for these nutrients, none of the alternative formats would give additional information to help the consumer evaluate the food with respect to nutrients that lack a DV. For example, no value will appear in the DV listing for the nutrients, so comparison of the amount in the product with the DV, as might be done with the CONTROL/DV format, would not be possible. No scheme for assigning adjectives or for highlighting would be able to include nutrients without a DV, so that formats using these elements would not present more information about such nutrients than the PERCENT DV format. Since no other format overcomes the gap in information that results from lack of DV's for some nutrients, the lack of DV's for specific nutrients cannot be seen a reason to reject the PERCENT DV format. The agency agrees with the comments that argued that presenting DV related information for some nutrients is more beneficial to consumers than withholding such information about all nutrients.

135. Some comments argued that PERCENT DV formats are calculated against a base that will change as scientific knowledge about nutrition changes, just as dietary guidance changes as knowledge increases, and that, therefore, a PERCENT DV declaration should not be required.

These comments address the issue of putting on the label dietary information that will change over time with increasing knowledge. The underlying assumption of these comments is that percent DV declarations will communicate quantitative dietary goals for specific nutrients, but, as discussed above (see comment 132 of this document), FDA's view is that percent DV's are not likely to be used for this purpose. U.S. RDA's have been subject to change in the same sense, but this fact has not prevented their successful use on nutrition labels as a basis for declaring nutrient amounts as percentages. Therefore, the agency disagrees that the possibility of change is a substantial reason to avoid percent declarations on the nutrition label.

136. A number of comments argued that PERCENT DV formats encourage good/bad food judgments.

The agency does not agree with this argument. Both FDA and industry research found that PERCENT DV declarations tend to produce the most accurate judgments about whether products are high or low in various nutrients. The g/mg formats were more likely to lead to extreme and inappropriate dietary judgments than PERCENT DV declarations (section V.D.2.b. of this document and Ref. 102).

137. One comment expressed the view that FDA does not have the legal authority to require percentages, since the 1990 amendments only require the declaration of amounts. Others argued that the 1990 amendments do not mandate that FDA change the current format.

FDA disagrees with these comments. As discussed above, section 2(b)(1)(A) of the 1990 amendments requires that the nutrition information be conveyed in a manner that enables the public to understand the relative significance of the nutrition information in the context of the total daily diet. Moreover, the legislative history states that this provision requires the Secretary to specify requirements that permit the consumer to understand the nutrition information about a particular food in relation to recommended dietary information (Ref. 16, p. 18). Expressing the level of a nutrient in the food as a percent of a reference amount (the DV) is the simplest and most straightforward way of permitting the consumer to understand the amount of a nutrient in the context of the total daily diet. Thus, the 1990 amendments provide clear authority to require percentages. Moreover, given the requirements of the 1990 amendments, and particularly the requirement in section 2(b)(1)(A) of the 1990 amendments, revision of the current format is unavoidable and necessary.

138. A comment from a foreign government stated that PERCENT DV information is country-specific because the DRV information on which it is based varies by country, and mandatory inclusion of percent DV information on a label would make it difficult to achieve equivalence in nutrition labeling requirements between the United States and other countries. The comment noted that their free trade agreement with the United States requires that the two countries work toward equivalent requirements on nutrition labeling. The comment pointed out that Codex guidelines provide for supplementary nutrition information only on a voluntary basis.

The agency supports efforts toward international harmonization of food labeling. However, the 1990 amendments direct FDA to require a number of format elements that are not in harmony with international food labeling. The agency believes that it has been directed to require a format that will enable consumers to choose appropriate foods and to place the food within the context of their total daily diet, without the constraints of meeting international guidelines.

3. The DV List on the Label

a. *Including the DV list on the label.* A number of comments from industry, consumer groups, and health promotion organizations addressed the issue of whether the DV list should be required, optional, or not permitted on the nutrition label.

139. The major arguments supporting mandatory inclusion of the DV list on the label, made primarily by consumer groups and health professional organizations, were: (1) That the DV's must be listed for people to estimate how their needs may vary from those represented on the label, particularly if the individual is on a more restrictive diet than represented in the DV's, (2) that consumers need the DV information on the label because they have to become comfortable and familiar with the DV concept in order for them to use the new nutrition label to place the food in the context of their daily diet, to put nutrient content information in perspective, or to provide a frame of reference for decision making, and (3) that consumers need the information because quantitative dietary goals are necessary in order to encourage and help consumers understand proper dietary practices.

The major argument against inclusion of the DV list on the label, made primarily by food manufacturers and food industry associations, was that consumers will misinterpret the DV's as dietary recommendations for their personal dietary needs, which will lead to the DV's providing inappropriate dietary guidance. Comments argued that DV's are unacceptable for dietary guidance because they are population based reference values for an "average" consumer that do not take account of individual differences such as sex, weight, activity level, and other factors influencing personal dietary needs.

Many comments opposed to requiring DV's argued that a listing of DV's on the nutrition label provides no product-specific information to consumers, and that mandating the listing on all labels requires repeating the same information on millions of food labels. One comment likened the requirement of placing the list of DV's on food labels to a requirement that banks provide addition and subtraction tables to their customers in each and every monthly statement. Many of these comments argued that inclusion of a list of DV's on the nutrition label will significantly increase the space requirements of the nutrition label, and that the increased space needs will make it extremely difficult for small packages to comply with nutrition labeling requirements.

Many comments opposed the mandatory inclusion of the DV's on the nutrition label because it will clutter the label and thereby decrease consumers' ability to readily observe and comprehend the nutrition information on the label. A number of comments, particularly from industry, supported optional inclusion of the DV list. The arguments for making the listing of DV's optional were similar to those for opposing it.

The agency finds merit in the argument that presenting the DV list on the label may potentially mislead consumers by giving undue prominence to values intended as references only and not as dietary guidance for individuals. The consumer research (see section V.D.4.b. of this document) showed that consumers were likely to interpret a single list of values labeled as "Daily Values" as personally applicable. At the same time, the agency agrees with the comments that argued that consumers should be able to assess how their personal dietary needs, which vary by factors such as age, sex, and activity level, may differ from the reference DV's used on the label. After extensive consideration, the agency is convinced that the best solution to these conflicting requirements is not to list the reference DV's identified as such as part of the primary information, but to provide a footnote as specified in § 101.9(d)(9)(i) that gives individualized daily values of total fat, saturated fat, cholesterol, sodium, total carbohydrate, and dietary fiber based on 2,000 calories and 2,500 calories.

Without a prominent display of the list of reference DV's for macronutrients on the label, the likelihood that consumers will misunderstand the reference DV's as personally relevant dietary guidance is greatly reduced. At the same time, a concrete example of how recommended nutrient amounts vary depending on an individual's needs will help consumers to understand how their own dietary needs stand with respect to the reference Daily Values.

The agency believes that the information in the footnote will accomplish virtually all the benefits that comments identified would follow from including the list of reference DV's on the label. By enabling consumers to evaluate the appropriateness of the percent DV's for their personal needs, the information in the footnote will serve to increase consumer confidence in the nutrition label and lead to more effective use. For consumers who want to practice quantitative dietary regulation that involves setting intake targets for certain nutrients and keeping a running tally of intake of these nutrients, the information in the footnote will provide maximum flexibility in the use of the nutrition label. The percent DV's on the label can be adjusted for different personal needs or an individual's caloric intake either by working with the percentages (such as having a target value of 120 percent

for 2,400 calorie diet and a target of 90 percent for an 1,800 calorie diet) or by working from absolute values derived from the calorie-based daily values in the footnote. The footnote will yield these benefits without implying that a specific reference DV is the appropriate target for every consumer.

However, FDA also agrees with comments that point out that inclusion of DV-related information on the nutrition label, such as that in the required footnote, imposes significant costs in terms of label space without providing product-specific information. Considering the appropriate balance, FDA is convinced that the agency should be flexible in requiring the footnote on product labels, particularly since the benefits of having such a listing are not relative to the specific food that carries the information, and that the information will be available to consumers if it appears on a significant percentage of food labels.

Therefore, the information specified in § 101.9 (d)(9) and (d)(10) may be omitted from small and intermediate sized packages as provided for by § 101.9(j)(13), and from products that qualify for a simplified format as provided for in § 101.9(f)(5).

140. Comments also addressed the placement on the label of information intended as context to help people more effectively use the nutrition information of the label. In the proposal, this information was a listing of the reference DV's. The agency has considered these comments in deciding the issue of the placement of the information in the footnote that FDA is requiring instead of a listing of the reference DV's. Several comments suggested that the daily value information should be required to be listed in a column beside the percent DV information, not in a footnote. Some comments agreed that placement in a footnote is sometimes necessary and suggested that FDA require a listing on separate lines rather than in a string. Others also recommended that placement in tabular form be required. Many of the industry comments stated that, in order to accommodate daily value information on many packages, flexibility in placement is essential.

Because the PERCENT DV formats do not require consumers to use information about the reference DV values to perform product-related dietary management tasks, the agency believes that allowing some flexibility in placement of the calorie-specific daily value information and excluding small and intermediate sized packages and products with simplified labels from the requirement to provide the footnote information will not compromise the effectiveness of the format (see comment 128 of this document). As long as the information appears on a substantial percentage of food packages, it will be readily available to consumers. FDA recognizes that the added information requires increased label space and agrees that manufacturers should have flexibility to place it so that they can use available label space efficiently. Thus, in § 101.9(d)(11), FDA is providing that the footnote information may be placed to the right of the percent DV information when there is not adequate space to place it beneath that information.

b. *Lack of reference values.* In its final rule on RDI's and DRV's published elsewhere in this issue of the Federal Register, FDA has established DRV's for total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, potassium, and protein. However, the agency has not established DRV's for polyunsaturated fat, monounsaturated fat, other carbohydrates, sugars, sugar alcohol, soluble fiber, and insoluble fiber. Formats that include these nutrients will show missing values under the percent DV and the DV columns. In the format proposal (57 FR 32059 at 32070), FDA requested comment as to whether the missing values will cause consumer confusion and, if so, whether it would be helpful to place an entry in the column stating that a reference value is not available.

141. The comments were divided on whether the lack of reference values for some nutrients would be confusing to consumers. Several comments stated that appropriate educational efforts would reduce consumer confusion, and that the potential confusion possibly caused by missing values does not outweigh the usefulness of providing the percent DV and DV information for nutrients for which such values exist. Several comments suggested that it was most appropriate to merely leave the entry blank, citing concerns about label clutter and the need to keep the label simple. Other comments suggested that the format include an entry of some type to indicate that a reference value has not been established. One comment pointed out that it is current practice for some food and supplement labels to state that a U.S. RDA has not been established for some nutrients.

As noted in comment 134, the agency agrees that presenting DV information for some nutrients is more beneficial to consumers than withholding such information about all nutrients. The agency is concerned about space limitations on food labels and label clutter. The label format presented in this final rule contains considerably more information than is required by the existing label, and comparisons to the current practice of stating that U.S. RDA's have not been established for some nutrients may overlook the increased information required on the nutrition label. Given the fact that nutrition labeling has been extended to virtually all foods regulated by the agency and the concern that too much information on the nutrition label may overwhelm consumers, FDA finds no basis to conclude that statements that a reference value is not available for the particular component will add clarity to the label. Therefore, FDA is not providing for the use of statements regarding the lack of established reference values.

c. *Use of qualifying terms in presentation of calorie-specific recommended nutrient amounts.* The agency proposed (57 FR 32058 at 32070) to require the use of the qualifying terms "or less" and "or more" in conjunction with the proposed DRV list. Comments about qualifying terms are relevant to the presentation of calorie-specific daily values, as provided for by § 101.9(d)(8). While the agency did not specifically discuss the nutrients for which each of these qualifying terms were appropriate in the proposal, the examples presented in the appendices made it clear that the agency's intent was to use these terms in conjunction with those nutrients for which current dietary guidance specifies an "open-ended" decrease or increase in consumption. Therefore, because recommendations for total fat, saturated fat, cholesterol, and sodium intake are stated in specific amounts or less (Refs. 2, 3, and 4), the agency used the qualifying term "or less" with these nutrients. On the other hand, the recommendation for carbohydrate is stated as 55 percent or more (Ref. 3). Thus the agency used the qualifier "or more" with this nutrient. FDA included such qualifiers in its research.

142. A few comments opposed the use of the qualifying terms because of the interest in reducing label clutter or because their use conveys a message that a food should be avoided if it contains high amounts of a nutrient qualified by "or less." Several comments opposed the use of the qualifying terms if a range of values was used rather than a single value. One comment considered the qualifying terms unnecessary if FDA adopts a 2,000 calorie base.

The majority of comments supported the use of qualifying terms and suggested that such terms convey to consumers the notion of a variable target intake rather than a prescriptive intake.

Some comments supported "or less" and "or more." Others stated that "less than" was preferable to "or less," and one stated that "no more than" and "no less than" were preferable to "or less" and "or more." These comments argued that the recommendation for saturated fat intake was less than 10 percent of calories from saturated fat, and therefore the use of "less than"as a qualifier in general was more appropriate. No comment presented data concerning consumer use and interpretation of qualifier terms. A comment suggested dropping "or more" for carbohydrate, regardless of calorie base, as it is in conflict with the Dietary Guidelines for Americans (Ref. 4), which recommend the use of sugars only in moderation.

FDA agrees that the use of qualifying terms assists consumers in appropriate interpretation of the daily value information and may help to preclude too literal an interpretation of the values. Moreover, since no single caloric level can be specific for all individuals, the agency concludes that qualifying terms are appropriate regardless of the caloric level used. Furthermore, the agency is convinced that regardless of which term is selected, the qualifiers should be used consistently to avoid consumer confusion.

FDA acknowledges that, while Diet and Health (Ref. 3) recommends that 55 percent or more of calories be consumed as carbohydrate, the Dietary Guidelines (Ref. 4) recommend the use of sugars only in moderation. The label format will list sugars as a subset of carbohydrate. The agency is persuaded that the use of the qualifying term "or more" or "more than" with carbohydrate has the potential to be misleading to consumers given that carbohydrate includes sugars. The use of this term may be particularly confusing to consumers when the source of carbohydrate in a food is primarily sugars. Therefore, FDA will not provide for the use on the label of the qualifier "more than" or "or more" with carbohydrate.

FDA finds merit in the term "or less" because this term is presented after the quantitative value and thus does not interfere with the consumer's ability to locate the quantitative values (especially when the daily values are presented in a column). However, the agency believes that the term "less than" conveys a less specific target and thus meets the concerns of many comments that asserted that consumers need to be alerted to the fact that recommended amounts vary greatly from individual to individual. The agency also acknowledges that the qualifying term "less than" is more consistent with the recommendation for saturated fat.

Therefore, FDA is persuaded that qualifying terms should be included when daily values are presented, and that the qualifying term should be "less than." The agency has included this requirement in § 101.9(d)(9)(i). For consistency and to avoid consumer confusion, FDA will not provide for the use of the term "or less."

143. One comment stated that the agency should allow the use of the term "or more" with dietary fiber because such a qualifier is consistent with current dietary guidance.

FDA disagrees that it is appropriate to use the qualifying term "or more" with dietary fiber. While there is relatively little evidence that high fiber intake impedes mineral absorption and bioavailability (Ref. 3), concerns about excessive fiber consumption have led to specific recommended ranges for dietary fiber intake rather than open-ended recommendations. The report from the Life Sciences Research Organization (Ref. 103), which provides the basis for the DV for dietary fiber, specifically provides a range for recommended dietary fiber intake (10 to 13 g per 1,000 calories, or approximately 20 to 35 g per day) and is not stated as 25 g or more. Therefore, the use of "or more" with fiber is not consistent with dietary recommendations, and FDA will not provide for its use on the label to qualify dietary fiber.

d. *Clarifying footnote for daily value caloric intake level.* In the format proposal (57 FR 32058 at 32071), FDA asked for comment on the effectiveness of a footnote to convey to consumers the need to modify the DV amounts to meet their nutritional needs and for suggestions for alternative footnote statements. The proposal included the following explanatory footnote in the PERCENT DV with DRV graphic format: "For a 2,350 calorie diet. Your Daily Value may be higher or lower depending on your calorie intake."

Comment was requested on the following three alternative footnotes listed in the proposal (57 FR 32058 at 32071):

(1) Based on a 2,300 calorie diet. Fewer calories are recommended for women and young children.

(2) As part of a 2,400 calorie diet. Many young children and women over 50 need 2,000 calories or less. For a 2,000 calorie diet the Daily Value would be less than 65 g Fat, less than 20 g Saturated Fat, less than 275 g Carbohydrate, and 25 g Fiber (Sodium and Cholesterol do not change).

(3) A 2,000 calorie diet is for women over 50 and young children. Most teenagers, sedentary men, active and very active persons, and pregnant and breastfeeding women need more calories.

144. Comments were received from manufacturers, health promotion organizations, State governments, trade associations, universities, and consumer advocate organizations. The majority of comments supported the requirement of a footnote to clarify the calorie base for the daily value listing.

The explanatory footnote in the PERCENT DV with DRV graphic format was specifically supported by five of the comments. This footnote stated "For a 2,350 calorie diet. Your Daily Value may be higher or lower, depending on your calorie intake." However, one manufacturer objected to this footnote on the basis that it was ambiguous and ineffective and did not provide the necessary information.

Most comments stated that it is important for the consumer to understand that the DV may need to be adjusted because it is based on the number of calories consumed, and recommended calorie consumption depends on various factors, such as physical activity level, age, sex, weight, height, and metabolism. Two comments, although opposing inclusion of the DV, argued that an explanatory footnote should be included if the DV is included.

Two comments objected to all of the alternatives. One comment, from a consumer advocacy organization, asserted that the third alternative listed above would create more confusion by attempting to identify every segment of the population.

Two comments, one from a health professional organization and the other from a food manufacturer, stated a preference for using the footnote in the format shown in appendix F (57 FR 32058 at 32089) as the footnote clarifying the DV list. This footnote summarizes the Dietary Guidelines and includes statements such as "Eat a wide variety of foods." However, it does not include a reference to the DV's or the caloric level on which they are based because the format that the footnote appears on does not list DV's. (The format in appendix F of the format proposal is discussed in section V.G.11 of this document). One of the comments recommending this footnote stated that the footnote should be prefaced with a statement about DV's varying with calorie needs. The following was suggested: "Your calorie, fat, carbohydrate, fiber, and protein intake will vary based on age, height, weight, metabolism and activity level."

A trade association opposed the footnote included in appendix F of the format proposal as the clarifying footnote for the DV list, stating that it added to the clutter, and that it did not provide any relevant information to the consumer because too many calculations would be required to use the information in the footnote. Two comments suggested that the statement in the footnote of appendix F, "choose a diet low in fat (30% or less)," be clarified to reference the total caloric intake for the day. One comment requested that footnote information be consistent with dietary guidance and the nutrition label by changing "Use sugar * * * in moderation" to "Use sugars * * * in moderation."

Various other suggestions were made for the appropriate wording of a footnote. Some comments were concerned with brevity in the interest of space. Other comments emphasized clarity, offering longer footnotes. Several comments were concerned with conciseness. Some variations arose from the preference for a range rather than a single number for the DV.

The various footnotes offered in the comments stated that an individual's DV depends on calorie needs, listed individual characteristics that affect calorie needs, or simply provided the calorie base of the DV on the label.

Three comments from manufacturers suggested that footnotes should be optional. Another comment suggested a voluntary program of explanatory information provided in footnotes, with a stipulation that the footnote become mandatory if 70 percent of packages were not including it by 1996. Two comments objected to inclusion of a footnote on the basis that the label cannot be a source of dietary guidance. Others were concerned about the space used by the footnote.

Two comments addressed other possible footnotes to the nutrition information. Inclusion of dietary guidance for special dietary needs was suggested by a manufacturer. A consumer advocacy organization suggested the use of footnotes to explain the use of adjectives such as "high" on the basis that FDA is wrong in assuming that people will relate "high" to the idea of limiting consumption elsewhere. The following statement was suggested: "People eating this food may need to limit the fat (or other nutrient) that they consume from other foods."

The agency notes that the consumer research suggests that many consumers do not notice footnotes. One survey asked respondents how many calories the DRV's were based on, while the respondents viewed a label with a footnote providing the information. Over half of the respondents could not give the answer (Ref. 87). Another study provided subjects with a nutrition label that had a footnote stating the caloric level base (2,350 calories) of the DRV list. Over 70 percent of the subjects stated that the DRV's applied to them (Ref. 71), even though, according to this report, this caloric base should apply to only 10 percent of the population. However, in other surveys, when respondents were asked directly whether DRV's based on a specific calorie level applied to them, most recognized that adjustment would be needed and were able to give the correct direction of adjustment (Refs. 87 and 97). These results show that although most consumers do not notice footnotes, those who are given the information (and by inference, those who do read the footnote) are able to interpret it appropriately.

FDA, in section V.B. of this document, has addressed comments regarding whether the nutrition label is subject to a requirement to provide general dietary guidance to consumers. The agency concluded that the first consideration for the nutrition label must be to help consumers make informed food choices by enabling them to both comprehend the nutritional value of the food and to understand its relative significance in the context of the total daily diet. Thus, general dietary guidance is not to be provided as part of the nutrition label. If a particular label has space, however, general dietary guidance may be included outside of the nutrition label, as discussed further below.

The agency does not agree that a footnote should be placed on the label urging people, after eating the food, to limit nutrients in which the food is high. Such information depends on the use of adjectives with the PERCENT DV format, which the agency is not allowing, as discussed in section H.4. of this document.

FDA agrees with the majority of comments that a footnote is necessary to help consumers determine how their individual dietary needs compare with the reference DV's used on the label and to prevent the possible misunderstanding of the applicability of the reference DV's (see comment 132 of this document). At a minimum, an acceptable footnote must specify the calorie level used for the reference DV's so that consumers have some basis to evaluate possible differences between their dietary needs and the reference DV's used on the label. Also, a statement that an individual's daily values vary according to calorie needs is essential when calorie-specific daily values are presented. FDA has provided for a footnote that includes this information in § 101.9(d)(9)(i).

The agency believes that many other pieces of information mentioned in comments, such as the information presented in Appendices E and F ... the format proposal, may be appropriately included on the food label to give useful context to the nutrition information. However, this information may not be included within the nutrition label itself because such additional information would require significant additional space to present and therefore would detract from the readily identifiable image of the nutrition label. Specifically, it would be appropriate to list typical calorie intakes for men, women, and children and to summarize dietary guidance on the food label. Furthermore, if the manufacturer is willing to supply copies of the Dietary Guidelines for Americans upon request, a statement of the availability of such information would be appropriate. Examples include the following:

(1) Typical intakes for women are 1,600 to 2,200 calories, for men 2,000 to 3,000 calories, and for children (ages 4 to 14) 1,800 to 2,500 calories.

(2) Use this nutrition information to help you plan your total daily diet. The Dietary Guidelines recommend that Americans:

- Eat a wide variety of foods
- Choose a diet with plenty of vegetables, fruits, and grain products
- Choose a diet low in fat (30 percent of calories or less), saturated fat (less than 10 percent of calories), and cholesterol
- Use sugars, salt, and sodium in moderation

(3) For more complete information, a copy of the "Dietary Guidelines for Americans" may be obtained from (manufacturer's name and address).

e. *Footnote listing the caloric conversion factors.* 145. A number of comments addressed the inclusion of caloric conversion factors for fat, carbohydrate, and protein on the label to help consumers use the nutrition information to apply the recommended Dietary Guidelines for Americans. Several comments agreed that stating the caloric value per gram of fat, carbohydrate, and protein would help consumers better understand and use the nutrition information on the label. Many other comments objected to the inclusion of caloric conversion factors because of space considerations and because of reservations about how many people would be able and likely to use such information.

The agency is persuaded by comments from nutrition education experts that the public will benefit from having the caloric conversion factors on the label. FDA recognizes, as discussed above, that 9, 4, and 4 calories per gram for fat, carbohydrate, and protein, respectively, are general factors that may not apply to all foods. However, they are applicable to the majority of foods, and therefore, inclusion of these factors will be useful as a general guide. Moreover, FDA finds that any concerns about space are eliminated by its providing for intermediate size labels in § 101.9(j)(13). Accordingly, § 101.9(d)(9) requires that this information be included on the label.

4. CONTROL Format; Expression of Absolute Amounts in Grams/Milligrams

The majority of comments that opposed the PERCENT DV formats supported the CONTROL format. A few comments supported the current format, rejecting the revised list of nutrients, the new order in which nutrients are declared, and the PERCENT DV display. FDA has responded to the comments opposing the revision in the required list of nutrients and the order of nutrients earlier in this document (section III.A.2. of this document). A majority of the industry comments supported the CONTROL format without the DRV list. Some consumer groups and health organizations also supported the CONTROL format; however, they recommended that the DRV list be included.

146. Most comments in favor of the CONTROL format stated that research has not consistently shown that any other format has better performance characteristics on label use tasks than the CONTROL format.

The agency disagrees with this argument. Both FDA's and industry's research found that the simplest label formats with the smallest amount of information and the least number of columns had the best performance for label use tasks that require only simple comparisons or identifying differences between products. Because it has the least amount of information, the CONTROL format performs well on this kind of task. FDA's research suggests that with certain placement of the information, some other formats, including the percent formats, that provide more information can perform as well as the CONTROL format on these tasks. The industry study demonstrates that these other formats can also be designed in ways that lead to poorer performance on simple comparison tasks (e.g., by adding more columns to the display).

Both FDA's and industry's research also shows that for label use tasks that require consumers to make dietary judgments about the product, such as whether the food is high or low in certain nutrients or how the food fits into a daily diet, the best performing formats are those that include either the PERCENT DV declaration or adjectives. Other design elements such as listing reference DV's, grouping nutrients, or highlighting nutrients do not appear to improve performance on these types of dietary judgment tasks. The CONTROL format is among the poorest performers on tasks that require dietary judgment.

Being able to comprehend the nutrition information and to understand its relative significance in the context of a total daily diet means, at least in part, that consumers must be able to make accurate high/low judgments about the food. PERCENT DV and ADJECTIVE displays present high/low information directly. The g/mg formats (such as the CONTROL format) require that the consumer calculate percentages to get the information. The CONTROL format requires, in addition, that the consumer know the recommended amount for each nutrient. Research results show that consumers do not know the recommended amounts for nutrients, that many are not able to make such calculations, and that many are not willing to make the large number of calculations that would be required to include all of the listed nutrients in the judgment (see comments 105, 106, and 107 of this document).

147. Other comments supported the CONTROL format because it is uncluttered, because consumers are used to it, and because it is more consistent with dietary guidance, which is given in terms of g/mg amounts, than is the PERCENT DV format.

The agency agrees that simplicity and lack of clutter are important criteria in selecting a format. However, enough effective information must be presented to make the nutrition label useful. Therefore, the selection of a required nutrition label cannot be based simply on which one has the least amount of information.

Some of the arguments about consumer familiarity with a format were addressed in section V.G. 2 above. The agency noted that evidence from consumer research shows that consumers are not able to effectively use the current format for some important label uses. Therefore, consumers' greater familiarity with it does not have important benefits. In contrast, research shows that consumers are able to effectively use the PERCENT DV format, even though the format is new to them. The agency also noted above that g/mg amounts will continue to appear on the nutrition label for use by consumers who have come to rely on nutrition information presented this way

148. A large number of comments were opposed to the CONTROL format because it does not meet the criterion in the 1990 amendments of enabling consumers to understand the significance of the nutrition information in the context of a total daily diet. This argument was sometimes stated in conjunction with FDA's research finding that the CONTROL format had poor performance characteristics, particularly with regard to the dietary judgment tasks.

FDA agrees with this argument. A summary of research findings related to the CONTROL format appears in section V.D.2. of this document. For all the reasons discussed in this section, FDA concludes that the CONTROL format is not adequate to meet the criteria of the 1990 amendments.

5. HIGHLIGHTING Format

Highlighting was discussed in the format proposal both as a separate format and as a format enhancement. Most comments regarding the use of HIGHLIGHTING dealt with it as a format enhancement, and these comments are discussed in a later section.

149. The comments that discussed HIGHLIGHTING as a format were from industry health professional organizations, and consumer advocacy organizations. Most comments were opposed to the format. Many of these comments discussed the HIGHLIGHTING, ADJECTIVE, and GROUPING formats together. The comments argued that the HIGHLIGHTING format is inadequate and misleading because it gives undue emphasis to desirable components, thus tending to obscure the levels of undesirable components. In addition the comments stated that the HIGHLIGHTING, ADJECTIVE, and GROUPING formats have no satisfactory means of communicating the level of components that do not have a DV, such as complex carbohydrates and sugars. Some comments argued that a modified HIGHLIGHTING format that flagged both desirable and undesirable components of a product should not be selected because extensive consumer testing would have to be conducted to determine whether people are able to distinguish between the two types of flags. Other comments argued that the HIGHLIGHTING, ADJECTIVE, and GROUPING formats foster good-bad food messages.

Several comments from professional organizations argued that the HIGHLIGHTING format is redundant because nutrient content claims can be made on the front of the package. These comments stated that if anything is highlighted, it should be undesirable components to balance the front panel. Other comments argued that this format did not score well in consumer research and did not improve consumer comprehension of the label. One comment noted that international harmonization is problematic with HIGHLIGHTING, ADJECTIVE, and GROUPING formats because in Canada, such information is generally required to be grouped together and given equal prominence, whereas these formats include some form of emphasis in one or more parts of the nutrition label.

A supporting comment argued that the HIGHLIGHTING format is best because it is straightforward, easy to understand, and information can be quickly gleaned from it. The agency is persuaded by the comments and the research that the HIGHLIGHTING format should not be selected. FDA notes that this format has most of the disadvantages of the CONTROL/DV format (of which it is a variant), and it has several additional limitations. The format did not score well in consumer research on measures that involved putting the food into the context of a total daily diet. In addition, it emphasizes desirable features of products, which may already be emphasized by front panel statements and which may tend to obscure the levels of less desirable components. Therefore, FDA is not requiring the use of the HIGHLIGHTING format.

6. ADJECTIVE Format

Issues regarding the use of adjectives to describe nutrient levels arose in three contexts: support or opposition to the ADJECTIVE format itself; mandatory use of adjectives with another format, particularly the PERCENT DV with DRV format; and voluntary use of adjectives as a format enhancement. Adjectives as a format enhancement are discussed in section V.H.2. of this document.

150. Some comments argued that adjectives are inherently value-laden and would communicate a good-bad food perception.

The agency does not agree with this argument. As noted above in the discussion of this argument for the PERCENT DV format (section V.G.2. of this document), both FDA and industry research found that the ADJECTIVE and the PERCENT DV declarations tended to produce the most accurate judgments about whether products are high or low in various nutrients (Refs. 70 and 71). The g/mg formats were more likely than ADJECTIVE formats to lead to extreme and inappropriate dietary judgments, such as responses that a food was high in a nutrient in which it was actually low, or that a food should be avoided altogether because of a particular nutrient level. The agency is not requiring the ADJECTIVE format for other reasons.

151. Several comments argued that a complete scheme for assigning adjectives to all nutrients required to be listed on the label does not exist. They argued that because DRV's have not been established for all nutrients, including sugars and polyunsaturated fats, an acceptable scheme would be time consuming to develop.

The agency agrees that a complete scheme for assigning adjectives to all nutrients does not currently exist, and that the lack of DV's for some nutrients would complicate the development of such a scheme. However, as explained in Comment 134, all of the alternative formats except the CONTROL format share the limitation that DV's have not been set for some nutrients. Because the limitation is constant for almost all formats, it cannot be seen as a disadvantage unique to one format. The agency believes that providing DV information for the nutrients that have DV's is more beneficial than withholding it for all nutrients because it is unavailable for some. Nonetheless, the agency is not requiring the ADJECTIVE format for reasons stated in comment 152 of this document. Therefore, the issue raised by these comments need not be addressed further.

152. Several comments opposed the ADJECTIVE format because it would be confusing to consumers. One comment argued that the format provides information on whether a nutrient is high, medium, or low, but not whether it is a desirable or undesirable nutrient. Some comments argued that the format is too cluttered and directive. Some comments noted that the ADJECTIVE format showed a number of weaknesses in the consumer research, particularly a tendency for consumers to fail to differentiate between products when different nutrient levels were described by the same adjective. The comments noted that wide ranges, as proposed for the category "medium," would be misleading to consumers who did not attend to the nutrient values.

Several comments supported the ADJECTIVE format, arguing that the format is easy to read and does not require math calculations or working with numbers at all. One stated that it would be easier for the elderly and visually impaired to use. Other comments supported it because it was preferred by consumers in the research.

FDA is not requiring the ADJECTIVE format for the following reasons. The agency agrees that the ADJECTIVE format showed weakness on an important label use task, the product comparison task that required detecting differences between nutrients. The agency also agrees with the comments that argued that the wide range for some of the adjective categories may be misleading to consumers who use the label in certain ways. The agency acknowledges that the ADJECTIVE format was the most preferred in some studies but notes that preference measures must be interpreted cautiously and cannot be used as a definitive criterion, for the reasons discussed in section V.D.3. of this document. The agency further notes that none of the studies provided evidence that the ADJECTIVE format is easier for elderly consumers to use.

7. GROUPING Format

Grouping by whether dietary guidelines recommend choosing a diet high or low in specific nutrients was tested in FDA's Study 2 (Ref. 70). This format element did not generate many comments, and the comments about it were frequently included in statements about the HIGHLIGHTING or ADJECTIVE format. Most of the comments were opposed to GROUPING.

153. One argument against the GROUPING format was that it is too value-laden, lending itself to a good–bad food message. Another comment argued that the GROUPING format does not provide meaningful information related to the particular product. Other related comments argued that the GROUPING format did not have good performance characteristics in research, and that subjects reported that they found it too prescriptive. Some comments argued that it would be confusing to consumers in general, and one comment argued that it would be especially confusing to consumers with diabetes.

The agency agrees with these comments. FDA's research showed that the GROUPING format did not perform well on the dietary management tasks and did not offer any significant advantages over other formats (Ref. 70). In addition, although the format was not strongly disliked, many subjects who disliked it reported that they found it too prescriptive. This complaint is consistent with the complaints of many of the comments.

The agency has decided not to require that nutrients be listed under the

GROUPING format headings for the reasons discussed in the paragraphs above and below.

154. A few comments argued that the GROUPING format would be a challenge to implement because adequate consensus does not exist on where to place some subcomponents, such as polyunsaturated fats. In addition, comments challenged the format because its recommendations are not entirely consistent with those of the dietary guidelines. For example, the dietary guidelines recommend moderate intake of some nutrients, such as sodium, but the GROUPING format recommends low intake.

The agency agrees that the placement of some nutrients and nutrient subcomponents is problematic under the GROUPING format. This problem in placing all nutrients is one of the reasons the agency has decided against the GROUPING format.

155. Several comments in support of the GROUPING format argued that it provides nutrition education by stating which nutrients should be eaten in greater and lesser amounts. A few comments argued that the proposed order of nutrients on the label tends to group them into those targeted for lower and higher intakes, so that the GROUPING format is unnecessary with the new nutrient order.

FDA agrees that the intent of the grouping format is to provide general dietary guidance. However, the fact that the format did not offer significant advantages over other formats on any performance measure considered in the consumer research shows that dietary guidance as offered in this format did not benefit consumers. The proposed new order of nutrients uses the widely accepted design of placing first the elements of greatest importance and is intended to accomplish some of the goals of the GROUPING format. The GROUPING format's failure to convey the intended dietary guidance, as measured in the consumer research (Ref. 70), is one of the reasons the agency has decided against this format.

8. Modified Grouping Format

A few comments mentioned the Modified Grouping format in which the order of the nutrients changed according to the amount in the product.

156. Almost all comments were opposed to the Modified Grouping format. The major argument against it was that it would reduce consistency and increase confusion among consumers. Comments stated that using this type of format is especially difficult for older people, who have a particular need for nutrition information. As the population ages, larger numbers of consumers will have difficulty with such a format.

The agency agrees with this argument and notes further that available research shows that with advancing age, consumers have increasing difficulty extracting relevant information from displays in which the order of nutrients vary (Ref. 104).

The agency is not requiring the Modified Grouping format because it has no reason to believe that this format would meet the requirements of the 1990 amendments for the reasons stated above. The agency further notes that consistency of placement of nutrition information is a principle that has guided the development of the new format because such consistency has been shown to help consumers, as noted above.

9. CONTROL Format With DV Ranges

In its format proposal (57 FR 32058 at 32072), the agency discussed several alternative formats to those tested by the agency. For those reference values based on caloric intake, one alternative was the use of a range of DV's based on a caloric intake range instead of a single caloric intake value (Appendix E in the format proposal). The agency requested comment on this alternative.

157. Comments were evenly divided concerning the use of ranges for DV's. A number of comments, primarily from food industry representatives, supported the use of a range for the DV's because a range could assist consumers in realizing that nutritional needs vary with individuals, and ranges are easier for consumers to work with than single DV values. Others supported the use of a range because the use of a specific reference value would cause consumers to conclude that the values applied directly to them as individuals. Several comments suggested specific caloric ranges to be used (including 1600 to 2800, 1600 to 2400, and 1500 to 2800).

A number of comments from a variety of groups, including consumer advocates and the food industry, argued against the use of ranges. Reasons for opposing the use of ranges included concerns that ranges would be confusing to consumers, that they would overwhelm consumers, that they are too broad to be meaningful, that they use more label space than single values, that consumers would not be able to calculate their reference value from a range, and that they have not been evaluated in appropriately designed studies to determine if they would be more effective and less misleading than a single value. One comment cited research conducted for the purposes of developing a dietary guidance graphic (Ref. 105) that showed that consumers experienced difficulties using a range of values relative to dietary guidance.

FDA has carefully considered these comments and concludes that there is not sufficient support, nor a substantial rationale, for providing reference values as a range. The agency notes that no comment contained research or other data to substantiate the utility or appropriateness of ranges. No evidence shows that consumers do in fact find ranges easier to work with, and no data suggest that ranges are less likely than single values to confuse or mislead consumers. In fact, the agency has reviewed the literature on how people assign magnitude to numbers (e.g., Ref. 120). This literature concludes that in order to estimate magnitude, people generally have to answer the question, "compared with what?" usually invoking a norm or reference standard as a context for comparison. The DV is intended to be such a reference standard. When expressed as a range, the value of the DV as a norm against which the level of the nutrient can be understood is compromised because the norm cannot be easily identified without additional assumptions and computations. Thus, the use of ranges is inconsistent with the 1990 amendments, which require that nutrition information be conveyed in a manner that allows consumers to comprehend the nutrition information (section 2(b)(1)(A) of the 1990 amendments). Ranges apparently have the opposite effect.

The agency is also concerned that the use of ranges would mislead some consumers to believe that the consumption of a nutrient at any level within the declared range is appropriate for them. For consumers whose calorie intake is at the middle or low end of the range, however, the label could induce consumption of nutrients such as fat or saturated fat in excess of the dietary guidelines, which would adversely affect public health.

For these reasons, FDA has rejected the presentation of reference values as ranges. The argument that consumers need assistance to realize that nutritional needs vary with individuals has been addressed by requiring daily value information for 2,000 and 2,500 calorie diets.

10. CONTROL Format With Sex-specific Daily Values

158. A few comments supported reference values based on gender (Appendix E in the format proposal). One comment suggested that gender specific reference values were appropriate because women have

different nutritional requirements than men. Other comments opposed the use of separate reference values for men and women. The primary concerns were the issues of space, readability, and clutter on the label. One comment suggested that the format presented too much information for the consumer to process. The same comment opposed gender-based reference values because their use did not recognize that some active women are more like men in terms of their calorie need, while some older men have calorie needs more like those suggested for women. Several comments argued that gender is only one factor to consider in determining an individuals's dietary intake, and therefore its presentation on the label has the potential of inappropriately emphasizing one factor.

While the agency acknowledges that women in general have different nutritional needs than men, FDA notes that such comparisons can be made for a variety of groups comprised of persons 4 or more years of age. Thus, the agency agrees that the use of gender specific reference values may inappropriately emphasize only one factor in evaluating dietary intake. However, the agency agrees that examples of recommended nutrient amounts for different calorie level intakes may help consumers to estimate their personal daily recommendations. Therefore, as discussed in comment 139 of this document, FDA is requiring the inclusion of recommended nutrient amount information for 2,000 calorie and for 2,500 calorie diets in the nutrition information.

11. CONTROL Format With dietary guidance

159. A number of comments, primarily from industry, supported the CONTROL Format with Dietary Guidance (Appendix F in the format proposal). Several comments supported this format on the basis that it was most like the current format and therefore familiar to consumers. Two comments argued that FDA should select the CONTROL Format with Dietary Guidance because USDA prefers it, and harmonization between the two agencies is important. Supporting comments argued that this format helps consumers to put the food in the context of a total daily diet, reinforces the dietary guidelines, and is simple and uncluttered. One comment suggested that the caloric equivalents of the macronutrients may enable consumers to better utilize the information provided.

The major arguments against CONTROL with Dietary Guidance were that the information is too vague to be effective and adds clutter to the label. Some of these comments noted that the footnote discusses foods when the information on the label is about nutrients, so that, except for vague information about fat, no relevant information about recommended nutrient amounts is available on this label. Several comments argued that it would not be clear to consumers that the dietary guidance information applied to total diet and not to individual foods. Other comments noted that because this format has not been tested, the agency has no basis to assume that consumers will be able to relate the dietary guidance to the nutrition information. Comments also pointed out that many calculation steps and further instruction would be required to apply the dietary guidance to the consumer's daily diet.

Some comments noted that the dietary guidance footnote would be problematic for meat products because it recommends a diet high in vegetables, fruits, and grain products, which might imply to consumers that they should not eat meat.

The agency does not agree that CONTROL with Dietary Guidance format as shown in the format proposal is consistent with the requirements, or effective for meeting the objectives, of the 1990 amendments. The addition of the dietary guideline and calorie conversion information does not serve to put the levels of nutrients in the food into the context of a daily diet. However, the format includes information that helps consumers to understand the significance of the nutrient levels in the food.

Therefore, the agency is incorporating one of the elements from this proposed format as a mandatory requirement of the nutrition label format. Specifically, FDA recognizes that it will be useful to some consumers to have the caloric conversion factors on the label. The placement beside the nutrient names as shown in Appendix F of the format proposal is not acceptable, however, because the g/mg amounts will be placed beside the nutrient names in the required format. Both pieces of information on the same line would decrease or eliminate the spacing that helps to make the format comprehensible. Therefore, the agency is requiring that the caloric conversion factors be included on the nutrition label as a footnote, as described in § 101.9(d)(10).

12. New Formats Submitted as Comments

160. One comment suggested a format for the nutrition label quite different from any other format suggested and quite different from any format that had been previously tested. Called a graphical profile, the format expressed quantitative nutrition information in terms of distance along a spoke radiating from a central point, where each spoke represented a mandatory nutrient component. The points on each spoke were connected with each other to form a pattern that distinctively identified the nutrient profile for the product. The comment claimed that the format has a number of advantages, including: (1) Providing consumers with easily remembered mental "shapes" of the products that they wish to consume or avoid and (2) helping consumers to place the food in the context of a total daily diet by allowing for easy comparison between the shape of the nutrient profile for the product and an ideal shape based on dietary recommendations.

FDA is impressed by the ingenuity of this format but is convinced that such an innovative format for the nutrition label cannot be required without extensive consumer testing. No consumer research to support use of this format to accomplish the requirements specified in the 1990 amendments was submitted. Furthermore, FDA notes that the format encourages a comparison between the specific food and the dietary guidelines, whereas the recommended comparison is between the total daily diet and the dietary guidelines. Therefore, FDA is not adopting the graphical profile format. The agency is prepared to work with interested persons to develop consumer research that would show the usefulness and validity of this format.

H. Graphic Enhancements and Format Elements

The agency received numerous comments concerning the various format elements and graphic enhancements discussed and illustrated in the format proposal.

1. Format Legibility

161. Many comments, particularly from older and vision-impaired consumers and from organizations and health care professionals serving their needs, suggested that the legibility of nutrition information should be improved through regulations specifying larger sized or boldface type, easier to read type styles, use of upper and lower case letters, minimum type

spacing, and greater color contrast between print material and background, such as black lettering on white background. An alternative suggestion was for FDA to specify minimum print size and color contrast.

A number of comments from package designers and from individual food companies pointed to the problems in requiring graphic elements that add to the space requirements for the nutrition label, given the limited size of many packages and the competition for label space from other required or desirable information (e.g., UPC information, storage and preparation instructions, recipes). Other comments urged the agency to set minimal and flexible standards for graphic requirements related to readability that would allow manufacturers to accommodate the wide variation in package sizes, package shapes, and current graphic elements on packages.

The agency recognizes that mandating graphic elements to assure a desirable level of readability for the required nutrition information has both advantages and disadvantages, particularly when these elements may require more space. The agency agrees that some flexibility in the mandated graphical elements is necessary in order to accommodate the wide range of packages on which the information will appear. However, FDA also agrees with the comments that stated that the readability of the nutrition label needs to be improved to help older and vision-impaired consumers who otherwise would be effectively denied access to nutrition information of food packages. The agency points out that, as stated in the format proposal (section V.B.), certain graphic techniques go directly to the requirements in the 1990 amendments (section 2(b)(1)(A)) that the information be presented in a way that enables consumers to readily observe the information.

With the aim of achieving minimal readability standards for the required nutrition information, FDA has developed for use in this document, and in the presentation of the new label, a format design that incorporates many of the graphic elements suggested by the comments to produce a more readable label. FDA agrees with comments that argue that a consistent "look" to the required nutrition information on food packages will help consumers to find the information on the package and to recognize the information for what it is—a profile of the nutrient content of the food. Although FDA is providing for some flexibility in label execution, companies are encouraged to use this label as a model for designing labels for their packages (see section 101.9(d)). The specifications for this presentation of the graphical elements are included in the Code of Federal Regulations as appendix B to part 101.

FDA understands that some flexibility in execution of the nutrition label is necessary to accommodate various package sizes and shapes and current graphic features that serve as brand identifiers. For these reasons, a number of graphic alternatives to the model label are permitted. For example, § 101.9(d)(11) allows the footnote to be moved to the right of the percent DV information if space is not adequate beneath the vitamin and mineral information, and § 101.9(d)(8) allows for a vertical display of vitamin and mineral information when more than four vitamins and minerals are declared.

In addition, although the model label calls for dark or one color type on a white or neutral color background, flexibility in background and type color is allowed § 101.9(d)(1)(i). FDA is aware that some products traditionally use color as a brand identifier and print nutrition information in white or neutral color type on a darker color background. This type of graphic technique, called "reverse type," is known to have poorer readability characteristics than regular type. FDA is not prohibiting the use of reverse type. However, FDA expects that unless impractical, the nutrition information will be presented in dark type on a light color background. Impracticability is presented by situations like those described above, in those situations in which reverse type will be significantly less expensive than the FDA preferred alternative, or in other similar appropriate circumstances. If reverse type is used, FDA expects that the impairment in readability resulting from such a technique will be compensated for by the use of other graphic techniques to improve readability, such as increased type size. It will not be acceptable to reduce the contrast between print and background, whether by light letters on a light background or dark letters on a dark background, to the point where readability of the label is significantly degraded.

Although the agency is committed to the flexible application of graphic techniques to achieve an acceptable level of readability for the required nutrition information, FDA considers it necessary in order to ensure that the nutrition information is conveyed in a manner that enables the public to readily observe and comprehend such information to set minimal standards and requirements for certain key graphic elements of the nutrition label. Such requirements will prevent confusion about the minimal level of readability that is necessary for the nutrition information. The key graphic elements that are specifically required on all packages are set forth in §§ 101.9(d)(1)(ii), 101.9(d)(1)(iii), and 101.9(d)(1)(iv). They consist principally of type size and type style requirements, namely that a consistent upper and lower case type style be used, that a single, easy-to-read type style be used, that product information be in at least 8 point type (the lower case "o" no smaller than 1/16th inch) with at least 2 points leading (i.e., space above and below letters) and kerned (space between letters) no tighter than −4 setting, and that headings, certain nutrient names, and percentage amounts be highlighted by bolding or other form of highlighting.

In addition, to preserve a readily identifiable image or "look" for the label, a number of other graphic elements are required, as discussed in § 101.9(d)(1)(i), (d)(1)(v), (d)(2), and (d)(7)(ii). These sections require a hairline box to set off the nutrition information, hairline rules in certain places within the nutrition label, larger print size for the title, "Nutrition Facts," and display of the percent sign (%) after the numerical value of the percent DV for each nutrient.

FDA has been persuaded by comments and careful consideration of alternatives that these requirements will benefit a substantial number of consumers who currently have difficulty reading nutrition information on food packages. FDA considers this benefit to be worth the cost of the small increase in space allotted to nutrition information that may be required for some food packages. The agency notes that the previous regulations on type size also mandated a minimum type size for the lower case "o" of 1/16th inch but applied the same minimum type size requirement to the upper case "o" as well, which resulted in most manufacturers using all upper case type styles. The practical effect of requiring upper and lower case type styles and keeping the same minimum type size requirement will be to increase the minimum size of upper case letters by approximately 30 percent. To further compensate for the increased demands on label space, FDA will allow the information in the footnote, which unlike the product specific information is the same for all products, to meet or exceed a 6 point type minimum type size requirement. FDA considers that the requirements for upper and lower case type styles, leading, and kerning will enhance the readability of 6 point

type enough that it will not present problems for most consumers.

2. Other Graphic Enhancements

162. Several comments from retailers, manufacturers, graphics designers, universities, and a nutrition professional group were directed specifically at reverse printing as used in the graphic adaptations of appendix C of the proposal. Two comments stated that reverse printing would be helpful to consumers and should be permitted on a voluntary basis. However, the remaining comments addressed technical or legibility problems. Several comments stated that the format examples were not readable, that the reverse printing overwhelmed the smaller type, and that "stacked" titles (i.e., with components arranged vertically, e.g., placing "servings" on one line and "per container" on the next line) were confusing. The principal technical problem mentioned was that reverse printing tends to fill in and become unreadable, depending on the printing process used and available label area.

One manufacturer of many products stated that only two out of four printing processes used by the firm would be able to implement the graphic adaptations of appendix C. Another manufacturer stated that it would be able to print reverse graphics only for large containers. A graphics design firm stated that reverse printing adds significant costs. Another design firm cited two technical barriers to reverse printing: Multi-screen labels are difficult to hold in alignment and retain clarity, and reverse printing cannot be applied to packages with light backgrounds because the background must be dark for light, reverse print, to show through. The comments stated that many brand identification colors are light, and manufacturers object to having to change them, arguing that brand identification would be lost.

FDA agrees that reverse printing should not be required, given the difficulties mentioned in the comments. The agency finds convincing the arguments against the legibility of reverse print discussed in the professional literature (Ref. 107).

Because of the need for flexibility to place the nutrition panel in variously sized panels, the agency does not object to stacked titles.

163. The majority of comments stated that other kinds of graphic enhancement of nutrition information, such as underlining, bolding, and using larger type size or contrasting color, would encourage and assist consumers in using the information. However, opinions were divided as to whether the combination of enhancements illustrated in appendix C of the proposal would be helpful. A number of comments criticized the graphic adaptations as cluttered, jumbled, obtrusive, or distracting from or overwhelming the smaller type. However, except for a few suggestions that graphic enhancements be entirely at the discretion of the manufacturer, the comments favored some degree of standardization through FDA regulations. Comments frequently stressed the need for uniformity of appearance of labels across the food supply to facilitate education efforts and consumer access to and use of the nutrition information.

Several comments from consumers, a graphics designer, and a nutrition professional group stated that the number of different font sizes on a label should be minimized to ensure legibility. One comment cited a book in support of this view (Ref. 108). Several comments urged FDA to keep the label uncluttered. Other comments provided specific guidelines for maximizing the label's usefulness. These guidelines generally involved removing as much print as possible, keeping titles linear rather than stacking them, and including only essential information.

Several comments from industry and health education organizations endorsed voluntary, judicious use of other graphic enhancements such as spacing, indentation, use of upper and lower case letters, and selection of type face and size. These comments generally opposed making such enhancements mandatory until consumer research is conducted to ensure that they effectively aid consumer comprehension. Other comments from groups representing older readers and the vision impaired provided research demonstrating the importance of type size, type style, type spacing, the use of upper and lower case letters, and contrast between type and background to these readers. A consumer organization suggested that FDA establish an advisory committee of experts to provide guidance for the selection of graphic devices for further consideration. Two manufacturers opposed graphic enhancements altogether as contrary to the requirements of 1990 amendments for consistency in presentation of information. One comment characterized the combination of extreme bolding and close proximity of columns in the graphic adaptation of the PERCENT DV with DRV format as diverting attention from the quantitative values and stated that, with respect to the objectives of the 1990 amendments, the format constitutes near misbranding.

Based on the research submitted in comments, the agency is convinced that it can proceed to require certain graphic enhancements. While some comments questioned the appropriateness of requiring such enhancements at this time, other comments submitted research that demonstrated that these enhancements are effective and appropriate for creating a nutrition label that is readily observable and comprehensible, as required by the 1990 amendments. The agency agrees that keeping the format uncluttered is important and therefore has minimized clutter in the model format. The agency has carefully considered which format enhancements to combine, based on the comments and the research presented.

FDA is convinced that the specific elements mandated provide a visually integrated image that will give the nutrition label a uniformity of appearance across the various types of packages in the market and will enhance consumer use of the information. For example, an important element in the appearance of the nutrition label is its pattern of bolding. In § 101.9(d)(1)(iv), the agency is requiring bolding of the heading "Nutrition Facts" which is being employed as an identifying title, like a logo or trademark, to distinguish the nutrition label from other information on the package, as well as bolding of headings of certain nutrient names and percentage amounts. The agency is convinced that this and the other measures that it is requiring will serve to establish the readily identifiable "look" that it is seeking and finds to be necessary to achieve the relevant goals of the 1990 amendments.

164. Comments were received from a consumer, a health care provider, a State government agency, and two manufacturers suggesting that industry be permitted to use graphical devices, such as pie charts, to illustrate nutrient content claims. Comments suggested that uniformity of labeling could be maintained by requiring that any supplementary graphics be placed outside the nutrition label area. Other suggestions were that FDA permit the voluntary inclusion on the label of information from authoritative sources, such as the Dietary Guidelines for Americans (Ref. 4) or Diet and Health (Ref. 3), to aid consumer understanding of nutrition information in the broader context of current dietary advice to the public.

FDA has no objections to the use of graphic devices to amplify or explain nutrition information, provided that the

illustrations are presented in a manner that is truthful and not misleading, and that the devices are not placed within the label area in which the nutrition information appears. The agency also agrees that supplementary information outside the nutrition label can help consumers better understand the characteristics of individual foods in relation to the total diet. However, such supplementary information must be consistent with the requirements for nutrient content or health claims that are established in companion documents published elsewhere in this issue of the **Federal Register**. Manufacturers are also encouraged to utilize other means to disseminate dietary guidance information, such as incorporation of such materials in promotional and print advertising materials or by means of shelf talkers and placards at point-of-sale.

165. Several industry comments requested that manufacturers be given flexibility, either in the case of small packages or in general, to declare vitamins and minerals and DRV's in either tabular or linear arrangement for both full and simplified formats. A manufacturer suggested permitting a linear array for micronutrients present at levels of at least 2 percent of the DV.

The agency agrees that manufacturers need flexibility in accommodating the required nutrition information, particularly for small packages and printable surface areas that are oddly shaped or narrow. Consequently, FDA is providing options in the display of a number of the types of information required. For example, in § 101.9(d)(ii), the agency is providing that the information about calorie-specific daily values and caloric conversion information may be placed beneath the vitamin and mineral declarations or to right of the Percent DV column. In § 101.9(d)(8), the agency is providing that the vitamin and mineral declarations may be presented vertically in the Percent DV column when more than four vitamins and minerals are declared or horizontally beneath the macronutrients. In § 101.9(f), the agency is providing for optional use of a simplified format under certain circumstances. In § 101.9(j)(13)(i), the agency is providing exemptions to the requirement to bear nutrition labeling for small packages, and in § 101.9(j)(13)(ii), the agency is providing options for intermediate sized packages to minimize the amount of label space that must be used for nutrition labeling. For small or intermediate sized packages, manufacturers may list nutrition information in a linear fashion, use certain abbreviations, omit the calorie-specific recommended nutrient amounts, or present the nutrition information on other label panels (see sections V.G.3., V.H.1., and V.J. of this document).

3. Highlighting

In the format proposal, the agency requested comments on the feasibility of allowing highlighting as a voluntary graphic enhancement of the principal format. Specifically, the agency requested comments related to whether the use of voluntary highlighting would confuse or assist consumers to observe and comprehend label information. Many different possible schemes for highlighting could be applied to the nutrition label. Many comments addressed noncontingent highlighting, in which certain material is highlighted regardless of any product characteristics, such as highlighting certain nutrient names (e.g., fat, sodium, cholesterol) or titles (e.g., Percent DV, Amount per serving) on the nutrition panel. Other comments addressed contingent highlighting, in which certain material is highlighted only if the product has certain characteristics, such as highlighting the nutrition information for fat on the label of a product that meets FDA's criterion for low fat. In it's research, the agency tested a contingent highlighting scheme that highlighted nutrients whose levels in the food qualified for adjectival descriptors (high or low depending on the nutrient) that were consistent with dietary guidelines.

Many different possible techniques of highlighting exist, including boldface print, all capital letters, italic print, larger print, reverse print, different colored print, and color banding. In the format examples published in the format proposal, only boldface print was used for highlighting.

166. Many of the comments that discussed noncontingent highlighting suggested that highlighting should be considered as a format enhancement and should be used for column headings and names of nutrients. Other comments argued that the agency should require the highlighting of certain nutrients because of their health significance regardless of the level in the product. The nutrients most frequently mentioned in the comments in this regard were those associated with chronic disease, such as sodium, fat, and cholesterol. Most of these comments suggested that boldface type and all capital letters are adequate to achieve such highlighting.

Several comments addressed the issue of whether noncontingent nutrition label highlighting should be mandatory or voluntary. Some manufacturers objected to any required highlighting because of the increased cost and increased label space required. Other comments argued that if highlighting is allowed at all, it should be mandatory so that the benefits of highlighting would be universally available to consumers, and so that labels would be uniform. Some of these comments argued that uniformity of labels is important to reduce consumer confusion.

The agency agrees than mandatory highlighting imposes some burden on manufacturers and needs to be justified on the basis of obvious benefits to consumers. The agency also agrees that the use of highlighting to enhance column headings and nutrient names can increase the visual interest of the label and make it more legible for some consumers.

However, the agency is concerned that allowing too many optional highlighting schemes will lead to less consistency between labels, and that highlighting has the potential to increase label clutter and consumer confusion. Therefore, in § 101.9(d)(i)(iv) the agency is requiring mandatory highlighting of the title of the nutrition panel, "Nutrition Facts", headings ("Amount per serving" and "% Daily Value"), nutrient names ("Calories", "Total Fat" "Cholesterol," "sodium," "total Carbohydrate," and "Protein") and percentage amounts for certain nutrients. The agency concludes that these requirements, by establishing a specific "look," strike an appropriate balance between establishing a nutrition label that is readily observable and one that only increases clutter and confusion.

The agency does not agree that nutrients associated with chronic disease should be highlighted. The agency notes that the revised order of the nutrients already calls attention to the nutrients of major public health significance.

167. Several comments supported or opposed the voluntary highlighting of certain nutrients based on their level in the product (contingent highlighting). Supporting comments, primarily from food manufacturers or trade associations, argued that allowing such highlighting would provide useful information to consumers. Opposing comments, primarily from health professionals, professional associations, and consumer advocate or health promotion organizations, argued that allowing contingent highlighting on a voluntary basis would likely lead to inconsistent and possibly self-serving

highlighting that would be more likely to misinform than inform consumers.

Several comments supported contingent highlighting but recommended that it be subject to the definitions used in FDA's research studies or to the requirements for nutrient content claims, because highlighting is a nutrient content claim. Related comments supported a link between a nutrient content claim on the front panel and highlighting the relevant information on the nutrition panel. For example, if a low fat claim is made on the front panel, the nutrition information for fat would be highlighted.

Some comments recommended that highlighting of undesirable rather than desirable aspects of foods be required because manufacturers will emphasize the good qualities, and such highlighting will provide a balance. In contrast, a trade association commented that the highlighting of "bad" nutrients should not be required because it would be misleading. Another comment suggested that highlighting be allowed only on a case-by-case basis so that both FDA and food manufacturers have maximum flexibility.

Some comments opposed highlighting and argued that attention should be drawn to specific nutrient levels by nutrient content claims rather than by highlighting. Other comments argued that the highlighting of positive information only will accentuate benefits without including information about risks and will lead consumers to ignore vital information on negative aspects of certain products. Several comments from industry were opposed to contingent highlighting because it would communicate a good food/bad food message. Several comments stated that highlighting will imply an educational message which is more appropriately addressed in educational materials.

Other comments opposed highlighting because, they claimed, FDA will not have adequate enforcement resources. Permitting voluntary highlighting will open the door for inappropriate use of highlighting, which will then require additional regulatory intervention. Another comment, consistent with comments about other forms of dietary guidance on the label, argued that selective highlighting based on current dietary recommendations will change over time, and that it is unwise to include shifting format elements on the label.

FDA is not persuaded by the comments that contingent highlighting on the nutrition label will benefit consumers. Consumer research did not find that contingent highlighting increases effective use of the nutrition label for product comparison or dietary judgment uses (see section V.D.2.a. and V.D.2.b. of this document). There is no consensus among the comments, and the consumer research does not support that requiring a particular contingent highlighting scheme is appropriate. FDA is persuaded by comments that voluntary contingent highlighting can be applied inconsistently in a way that would be potentially misleading to consumers. Among products with similar nutrition profiles, some would highlight certain nutrients and others would not. Consumers who read nutrition labels could not depend on the fact that all labels of similar products would look the same, and the differences could undermine the credibility of the information on the nutrition label and lead to consumer confusion.

The inconsistency of labels that would result also leads the agency to disagree that highlighting should be allowed on a case-by-case basis. Consistent treatment of similar information is important for effective use of the nutrition label by consumers. FDA agrees that attention can be drawn to the levels of specific nutrients in a food by nutrient content claims rather than by highlighting information on the nutrition label. Because of problems of inconsistent treatment of similar information and the lack of demonstrated benefits in the research, FDA is not allowing the use of contingent highlighting on the nutrition label.

4. Adjectives

168. A majority of the comments that addressed the issue of adjectives were in favor of their use in some context. Several consumer groups recommended that the PERCENT DV with DRV format be enhanced by a footnote providing FDA's definition of high and low for nutrients. The comments argued that adjectives help consumers to make qualitative judgments about the food without having to make calculations or evaluate percentages. Some comments noted that the ADJECTIVE format was the most preferred in FDA's research.

In contrast, comments opposed to adjectives in the nutrition label argued that they clutter the format and would be redundant with PERCENT DV formats. Comments also expressed the concern that the wide range of values that will fall in the medium category may mislead consumers.

The agency does not agree that there is a need to include adjectives on the PERCENT DV with DRV format. The agency's research showed that consumers are able to make accurate high/low judgments using percents alone, and that when consumers relied on adjectives (see section V.D.2.a. above), they tended to overlook nutrient differences if the nutrients were described by the same adjective. The additional words would add clutter to the label without benefit to consumers. Therefore, FDA is not providing for the addition of adjectives to the PERCENT DV with DV format.

I. Dual Declarations

A few comments raised format issues with respect to foods that use dual declaration displays on the nutrition label (i.e., nutrition information declared both on as packaged/as prepared or per serving/per 100 g bases) A number of issues related to the topic of dual declarations are discussed in detail in the companion document on serving sizes published elsewhere in this issue of the **Federal Register**. FDA recognizes that such displays raise special format issues, and these are discussed here.

169. One trade association comment urged that FDA consider the label space requirements of dual declaration formats before deciding to require a change in the current nutrition label format. Several comments stated that the PERCENT DV with DRV format would not leave room enough for both "as packaged" and "as prepared" columns on nutrition labels. One industry comment stated that industry sponsored research has shown that the PERCENT DV with DRV format becomes particularly complex and cumbersome when used on food labels using dual declaration displays.

FDA agrees that dual declaration displays have much greater space requirements than the single base display required for most food products. FDA notes, however, that dual declaration displays are voluntary, not mandatory. For this reason, FDA does not agree that the requirements of dual declaration displays should be a determining factor in the decision about the nutrition label format. However, FDA does agree that the unique requirements of dual declaration displays should be accommodated as much as possible within the constraints of the format that is required for all nutrition labels, and the agency therefore has created a new section, § 101.9(e), to specifically address the format of the nutrition label when dual columns are utilized.

FDA notes that several studies submitted as comments or listed in the format proposal found that dual

declaration displays of any kind made the product nutrition label significantly harder for consumers to use and understand (see section V.D.2. of this document). The execution of dual declaration displays for the PERCENT DV with DV format in the GMA/NFPA industry study (Ref. 71) demonstrated the problem with multiple column displays on the nutrition label. In that study, a number of the dual declaration displays placed both g/mg and PERCENT DV declarations in separate columns on the nutrition label, resulting in as many as five columns of information when DV's were listed. The display was complex and cumbersome, but it is not the only, and certainly not the best, way to execute the PERCENT DV format with dual declarations.

FDA's execution of the PERCENT DV format in Study 2 (Ref. 70) purposely arranged the percent declarations in two columns and presented a single g/mg declaration per nutrient in a noncolumn array next to the nutrient name so as not to intrude visually on the columns of percents. With this execution, the PERCENT DV with DRV format performed as well as other formats on labels using dual declaration displays. The agency is convinced that dual declaration executions of the PERCENT DV with DV format should follow the pattern of minimizing the number of columns displaying nutrient amount per serving information. Accordingly, in § 101.9(e) the declaration of the required g/mg nutrient amounts on dual declaration nutrition labels is required to follow the same requirements as for single declaration nutrition labels, which is to be in an unordered array next to the nutrient name. Placement of optional g/mg amounts is discussed in comment 170 of this document.

170. A comment argued that declaring two g/mg amounts in parentheses next to the nutrient name as proposed in the dual declaration format example included in the format proposal looks like "matrix coordinates" and is likely to be confusing to many consumers. One comment suggested an alternative for presenting dual declaration g amounts. The comment suggested that only the g/mg amounts of the product as packaged be in the table, and that a footnote provide the additional amounts in the second declaration for the food.

FDA agrees that even when presented in a noncolumn array, the declaration of two g/mg amounts for each nutrient on the nutrition label (e.g., one each for as packaged/as prepared or per serving/per 100 g) in addition to two columns of percent DV amounts for nutrients having DV's is likely to be cumbersome and confusing to some consumers. Based on the research findings (see section V.D.2. of this document), FDA is confident that a single g/mg amount declared in a noncolumn array does not have a detrimental effect on consumers' abilities to understand and use the nutrition information on the label, but FDA did not test a format with two g/mg amounts for each nutrient. FDA is convinced by this comment that only a single g/mg amount (as packaged and according to the label serving size based on reference amounts in § 101.12(b)) for each nutrient should be required in dual declaration labels. The second set of g/mg amounts may be presented optionally next to the required g/mg values, differentiated from them by a comma or other means. Alternatively, the second set of g/mg amounts may be presented in a footnote. When the second set of g/mg amounts is presented in a footnote, either the total amounts or the additional amounts may be declared. When the additional amounts are declared, only those nutrients that are present in different amounts than the amounts declared in the required g/mg information may be listed. The footnote must clearly state which amount is declared. The agency has included this provision in § 101.9(e)(3)(i).

Examples of nutrition label formats for products using a dual declaration display that conforms to the new regulations are presented in appendix E.

J. Simplified Format

Most comments from consumers, industry, and professional organizations supported the concept of using a simplified format stating that it is easier for consumers to understand, cuts down on label clutter, and gives manufacturers flexibility in preparation of labels. The comments and FDA's response to concerns raised by the comments are summarized below.

1. Terminology

171. A few comments commended FDA and USDA for attempting to bring consistency to nutrition labeling regulations by allowing for similar types of simplified formats but requested that the two agencies use the same term rather than "simplified" format in FDA regulations and "abbreviated" format in USDA regulations.

Both FDA and USDA are in agreement with these comments. In accordance with the language in the 1990 amendments, they will use the term "simplified" format. However, because the foods regulated by each agency are different, the specific regulations pertaining to the simplified format will differ somewhat by agency.

2. Required Use and Criteria

172. Several comments disagreed with FDA's interpretation of that part of section 403(q)(5)(C) of the act which states "the Secretary *shall require* the amounts of such nutrients to be stated in a simplified form * * *" (emphasis added) to mean that foods that qualify for the simplified format must use that format, i.e., they may not choose to use the full nutrition labeling format. These comments urged that use of the simplified format be optional as, in some instances, consumers may be better served by one uniform nutrition label, and manufacturers should be given the flexibility to meet consumer preferences. In support of such labeling being voluntary, the comment cited the following legislative history:

> However, the bill provides that the Secretary *may permit* the information to be included on the label or labeling in a simplified form if a food contains insignificant amounts of more than one-half of the nutrients required to be on the label. (emphasis added)

(Ref. 16)

FDA advises that the draft legislation was revised by the Senate subsequent to the above House report to replace the word "may" with "shall" and to add that the form of the simplified format was to be "prescribed by the Secretary" (136 Congressional Record, S. 16607 (Oct. 24, 1990)). The changes were not explained in legislative history, so that the intent of Congress is not clear. The agency acknowledges that it is possible that Congress was merely trying to require that the final regulations provide for a simplified format rather than requiring that the format be used whenever a food met the qualifying criteria. In fact, inasmuch as the intent of the 1990 amendments was to increase the amount of nutrient information provided to consumers, it is not entirely consistent that the act would require less information on certain foods.

Based on reassessment of the statute and its legislative history in response to the comments, FDA concludes that use of the simplified format should be at the manufacturer's discretion, whenever a food product meets the criteria of containing insignificant amounts of half of the required nutrients. Accordingly, FDA has modified § 101.9(f)(1) by changing the word "shall" to "may."

173. A comment from a consumer group suggested that FDA require a different base than one-half of all 15 required nutrients for determining if a product qualifies for the simplified format because using all 15 nutrients results in "double-dipping." The comment suggested that calories from

fat should not be included because total fat represents the same nutrient, and that total carbohydrate should also not be included because complex carbohydrate and sugars comprise total carbohydrate. The comment stated that this procedure would result in a base of 13 different nutrients, of which seven must be present in insignificant amounts to qualify to use the simplified format.

FDA agrees that counting both "total fat" and "calories from fat" for the purpose of determining whether a food qualifies for use of the simplified format results in a double count being given to the fat content of a product. The agency, therefore, has deleted calories from fat from the qualifying criteria. However, in the case of "total carbohydrate," the agency notes that § 101.9(c)(6) is revised to delete "complex carbohydrate" as an element of nutrition labeling. Although "other carbohydrate" replaced "complex carbohydrate," the declaration of "other carbohydrate" is not mandatory. Therefore, the required subcomponents in § 101.9(f) no longer comprise the total amount of the component "total carbohydrate." Accordingly, "total carbohydrate" must continue to be included among the nutrients used as a base for determining whether a food qualifies for use of the simplified format.

The deletion of "calories from fat" and "complex carbohydrate" results in a base of only 13 nutrients. According to section 403(q)(5)(C) of the act, the simplified format is to be allowed if a food contains insignificant amounts of "more than one-half the nutrients required * * *." Therefore, it follows that the simplified format may be used when a food contains insignificant amounts of seven or more of the base nutrients.

As a result, and in accordance with the reordering of nutrients in § 101.9(c), FDA has modified § 101.9(f) to state that the nutrition information may be presented in a simplified format "when a food product contains insignificant amounts of seven or more of the following: Calories, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron."

Although FDA has deleted "calories from fat" from the list of nutrients in § 101.9(f) used to determine when a product may use the simplified format, "calories from fat" continues to be a nutrient that must be declared under section 403(a) of the act in nutrition labeling when present in more than insignificant amounts. Therefore, FDA has modified § 101.9(f)(3)(ii), redesignated as § 101.9(f)(2)(ii), to require declaration of calories from fat in addition to any other nutrients identified in § 101.9(f) that are present in more than insignificant amounts. For the same reason, the agency has modified § 101.9(f)(4) to require calories from fat to be included in the statement "not a significant source of _____" if it is present in insignificant amounts.

174. One comment requested that FDA confirm that eligibility for use of the simplified format is not limited to those foods listed in the supplementary proposal as examples of foods that would use the simplified format (56 FR 60421 at 60474), but that the use of a simplified format is determined on a product-by-product basis.

FDA advises that the interpretation in the comment is correct. The determination that a food qualifies for the simplified format is dependent on the amount of nutrients in that food.

175. Some industry comments requested that FDA provide guidance on how the simplified format applies to foods for children under two years of age as these products are exempted by proposed § 101.9(j)(4) from labeling of calories from fat, saturated fat, and cholesterol, all of which are included in the list in proposed § 101.9(f)(1) of the 15 "required nutrients." Comments questioned whether the stipulation of insignificant amounts of eight or more required nutrients for the simplified format applies to such foods and if it does apply, whether calories from fat, saturated fat, and cholesterol are included in the eight insignificant nutrients, even though they are not required to be labeled.

In developing the proposed rules, FDA did not consider the application of regulations governing the use of the simplified format to foods for children less than 2 years of age. Since these foods have a required base of only 11 nutrients (i.e., calories, total fat, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron), it is appropriate that they be allowed to use a simplified format when more than one-half (i.e., 6) of these 11 nutrients are present in insignificant amounts. Section 101.9(f) has been modified to include this provision for foods for children less than 2 years of age.

3. Definition of "insignificant amount"

176. A few comments recommended changes in FDA's proposed definition of "insignificant amount" of a nutrient as that amount that allows a declaration of zero in nutrition labeling. The term "insignificant amount" was used in section 403(q)(5)(C) of the act in reference to when a food would be exempt from nutrition labeling (proposed § 101.9(a)) and to when a food would qualify for the simplified format (proposed § 101.9(f)(1)). Comments on both uses of the term are discussed in this section to ensure consistent use of the term.

A few comments stated that the use of a mathematical base for determining "insignificant amounts" does not consider the actual need for the nutrients in the maintenance of good health, and that because FDA proposed to define "source" as from 10 to 19 percent of the RDI or DRV, anything less than 10 percent should be "insignificant." Other comments recommended the level of insignificance be changed to 0.5, 2, 5, or 8 percent of the RDI or DRV for particular nutrients. Another comment noted that defining "insignificant amount" as an amount less than 0.5 g of carbohydrate and protein is in conflict with the definition of "insignificant amount" for calories as less than 5 calories, given that 1 g of carbohydrate and protein furnishes only 4 calories. A comment also stated that, as a practical matter, consumers cannot reasonably be expected to differentiate between 0.5 g amounts.

FDA did take maintenance of health into consideration when it based its proposed definition of "insignificant amount" for calories (including calories from fat), total fat, cholesterol, sugars, and sodium on the amount defined as "free" under the proposed nutrient content claims rule (see final rule entitled "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms" published elsewhere in this issue of the **Federal Register**). (In addition, in the final rule on nutrient content claims, FDA defined "saturated fat free" as less than 0.5 g of saturated fat per serving.) For most nutrients, FDA has determined the level that is dietetically trivial or physiologically inconsequential (56 FR 60421 at 60433) and has established those levels as the "free" levels. Therefore, for those nutrients for which a level of "free" has been defined, FDA is denying the request to change the definition of "insignificant amount."

For those macronutrients that are required to be included in nutrition labeling but that do not have definitions of "free" levels (i.e., total carbohydrate, dietary fiber, and protein), FDA has reconsidered the proposed amounts and, in accordance with the comments, it is specifying in § 101.9 (f)(1) and (j)(4) that an insignificant amount of these nutrients is "an amount that allows a declaration of less than 1 g." Because 1 g of each of these food components

yields 4 calories, this amount is closer to the amount that will yield an "insignificant" amount of calories. By doing this, differentiation of amounts of 0.5 g will no longer be necessary.

In the case of vitamins and minerals, which also do not have definitions of "free" levels, FDA is not persuaded that amounts less than the amount defined as a source of a nutrient (i.e., less than 10 percent of the RDI) in § 101.54(c)(1) in the document on nutrient content claims published elsewhere in this issue of the **Federal Register** can be considered "insignificant." In fact, assuming that as many as 20 foods are consumed in a day (Ref. 109), levels of 5 percent or more of the RDI per food would be sufficient to assure that a person's daily requirements were met. Therefore, FDA rejects the suggestions that amounts greater than 2 percent but less than 10 percent of the RDI be considered insignificant.

177. One comment expressed concern about a potential compliance problem with § 101.9(f)(1) for firms who elect to "round down" Class II nutrients under § 101.9(g)(4)(ii) and to "round up" calories, sugars, total fat, saturated fat, cholesterol, or sodium under § 101.9(g)(5). The comment stated that by defining "insignificant" based on analytical capabilities while at the same time requiring that the simplified format be used, a firm could find itself in violation of § 101.9(f)(1) by either claiming that it is required to use the simplified format, or by asserting that it must use the complete nutrition format.

FDA does not believe its proposed definition of "insignificant" has any bearing on this concern because the concern could exist at any defined level. However, the amendment of § 101.9(f)(1) discussed above, whereby the simplified format is allowed, not required, on foods that meet the qualifying criteria, resolves the comment's concerns for Class II nutrients. For other nutrients, FDA advises that firms should determine label values to be in compliance with § 101.9(g) and then determine, based on those values, whether or not a food qualifies to use the simplified format.

4. Nutrients To Be Declared

178. While most comments supported the required declaration of "core" nutrients (i.e., calories, total fat, total carbohydrate, protein, and sodium) in the simplified format, a few comments requested that the proposed mandatory declaration of the "core" nutrients be deleted. Comments from firms manufacturing honey, chewing gum, and spices requested that FDA adopt a more simplified format for foods that have very limited nutritional value. These comments requested that only those nutrients that are present at more than insignificant levels be required to be declared. For example, chewing gum would declare only calories and carbohydrates, and seasoned salt only sodium.

FDA is not persuaded that it should drop the requirement for declaration of the core nutrients. This core information is essential to aid consumers in learning about the relative nutritional qualities of all foods, and it allows them to judge the consequences of the food selections they make. Most comments supported this position. Also, as discussed above in this section on format, consistency in presentation is a principle that has guided the agency in developing the new format because such consistency has been shown to help consumers. Therefore, FDA is not making the requested change.

179. A few comments from the soft drink industry expressed opposition to mandatory listing of sugars in the simplified format stating that it is not consistent with the intent of the law which is to enhance consumers' understanding of sound dietary practices. The comments contended that mandatory declaration of sugars places undue emphasis on a nutrient that does not warrant such emphasis in light of its physiological impact. One comment explained that the greatest concern posed by sugars is their potential carcinogenicity which, considering the rapid passage of soft drinks through the mouth, is significantly lower than other sugar-containing foods.

A comment from the honey industry also objected to required declaration of sugars on honey products on the basis that it "could mislead consumers into thinking that the honey had been manufactured from what consumers most likely regard as 'sugar'—table sugar."

As discussed in section III.F.3. of this document, the agency has concluded that the mandatory declaration of sugars content in nutrition labeling is consistent with the law. In regard to the simplified format, the 1990 amendments and its legislative history give no direction on the content of the simplified label, only that it be "in a simplified form prescribed by the Secretary." Based on the criteria Congress put on the use of the simplified format, it is possible to infer that its purpose is not to save space on the label nor to allow the declaration of otherwise mandatory nutrients to be omitted, but rather to modify the label by allowing nutrients not present in significant amounts to be omitted. FDA does not believe that the legislation allows it, or that there is any reason, to permit a nutrient that is required to be declared in complete nutrition labeling to be omitted from the simplified format when that nutrient is present in more than insignificant amounts.

In response to the comments from the honey industry, FDA acknowledges that consumers must be made aware of the different purposes of the ingredient statement and the nutrition label and be taught how to use the information in each. Developing this awareness will be a component of the consumer education program discussed in section IX. of this document.

The comment presented no data to show that consumers will be misled by a declaration of sugars in the nutrition label. As discussed in section III.F.3. of this document, FDA believes that sugars should be a mandatory component of nutrition labeling because it will assist consumers in planning diets that conform to current dietary guidelines and is of great interest to consumers. Therefore, FDA finds no basis not to require that sugars be treated in the nutrition label of honey as they would be in the nutrition label of any other product that is a natural source of sugars, such as fruits.

5. Use of statement "Not a Significant Source of"

A number of comments were received that addressed the requirement in § 101.9(f)(4) that the simplified format include the statement "Not a significant source of _____," with the blank filled in with the name of the missing nutrient, when additional nutrients are voluntarily added to the food or declared in the simplified format.

180. Many comments on this subject supported the proposal. However, a few comments from consumers, health professional associations, and industry suggested that all simplified labels should include a statement identifying those nutrients present in insignificant amounts, such as "Not a significant source of _____." One comment stated that consumers may be misled by the missing information unless the nutrients that are not present are identified. Two other statements that were suggested were: "This product does not provide you with any _____" where the blank is filled in with the names of nutrients present in insignificant amounts, or a statement that informs consumers that "This food contains less than ½ of the nutrients required for full nutrition labeling."

FDA is not persuaded that consumers will be confused by the absence of certain nutrients on simplified labels.

Most of the foods that will be able to use this format are basic commodities or simple foods (e.g., oil, butter, sugar, syrups, juices, drinks) for which it is reasonable to expect that consumers will know that the missing nutrients are not present in the food. Therefore, in response to the Congressional intent that the label be "simplified," the agency is not making the suggested change.

181. Other industry comments generally opposed requiring such a statement when additional nutrients are voluntarily added to the food or declared in the simplified format on the grounds that it clutters the label with a long list of nutrients that are not present. One comment stated such a requirement is discriminatory, especially if the additional nutrient is declared because of a nutrient content claim. Another comment suggested that simplified labels that declare naturally occurring nutrients be treated differently from those that declare added nutrients. Several comments suggested that the statement "Not a significant source of other nutrients" be used in lieu of the proposed statement as this would provide consumers information without cluttering the label.

FDA disagrees with the comments. When nutrients are voluntarily added to a food or voluntarily declared in the nutrition label, or when a nutrient content claim is made on the label, the food is being marketed as a significant source of nutrients. In such cases, the food label would be in violation of section 201(n) of the act unless consumers are advised about the full nutritional profile of the food.

FDA shares the concern about the space required by the list of nutrients not present. However, the statement "Not a significant source of other nutrients" is too broad and therefore could be misleading on a large proportion of foods. Even though the food may not contain significant amounts of the nutrients required in § 101.9(c), it may contain significant amounts of other essential nutrients that are not required to be declared in nutrition labeling. The language suggested by the comment, however, asserts that the food is not a source of any other nutrients. Thus, to determine whether such a statement is true, it would be necessary to analyze for all known essential nutrients. The agency believes that such a situation makes no sense and therefore is not making the suggested change.

182. One industry comment opposed the exemption of standardized enriched foods from the required statement "Not a significant source of _____," stating that there is no basis for treating different food products (i.e., nonstandardized enriched foods) discriminatorily. Another comment wanted FDA to state that the addition of a nutrient such as vitamin C to a food, if required by a standard of identity or another government standard (i.e., a purchase specification to qualify for use in the Special Supplemental Food Program for Women, Infants, and Children (WIC)) would not require the statement "Not a significant source of _____."

FDA is persuaded that foods containing added vitamins and minerals, whether under a food standard or not and whether required by purchase specifications or not, should be treated similarly. Therefore, FDA has modified proposed § 101.9(f)(4) to require that if any vitamins or minerals are declared as part of the simplified format for any reason, the statement "not a significant source of _____" shall be included at the bottom of the nutrition label. This statement is also required if any additional naturally occurring nutrients are voluntarily declared in the simplified format. To clarify the regulation, the requirement that any added vitamins and minerals must be declared as part of the simplified format is removed from proposed § 101.9(f)(4) to become new § 101.9(f)(2)(iv). Additionally, § 101.9(f)(4) is subdivided into § 101.9 (f)(3) and (f)(4).

6. Format for the Simplified Label

183. Many comments from industry responding to the supplementary proposal were opposed to requiring the DRV list in the simplified format, arguing that such a required list would considerably expand the simplified format and therefore defeat its purpose.

A few comments responding to the format proposal argued that examples of simplified formats illustrated at appendix D of the proposed rule were merely abbreviated versions of the nutrition label format and not simplified formats as called for by the 1990 amendments. These comments were particularly critical of the inclusion of the listing of DRV's in the simplified format because they argued that an abbreviated list of DRV's would communicate incomplete, and therefore misleading, information about a total daily diet. Other comments supported the examples of simplified formats in the proposed rule on the grounds that they eliminated unnecessary information but retained a consistent appearance with the regular format.

FDA agrees that an important consideration for the simplified format is that it retain common elements with the regular format to facilitate consumer understanding and use of the nutrition information. FDA does not agree that section 403(q)(5)(C) of the act requires a simplified format that is simpler in other respects than being an abbreviated version of the regular format. As discussed in comment 179 of this document, the 1990 amendments and their legislative history give no direction on the content of the simplified format. However, FDA agrees with the concern expressed about the value of an abbreviated list of DRV's. After careful consideration of the comments, the agency is convinced that by declaring quantitative amounts as percent of Daily Values, the simplified format will retain sufficient common elements with the regular format to facilitate consumer use and comprehension. The agency is also convinced that not requiring the full footnote and calorie conversion information required in § 101.9 (d)(8) and (d)(9) on the simplified format will not sacrifice important objectives of the legislation because the information is not specific to the particular food and is available on a significant portion of the food supply. Therefore, FDA is requiring in § 101.9(f)(5) that a simplified format contain only quantitative and Percent of Daily Value information in the same format as required for full or dual nutrition labeling in § 101.9 (d) and (e), respectively.

184. Comments to the format proposal addressing the use of the simplified PERCENT DV formats generally preferred the use of columns rather than the in-line presentation. Comments stated that the in-line presentations appear significantly more difficult to use and make it difficult to distinguish the actual quantitative amounts from the DRV's. One comment was received from a consumer interest group opposing the line concept on the grounds that it is difficult to read, confusing, and will allow a company to hide the content of fat, sodium, or other undesirable nutrients in the product. The comment maintained that if a line format is allowed, it should only be permitted when no additional voluntary disclosures are made. The comment stated that such additions would make the nutrition information comparable in length to the required format, and FDA has already determined that the required format would not be legible in a line format. However, several industry comments were received in support of allowing the abbreviated nutrition information to be presented in either vertical columns or lines because of the

flexibility and saving in space provided in this option.

FDA agrees that, where label space is adequate, the simplified label is best understood when the information is presented in columns, particularly when additional nutrients are voluntarily disclosed. However, as discussed in section VI.K. of this document, the agency is aware that special allowances are necessary on labels of small or intermediate sized packages. Therefore, in § 101.9(f)(5) the agency is requiring that nutrition labels on products qualifying for the simplified format present the required information in the same format as is required in § 101.9 (d) and (e) for other packaged foods, except that foods in small and intermediate sized packages that come under § 101.9(j)(13) are allowed by that section to present the information in a linear fashion. Examples of simplified formats are seen in appendix F.

185. One industry comment said that while it supported the simplified nutrition label format for sugar, this format, as depicted in the proposal, may be confusing on labels of soft drinks because consumers may conclude that the soft drink has 36 g carbohydrate and 36 g sugars. If sugars are required to be listed, the format should provide for indentation that would clarify that sugars are a subcategory of total carbohydrates.

FDA agrees that the format must allow for subcomponents to be indented under the primary component. Accordingly, § 101.9(c)(6)(ii) specifies that sugars are to be indented under total carbohydrate. A similar requirement is specified for each subcomponent. In addition, § 101.9(d)(1)(iv) requires the primary component to be highlighted to further differentiate it from its subcomponents.

VI. Exemptions and Special Conditions

A. Small Business

The 1990 amendments granted an exemption from mandatory nutrition labeling for small businesses. Under section 403(q)(5)(D) of the act, a small business is defined as a business with less than $500,000 annual gross sales of food or any commodity, or a business with annual gross sales of more than $500,000 but less than $50,000 in food sales. The exemption does not apply to those products that make nutrition claims or provide nutrition information.

186. Many comments from industry, trade associations, and international organizations have stressed that the dollar exemption limits in proposed § 101.9(j)(1) that implement the 1990 amendments are too low. The comments note that the sum of analytical, printing, and other costs of nutrition labeling are prohibitively expensive for low volume products. Many small food producers that exceed the $500,000/$50,000 sales limit report that they will suffer a severe economic hardship if forced to comply with the nutrition labeling rules. One comment stated that without an increased exemption, 25 percent of food businesses in Kansas would close. Retail bakery and confectionery trade groups stated that the nature of their business dictates that they offer hundreds of different products throughout the year, and that limiting and standardizing product lines would cause a retail operation to lose its character and appeal. Yet, the need to nutrition label products would force such standardization. Other consequences for small businesses that would not qualify for the exemption that were identified in the comments included the loss of a substantial portion of annual profits, loss of low volume product lines, and small business failure.

FDA has considered these comments and believes that there is merit in many of the contentions they raise. To gain adequate information on what to recommend as a reasonable and appropriate adjustment to the 1990 amendments' standard, FDA participated in a series of public forums that had been scheduled by USDA to discuss the small business issue. These forums were held in May, 1992, in Kansas City, MO; Atlanta, GA; and San Francisco, CA. In a notice of the public forums (57 FR 19410, May 6, 1992), FDA announced its participation in the forums and requested comment on a number of issues, such as which option should be used to amend the current statutory exemption—increasing the gross annual sales exemption, providing an exemption based on the number of units sold of a particular product line, basing the exemption on the number of employees, or any combination of such options. Comments were also requested on the feasibility of compliance with various limits and the effect on the percent of the diet bearing nutrition labeling.

The agency has compiled the information it received. However, at the current time the agency is constrained by the requirements of section 403(q)(5)(D) of the act. Therefore, § 101.9(j)(1)(i) has not been changed. If Congress amends the statute, FDA will implement the change as soon as possible thereafter.

187. Comments have questioned FDA's interpretation of that part of section 403(q)(5)(D) of the act that states "If a person offers food for sale * * * or has business done in sales to consumers" to mean that foods produced by small businesses that are exempt would have to bear nutrition labeling if they were sold by a larger retailer who was not exempt. The comments stated that this interpretation would have a devastating impact on many small entrepreneurs who primarily sell their products through larger retailers or department stores.

In § 101.9(j)(1)(ii), FDA proposed that this exemption applied to any "person who manufactures, packs, or distributes food for ultimate sale to consumers at the retail level as well as any person directly involved in the retail sale of foods to consumers." The legislative history was not specific as to whether the term "retailer" applied only to the small business retailer/producer or to a larger retailer acting as a middle-man in handling the sale of the items to the ultimate consumer (Ref. 16). The agency is convinced by the comments that its interpretation would have unintended consequences on small businesses and, therefore, is removing "as well as any person directly involved in the retail sale of foods to consumers" from § 101.9(j)(1)(ii). To further clarify which foods are covered by the small business exemption and to streamline the regulations, FDA is also deleting the remaining portion of § 101.9(j)(1)(ii) and revising § 101.9(j)(1)(i) to state that "Food offered for sale by a manufacturer, packer, or distributor who has annual gross sales made or business done in sales to consumers that is not more than * * *." The agency's intent with this change is that the exemption will apply to persons whose name appears on the label as the manufacturer, packer, or distributor of the product, regardless of who ultimately sells the product to the consumer. As a consequence, § 101.9(j)(1)(iii) is redesignated as § 101.9(j)(1)(ii).

B. Ready-to-Eat Foods

188. Comments stated that proposed § 101.9 (j)(2) and (j)(3) did not adequately track section 403(q)(5)(A)(i) and (q)(5)(A)(ii) of the act, which both pertain to foods ready for consumption but differ in that section 403(q)(5)(A)(i) of the act addresses foods served for immediate human consumption and section 403(q)(5)(A)(ii) addresses similar types of foods that are sold ready for human consumption but not for immediate human consumption and that are processed and prepared primarily on the premises.

The agency is persuaded that proposed § 101.9 (j)(2) and (j)(3) in its supplementary mandatory nutrition

labeling proposal (56 FR 60366) (which were based on proposed § 101.9 (h)(2) and (h)(3) in FDA's July 19, 1990, mandatory nutrition labeling proposal) did not adequately implement the 1990 amendments. FDA is therefore revising these two sections as discussed below in accordance with the 1990 amendments and in response to comments.

1. Foods for Immediate Human Consumption

In proposed § 101.9(j)(2) of its supplementary proposal (56 FR 60366), FDA proposed to exempt "food products provided by restaurants or other food service facilities offering restaurant-type services (e.g., delicatessens, bakeries, feeding facilities in organizations such as schools, colleges, hospitals, and transportation carriers (such as trains and airplanes))." While this list was not all-inclusive, it was intended to respond to section 403(q)(5)(A)(i) of the act which directed the agency to exempt food "which is served in restaurants or other establishments in which food is served for immediate human consumption * * *." Examples of congressional intent concerning the types of facilities covered by section 403(q)(5)(A)(i) of the act are limited in the legislative history to cafeterias and hospitals (Ref. 16).

189. While many comments supported the exemption in § 101.9(j)(2) for restaurants, several comments requested clarification about the coverage of the proposed section. For example, comments asked whether it covers retail confectioners, ready-to-eat food carryouts, vending machines, and food delivery systems such as meals-on-wheels programs or establishments such as pizza-delivery companies. Comments also pointed out the great diversity in the types of establishments in which food is served for immediate human consumption in the United States. For instance, comments stated that in addition to full-service restaurants, many establishments such as delicatessens, bakeries, candy stores, and convenience stores provide customers with tables and chairs to sit and immediately consume foods purchased. Others, whether for lack of space or for other reasons, do not provide such facilities. For example, frequently food franchises in shopping malls sell cookies or other snack foods expecting customers to eat the foods while walking in the mall or while sitting on benches located throughout the mall.

Comments from a company producing sandwich and salad items in a commissary for sale in vending machines requested to be included under this exemption because the subject foods are sold for immediate consumption, not for "take-home" use, and because the foods are prepared in a commissary kitchen similar to a restaurant/cafeteria kitchen, where foods are assembled by hand and subject to individual product variations. The comment argued that mandatory nutrition labeling would require standardization of menu items, thereby prohibiting common day-to-day variations in the food items produced, and would require larger labels or smaller type-size, both of which would be difficult or impossible to read through the small glass door of a refrigerated vending machine.

Similarly, one comment pointed out that some foods sold in convenience stores are intended for immediate human consumption and compete directly with foods served by restaurants and delicatessens. It stated that many stores have seating areas for customers to use while eating foods purchased on-site, and that in some states, such convenience stores must have restaurant licenses. Foods sold range from self-service beverages to prewrapped sandwiches, prepared off-site by vendors and offered for sale in store display cases.

FDA notes that section 403(q)(5)(A)(i) of the act addresses restaurants and "other establishments in which food is served for immediate human consumption." To respond to the comments stating the proposed rules did not adequately track the 1990 amendments, the agency is revising proposed § 101.9(j)(2) to include a new paragraph (ii) that states that the exemption is to include food products served in "other establishments in which food is served for immediate human consumption." In addition, in response to comments seeking clarification of the coverage of such "other establishments," and in recognition of the diversity of food service operations in the United States, the agency advises that while some enforcement decisions will need to be made on a case-by-case basis, for efficient enforcement of the act, it is providing in § 101.9(j)(2)(ii) that, in addition to food service in hospitals and cafeterias, the agency considers that this exemption applies to establishments such as bakeries, delicatessens, and retail confectionery stores where there are facilities for "immediate consumption" on the premises (i.e., tables or counters with chairs); to food service vendors such as lunch wagons, mall cookie counters, vending machines, and sidewalk carts where foods are generally consumed immediately where purchased or while walking away (including similar foods sold from convenience stores); and to food delivery systems or establishments where ready-to-eat foods are delivered to homes or offices for immediate consumption.

FDA recognizes that some persons might consider that it is inconsistent for the agency to exempt packaged foods sold in vending machines from nutrition labeling but not from ingredient labeling. However, the agency is convinced that such foods are exempted from nutrition labeling by section 403(q)(5)(A)(i) of the act because vending machines serve food for immediate consumption, and there is no similar statutory exemption from ingredient labeling.

Regarding convenience stores, FDA agrees that some foods sold in such stores bear many similarities to foods sold at restaurants and delicatessens and should qualify for similar exemptions. Because circumstances will vary greatly according to the services a particular convenience store offers, it is not possible to state precisely which foods do or do not have to provide nutrition labeling. Rather, determinations will have to be made on a case-by-case basis. However, § 101.9(j)(2) generally provides an exemption for foods of the type served in restaurants or other establishments in which food is served for immediate human consumption. Such foods might include beverages (both self-service and those served by store personnel), frankfurters in a roll, cold sandwiches, pizzas, and hand-packed ice cream cones.

190. Many comments requested that proposed § 101.9(j)(2) be amended to clearly exempt foods "sold for sale or use" in restaurants or other establishments in which food is served for immediate human consumption as specified in section 403(q)(5)(A)(i) of the act. They argued that the statutory language indicates that food intended for use in restaurants is exempt from mandatory nutrition labeling in the absence of nutrient content or health claims. The comments pointed out that proposed § 101.9(j)(2) merely provided an exemption for foods provided by restaurants and did not cover foods intended for sale or use in restaurants.

The agency agrees that the proposed regulations did not fully implement section 403(q)(5)(A)(i) of the act that covers foods sold for sale or use in restaurants or other such establishments. As directed in the statute, this exemption applies to all foods sold in restaurants, including packaged products such as a specialty

house dressings made by the restaurant, or used in restaurants, such as portion controlled packages (e.g., individual catsup or coffee whitener packages) for use only in restaurants. If a manufacturer makes a product for sale only in restaurants (e.g., a package of candy), that product need not be nutrition labeled. However, if there is a reasonable possibility that the product will be purchased directly by consumers in a setting other than a restaurant or other establishment in which it is served for immediate consumption, it must be nutrition labeled (see Ref. 25). Accordingly, FDA has modified proposed § 101.9(j)(2) to add a new paragraph (iii) that exempts foods sold for sale or use only in restaurants or other establishments in which food is served for immediate human consumption.

191. A few comments requested that the second sentence of proposed § 101.9(j)(2) be revised to adequately implement section 403(q)(5)(F) of the act that exempts food "which is sold by a food distributor if the food distributor principally sells food to restaurants or other establishments in which food is served for immediate human consumption and does not manufacture, process, or repackage the food it sells." The comments pointed out that the second sentence in proposed § 101.9(j)(2) would only exempt "foods sold to restaurants by distributors * * *" which is duplicative of that part of 403(q)(5)(A)(i) of the act that stipulates an exemption for foods sold for sale or use in restaurants and fails to include the broader exemption in 403(q)(5)(F) of the act for all foods sold by distributors who principally sell food to restaurants or other establishments in which food is served for immediate human consumption and who do not manufacture, process, or repackage the food they sell.

The agency is persuaded that there is a need to revise the second sentence of proposed § 101.9(j)(2). As discussed in the legislative history (Ref. 25), the food distributor that sells principally to restaurants and other food service establishments is exempted from mandatory nutrition labeling requirements as long as the food distributor does not manufacture the product sold to the consumer. However, the legislative history states:

> The manufacturer of such products would be responsible for providing the nutrition information on the products if there is a reasonable possibility that the product will be purchased directly by consumers, even if the principal customers are restaurants and other wholesale purchasers. * * * [T]he distributor is not liable as long as the distributor does not manufacture the product sold to the consumer.
> (Ref. 25)

In essence, this legislative history makes clear that section 403(q)(5)(F) of the act is intended to direct the agency to do for foods sold to restaurants what it does for foods sold to consumers; that is, to hold the manufacturer, not the seller, responsible for nutrition labeling of foods. (The only exception to this approach is the voluntary nutrition labeling program for raw fruits, vegetables, and fish in which the retailer is to provide the nutrition information.) This exemption would apply to an independent distributor who principally distributes institutional foods directly to restaurants and similar establishments and does not manufacture, process, or repackage the food it sells.

Thus, under this exemption, such a distributor is not responsible for nutrition labeling a product, even if it sells the product in a so-called "cash and carry" store, unless it manufactures, processes, or repackages the food for sale to consumers. On the other hand, a manufacturer of institutional size food products is responsible for nutritionally labeling those products if there is a reasonable possibility that they will be sold to consumers, for example, through such a mechanism as a cash and carry store.

Therefore, proposed § 101.9(j)(2) is modified by adding § 101.9(j)(2)(iv) to fully implement this exemption.

192. One comment recommended that statements such as "for food service use" or "not labeled for retail sale" be used as one means of qualifying for the exemption or that such foods be identified by the size of the package. The comment suggested that such a rule would be of particular help for foods imported for the food service trade.

The legislative history quoted in the preceding comment makes clear that nutrition labeling is required "if there is a reasonable possibility that the product will be purchased directly by consumers * * *." Therefore, the agency does not believe that a label statement can be used as the basis for this exemption. The agency is concerned that, if permitted, a label statement such as "for food-service use" would be used to claim exemption for products that Congress intended to be nutrition labeled. Therefore, rather than create the possibility for potentially misleading labeling, FDA is denying this request.

Imported foods that are in large packages that are obviously not intended or packaged for sale to consumers would be considered exempt under § 101.9(j)(9) which deals with foods shipped in bulk form that are to be processed, labeled, or repacked at a subsequent site.

193. Several comments opposed proposed § 101.9(j)(2) because it would exempt restaurants from mandatory nutrition labeling. These comments urged that restaurants, particularly the regional and national chain restaurants, be required to have nutrition information available to consumers. Some comments suggested that the required information could be: (1) limited to calories, fat, saturated fat, cholesterol, and sodium; (2) based on computer analysis of nutrient databases; and (3) presented in alternative ways such as brochures, menu boards, posters, or tray liners. A few large fast food restaurant chains requested guidelines for voluntary nutrition labeling with flexibility in format and content. They requested that restaurants be allowed to use their own serving sizes, present information on an as-served basis, and update information annually.

In response to comments requesting that restaurants be required to provide nutrition information, the agency points out that section 403(q)(5)(A)(i) of the act specifically exempts restaurants and other establishments in which food is served for immediate human consumption from mandatory nutrition labeling, unless a nutrient content claim or a health claim is made. The requirements that pertain when claims are made are discussed extensively in the final rules on the general requirements for nutrient content claims and health claims that are published elsewhere in this issue of the **Federal Register**.

FDA is aware, however, of the consumer interest in knowing the nutrient content of foods eaten away from home. In response to that interest and to the comments from fast food chains, the agency intends to work closely with all interested parties, particularly those in the food-service sector, to develop guidelines for presenting nutrition content information in a restaurant setting in such a way that it will not inhibit the flow of useful nutrition information (e.g., claims) to the consumer, while at the same time providing assurance of the reasonable accuracy of the information, thus furthering the goal of the 1990 amendments to aid consumers in maintaining healthy dietary practices.

194. One comment agreed that the 1990 amendments exempt restaurants from mandatory nutrition labeling but requested that they be regulated under sections 201 and 403(a) of the act. The comment also requested that FDA clarify that the 1990 amendments have

no preemptive effect on state or local regulation of the nutritional disclosures by restaurants.

FDA advises that the exemptions in § 101.9(j) in no way exempt any foods from regulations promulgated under sections 201 and 403(a) of the act. In regard to State and local preemption, the legislative history states that "Because food sold in restaurants is exempt from the nutrition labeling requirements of section 403(q)(1) through (q)(4) of the act, the bill does not preempt any State nutrition labeling requirements for restaurants. If States do require such labeling in restaurants, it is important that they make every effort to make those requirements consistent with the requirements of the bill." (Ref. 110).

2. *Foods Not for Immediate Consumption.* 195. Many comments objected to proposed § 101.9(j)(3) that allowed an exemption for in-store delicatessen and bakery foods only when they were sold from behind service counters. Comments pointed out that the 1990 amendments made no distinction for such foods when sold from behind the counter rather than from a self-service display. They stated that such a rule would be totally unworkable and would adversely affect the bakery and deli departments. Such a rule, according to the comments, would make it impossible to sell foods that are sold from behind the service counter during the day, at night, when no service clerks are available, or to assemble sandwiches and salads for fast pickup during the lunch hour from self-service counters, without nutrition labeling those foods. A trade association reported that 21 percent of in-store bakeries' sales come from bulk self-service units and 42 percent from prepackaged self-service cases, and that, if compelled to standardize and label their products, such bakeries would be unable to continue in competition with wholesale bakery items.

The comments argued that in-store delicatessens and bakeries should be able to adhere to the same regulations as their independent counterparts, with whom they compete for business. They stated that in-store delicatessens and bakeries operate as independent bakeries in that their accountability is separate from the rest of the store.

Other comments stated that the intent of Congress was that foods similar to restaurant foods that are ready for immediate consumption, and that are produced by retailers that offer variable and nonstandardized products, should be exempt from nutrition labeling to eliminate the substantial burdens that would otherwise be imposed if such labeling were mandatory. Many comments have pointed out that the average baker or confectioner produces hundreds of different products each year, and that the average sales per product are relatively low. Comments stated that the precise selection of foods produced is frequently modified according to changing preferences of customers, seasons, holidays, ingredient availability, and the individuality of the baker/confectioner. Comments argued that it is this ability of the retailer to vary and customize food products that gives the establishment its character and appeal, and that forced standardization to allow for nutrition labeling would eliminate product competitiveness by disallowing innovation and creativity. This loss of competitiveness, in turn, would create a major economic burden and thereby lessen consumer choice.

The agency is persuaded that proposed § 101.9(j)(3) did not adequately implement section 403(q)(5)(A)(ii) of the act, could result in economic harm to in-store delicatessens and bakeries, and created an artificial demarcation between foods sold from service versus self-service areas of the delicatessen or bakery. Therefore, FDA believes that it is necessary to revise § 101.9(j)(3) to more closely reflect the language of the act.

As stated above, section 403(q)(5)(A)(ii) of the act applies to foods that are: (1) Similar to the type addressed in section 403(q)(5)(A)(i) of the act, (2) ready for human consumption, and (3) offered for sale to consumers but not for immediate human consumption. Accordingly, FDA is modifying § 101.9(j)(3) by adding paragraphs (i) through (iii) to reflect these three statutory requirements. There were no specific concerns presented in comments that suggest any problems with these requirements.

Section 403(q)(5)(A)(ii) of the act also requires that the foods to which it applies be processed and prepared primarily in the retail establishment. The agency is codifying this requirement in § 101.9(j)(3)(iv). Comments were very divided on this issue, particularly for bakery items. Some comments argued that breads shipped to a retail store in a semi-finished condition and baked-off just before retail sale would not meet the criteria of "prepared and processed primarily" at the retail store and should not be exempt. However, other comments disagreed with this position, stating that frozen dough products are further processed at the bakery by being proofed, shaped, molded, filled, decorated, cut, assembled, customized, or otherwise completed or further processed and should be exempt.

The legislative history discusses this situation stating that for bakeries "simply thawing frozen bread would not be sufficient; the bread would have to be baked on the premise" (Ref. 16). While this statement appears to indicate that baking (i.e., cooking at a high temperature in an oven) is sufficient to qualify a food for this exemption, comments have argued that "baking" is not equivalent to heating but includes a number of steps, such as "selecting, weighing, and mixing ingredients, fermentation, and shaping and forming the dough prior to actual heating the product."

This example with bread illustrates the difficulty in applying the criterion of "processed and prepared primarily in a retail establishment." Because of the wide variety of foods sold in delicatessens, bakeries, retail confectionery stores, and other stores of this type that may not qualify for exemption under § 101.9(j)(2), it becomes administratively impossible to identify for each type of food sold the exact amount of processing or preparation that would be needed to say that that food was "processed and prepared primarily" on-site.

In many establishments, foods such as bakery items or salads, may be prepared entirely on-site; however, in other similar establishments, much less of the processing and preparation of these foods is actually done on the premises. Similar variations are encountered with other foods, such as cheeses, which may only need to be sliced and portioned, or puddings, which may be purchased in cans and only need to be put in trays in the display case for portioning. The characteristics that all of these foods have in common is that they are ready-to-eat, they are the same type of foods sold in restaurants, and they are portioned and packaged on-site.

Legislative guidance to assist the agency in defining what is meant by "processed and prepared primarily in a retail establishment" in addition to that cited above is scant. However during Senate debate, one of the sponsors of the bill that became the 1990 amendments stated that:

> This exemption recognizes that when food is processed and prepared primarily on the premises and sold there, as in the prepared food sections of supermarkets, nutrition labeling is not appropriate. On the other hand, if the preparation or processing of food is standardized and is accomplished primarily at another establishment and the same food is then shipped to a retail food store in a form that requires minimal or no further processing, nutrition labeling can be easily accomplished and is required.

(Ref. 110).

The agency interprets this legislative history to mean that if the food arrives at a store in a form to be sold directly to the consumer (i.e., it is "standardized"), then nutrition labeling must be required. However, if the food is not standardized, i.e., it has to undergo processing or preparation, including portioning, before being sold to the consumer, then nutrition labeling is inappropriate and should not be required. In the case of the examples cited above, FDA finds that nutrition labeling would therefore not be required on bread that is shaped; filled, decorated, assembled, or customized and baked (i.e., cooked at a high temperature) in the retail establishment. Cheese that is sliced and portioned according to directions given by the consumer, and pudding that is portioned according to directions given by the consumer, also need not be nutrition labeled. In these examples, the food is not "standardized" in the form that it is to be sold to consumers when it arrives at the store. Similarly, candies sold in retail confectionery stores that are selected by consumers to be part of a packaged assortment are not "standardized."

However, because of the great diversity of situations in which foods are sold, it must be recognized that a decision regarding exactly what foods do or do not require nutrition labeling cannot be fully resolved by regulation. Circumstances at the retail location must be the deciding factor.

196. A few comments from the retail baking and confectionery industries and from grocery stores requested that the exemption for single-unit bakeries, delicatessens, and confectioneries apply equally to multi-unit establishments that do most or all of their preparation at a central facility or shop. Each type of respondent attempted to limit such an exemption by describing what it would encompass. For example, a comment from the retail baking industry described multi-unit bakeries as being owned, controlled, and operated by the same entity and stated that finished products would be delivered unwrapped or in bulk delivery boxes to each store or outlet. The confectionery industry requested that the exemption cover satellite operations operated by the same businesses, selling the same products, and using the same packaging. A small retail grocery chain suggested limiting the exemption to foods prepared in central kitchens for use in the retailer's own stores. Reasons given for using central facilities included ensuring quality control through a controlled environment that promotes food safety and integrity and allowing for economies of scale. Comments stated that the average number of bakeries operated by a multi-unit retail bakery was 2.4 in 1988, and that many small independent confectioneries only operate one additional outlet.

FDA does not believe that the 1990 amendments allow for exemptions beyond those discussed in the preceding comments. This position is based on the final criterion given in section 403(q)(5)(A)(ii) of the act, which states that foods to which the section applies shall not be offered for sale outside the retail establishment in which they are primarily processed and prepared. The agency is codifying this requirement in § 101.9(j)(3)(v). While foods that are fully prepared and portioned (i.e., "standardized") at the central facility are required to bear nutrition labeling, there may be some types of food products or circumstances in which the portioning or packaging is not standardized, and in which nutrition labeling would consequently not be required (e.g., salads that are portioned and packaged according to directions given by the consumer).

FDA notes that the problems presented in most of the comments on this aspect of this exemption have more to do with the size of the businesses than whether there are good reasons not to require nutrition labeling. FDA believes that the best way to deal with most of these comments is through a change in the small business exemption.

C. Foods of No Nutritional Significance

To reflect the first sentence in section 403(q)(5)(C) of the act, FDA proposed an exemption for foods of no nutritional significance in § 101.9(a). It proposed to include the other exemptions in § 101.9(j). To minimize any confusion that these differences in placement may cause, the agency has decided to group all exemptions in one place in this final rule. Accordingly, that part of proposed § 101.9(a) that exempted foods of no nutritional significance is redesignated as § 101.9(j)(4).

197. Comments from the coffee industry noted that, unlike FDA's mandatory nutrition labeling proposal, the supplementary proposal did not explicitly identify coffee as being nutritionally insignificant. Thus, the comment requested clarification in the final rule. The comments pointed out that coffee is always consumed as a brew. An analogy was drawn to § 101.45(b)(4) in the guidelines for voluntary nutrition labeling of raw fruit, vegetables, and fish, which states that nutrition information is to be based on the edible portion of the food. Comments stated that the available nutrients in brewed or plain instant coffee would meet the criteria for being nutritionally insignificant.

The agency agrees that only the edible portion of coffee should be considered in determining the nutritional significance of the product. Therefore, based on a review of available nutritional data on a serving of coffee and on the revisions in the levels that are significant, discussed in comment 176 of this document, FDA has concluded that coffee beans, roasted ground coffee, or dry plain (i.e., unsweetened) instant coffees contain no nutrients at other than nutritionally insignificant levels. As a result, these foods are exempt from mandatory nutrition labeling. Unsweetened plain tea powders or tea leaves likewise would be exempt.

In response to comments requesting clarification of the exempt status of coffee and tea, FDA has included in § 101.9(j)(4) a listing of coffee beans (whole or ground), tea leaves, and unsweetened plain instant coffee and tea as examples of foods that are exempt from nutrition labeling because of their lack of nutrients. The agency reiterates, however, that this exemption is available only when there are no nutrient content or health claims on the label or in labeling or in advertising of the coffee or tea.

198. The spice industry commented that FDA did not establish a reference amount for spices, thereby implying that spices are exempt from mandatory nutrition labeling. Comments requested that the agency provide an explicit statement in the final rule regarding the exemption of spices, spice blends (e.g., curry powder), and condiment-type dehydrated vegetables (e.g., dried garlic) as well as flavor extracts and food colors, from the nutrition labeling requirements.

As discussed in the final rule on serving size published elsewhere in this issue of the Federal Register, FDA has set a reference amount of ¼ teaspoon for most spices and condiment-type dehydrated vegetables. In reviewing the nutritional data in Agriculture Handbook No. 8–2 and 8–11 (Refs. 111 and 112), the agency has found that, under FDA's criteria for determining nutritional insignificance, the vast majority of spices, spice blends, and condiment-type vegetables are exempt from mandatory nutrition labeling. FDA found, however, that one spice (paprika) and one spice blend (chili powder), exceed the cutoff levels for one or two nutrients. Using the appropriate rounding procedures, paprika is over

the cutoff for vitamin A (6 percent of the RDI), and chili powder is over the cutoff for both vitamin A (4 percent of the RDI) and sodium (5 mg) per ¼ teaspoon serving. The levels at which these nutrients are nutritionally insignificant (i.e., the amounts that can be rounded to zero) are less than 2 percent of the RDI for vitamin A and less than 5 mg for sodium. Therefore, under the act, paprika and chili powder will have to be nutrition labeled (see Ref. 16, p. 16: "Foods such as certain spices, which have insignificant amounts of most but not all nutrients, are covered by the nutrition labeling requirements."). Because not all spices and spice blends are nutritionally insignificant, they are not included as a category under § 101.9(j)(4).

Condiment-type dehydrated vegetables, flavor extracts, and food colors do meet the criteria for foods of no nutritional significance and, therefore, are exempt from mandatory nutrition labeling. As with unsweetened coffee and tea, § 101.9(j)(4) will include these examples of nutritionally insignificant foods.

199. One comment suggested that "fun foods" defined as foods with empty calories (i.e., those with no nutrients other than calories), such as plain sugar candies, gum, and carbonated beverages, should be exempt from mandatory nutrition labeling except for a declaration of calories and the statement "no other significant sources of nutrients." The comment argued that the statement "Contains less than 2 percent of the RDI" for such foods is deceptive and miseducates consumers.

FDA advises that these types of foods would qualify under § 101.9(f) for the simplified label and would only be required to list the core nutrients, not the statement "Contains less than 2 percent of * * *." Moreover, Congress did not provide for an exemption of such a category of foods in the statute. Therefore, the agency is taking no action on this comment.

200. The pickle industry commented that, as a cost-saving measure, only sodium content (as is permitted under current regulations) should be required to be labeled on dill pickle products, rather than the full simplified format. The comment argued that, even though a serving of dill pickles also contains 1 g of carbohydrate, sodium is the only nutrient of any concern to consumers.

FDA rejects this comment. Section 403(q)(5)(C) of the act exempts from nutrition labeling foods that contain insignificant amounts of all of the nutrients required within nutrition labeling. The same section also provides for a simplified form of nutrition labeling if a food contains insignificant amounts of more than one-half the mandatory nutrients. No provisions of the 1990 amendments would allow for declaration of only a single nutrient in nutrition labeling. Accordingly, FDA is not making the suggested changes in the regulations.

201. One trade association commented that bottled water products have little or no nutritional value, and that such products should be exempt from mandatory nutrition labeling. The comment asserted that the following industry practices should be permitted without triggering nutrition labeling obligations: (1) Bottlers should be allowed to add back minerals as flavor enhancers that are removed during purification and declare "minerals added" on the principal display panel; (2) bottlers should be allowed to describe bottled water with natural or added fluoride as "fluoridated water;" (3) bottlers should be allowed to add sodium fluoride or add back trace minerals that may contain sodium as an incidental additive and still be permitted to claim "sodium free" on the label; (4) "essence" bottled water products (i.e., those containing 1 percent or less of juice or flavors) should be considered nutritionally insignificant; and (5) bottled mineral water products should be permitted to have a listing on the label of certain minerals, e.g., sodium, bicarbonate, calcium, magnesium, and other trace minerals in mg per liter in addition to a declaration of total dissolved solids content (which some state laws currently require). The comment argued that the EC Directive on Nutrition Labeling expressly exempts mineral water and other waters from nutrition labeling, and, for the sake of harmonization, FDA should do likewise.

FDA points out that, separate from this rulemaking on nutrition labeling to implement the 1990 amendments, the agency is in the process of amending its regulations on bottled water, partly in response to a petition from the trade association that submitted the comment. The bottled water regulations will address certain aspects of labeling apart from nutrition labeling, e.g., definitions, information about mineral content, and required label statements. Under the 1990 amendments, Federal regulations will preempt any State standards of identity that are not identical to it (section 403(a)(1) of the act).

A recent IOM report, "Food Labeling: Toward National Uniformity" (Ref. 113), noted that many States have expressed concern about the heightened potential for consumer confusion because of the increased number of bottled water products on the market and the aggressive marketing and advertising claims of superiority made for them. Thus, FDA maintains its position that nutrition information relating to food must be provided for all products, including bottled and mineral water, that contain more than insignificant amounts of any of the nutrients or food components that are required to be listed, or whose label, labeling, or advertising contains a nutrient content claim or any other nutrition information in any context. For products that qualify for the simplified format, if manufacturers voluntarily declare nutrients allowable under § 101.9(c) that are not among the 14 required nutrients (e.g., potassium), the required statement "Not a significant source of _____," must be used, with the blank filled in with the name of any of the 14 required nutrients or food components that are not present or are present in insignificant amounts. Moreover, if a product is voluntarily enriched or fortified with added vitamins or minerals, any such nutrients must be declared using the simplified format and followed by the above statement. Thus, a product labeled as "bottled water, minerals added" will have to bear nutrition labeling.

The agency considers the identity statement "fluoridated water" misleading if the product is derived from a source naturally containing fluoride. Use of the term "fluoridated" represents that fluoride has been added in the processing. Thus, the term "fluoridated water" should be used to describe only products to which fluoride has been added in the manufacturing process, and such products would be required to bear nutrition labeling that complies with the simplified format.

Bottled water products containing juice or other flavors are subject to the same nutrition labeling requirements as any other food. If a product meets the criteria for no nutritional significance, and no claims are made, then nutrition labeling is not required. A "sodium free" declaration on bottled water or on any other food label will trigger nutrition labeling, because such a claim promotes the nutritional properties of the product.

202. One comment stated that, to avoid varying interpretation, FDA should clarify what it means by the term "implicit" as it applies to nutrient content claims or information that will bar a food from an exemption from nutrition labeling under the "no nutritional significance" provisions.

A thorough discussion of implicit claims may be found in the companion documents on nutrient content claims and health claims, found elsewhere in this issue of the **Federal Register**.

D. Foods for Infants and Children Less Than 2 Years of Age

In the mandatory nutrition labeling proposal (§ 101.9(h)(4)) and in the supplementary proposal (§ 101.9(j)(4)), the agency proposed to require that foods, other than infant formula, that are represented or that purport to be specifically for infants and toddlers less than 2 years of age bear nutrition labeling, except that such labeling shall not include information on the number of calories from fat or the amount of saturated fat and cholesterol present in the food.

203. The comments supported this proposal. One comment, noting that proposed § 101.9(j)(4) refers to "toddlers less than 2 years of age" and other references in § 101.9 refer to toddlers as children less than 4 years of age, recommended that "children less than 4 years of age" be used, or that the term "toddler" be clarified. Another comment pointed out the practical fact that some foods used in the 1 to 2 year age bracket are also used by some children up to 4 years of age as well as by adults who have problems chewing food.

FDA does not agree that these special labeling requirements proposed for foods for infants (other than infant formula) and toddlers less than 2 years of age should be extended to children less than 4 years of age despite the fact that no other nutrition labeling requirements use 2 years of age as a cutoff. The agency does not believe there is scientific support to change the cutoff to 4 years because dietary recommendations for very young children are specific in citing 2 years of age as the age under which dietary modifications are not appropriate. For instance, the "Report of the Expert Panel on Blood Cholesterol Levels in Children and Adolescents" of the National Cholesterol Education Program (NCEP) states:

> The fast growth of infants requires an energy-dense diet with a higher percentage of calories from fat than is needed by older children. Based on current knowledge, it is inappropriate to apply nutrient guidelines for fats, cholesterol, and calories to children under 2 years of age.

(Ref. 114.)

and:

> As toddlers over 2 years of age begin to eat with the family, they may safely make the transition to this [recommended] eating pattern.

(Ref. 114.)

However, FDA believes that some clarification is needed as to the types of foods addressed in § 101.9(j)(4) (which is redesignated as § 101.9(j)(5)(i)). The agency advises that the infant and toddler foods to which the special labeling requirements are intended to apply are the types of foods represented in § 101.12(b), Table 1 entitled "Reference Amounts Customarily Consumed: Infant and Toddler Foods" in the rule entitled "Food Labeling; Serving Sizes" published elsewhere in this issue of the **Federal Register**. FDA notes, however, that in its serving size reproposal (November 27, 1991, 56 FR 60394 at 60397), "toddlers" was interpreted to mean children 1 through 3 years of age. Therefore, the agency advises that no special significance should be given to the word "toddler;" rather it is the age category that is important. To reduce the possibility of confusion, FDA is replacing the word "toddler" with "children." The distinguishing characteristic of foods to which the special labeling requirements in § 101.9(j)(5)(i) apply is that they are specifically represented or purported to be "for use by infants and children less than 2 years of age." Foods represented or purported to be for use by "children less than 4 years of age" or by "children 3 or more years of age" are not subject to the special labeling requirements of § 101.9(j)(5)(i) but should fully declare required information on fats and cholesterol.

With regard to the comment that these foods are sometimes used by older children or adults, FDA acknowledges that this occurs. The agency believes, however, that the represented use of the product must be the deciding factor. Inasmuch as the foods to which § 101.9(j)(5)(i) applies are represented to be for use by infants and children less than 2 years of age, the agency considers the use of these types of foods by children over 2 years of age or by older persons to be not particularly relevant in determining how these foods should be labeled. Accordingly, FDA has not made any change to § 101.9(j)(5)(i) in response to this comment.

204. One comment stated that the word "or" was used ambiguously in the proposed version of § 101.9(j)(5)(i) so that it was not clear whether "calories from saturated fat" or "saturated fat content" was prohibited. The comment also suggested that information on calories from saturated and unsaturated fat and the amount of unsaturated fat also should be prohibited, and that § 101.9(j)(5)(i) should be clarified by enumerating those parts of § 101.9(c) that are affected.

FDA agrees that all information relating to fatty acids should be prohibited on foods represented or purported to be for use by infants and toddlers (i.e., children) less than 2 years of age. In the proposed version of § 101.9(j)(5)(i), FDA only specified the fatty acid component that is required in nutrition labeling.

Therefore, to make the suggested change and to clear up any confusion, § 101.9(j)(5)(i) is modified to state: "* * * such labeling shall not include calories from fat ((c)(1)(ii) of this section), calories from saturated fat ((c)(1)(iii)), saturated fat ((c)(2)(i)), polyunsaturated fat (c)(2)(ii)), monounsaturated fat ((c)(2)(iii)), and cholesterol ((c)(3))."

205. One comment suggested the additional exclusion of fiber on labels of foods for infants, citing a statement made by the American Academy of Pediatrics that fiber probably is not needed in infants less that 1 year old.

FDA, in reviewing the reference cited by the comment (Ref. 115), noted that on the same page as this cited statement is the additional statement that more work needs to be done before any firm recommendations can be made on dietary fiber in pediatric nutrition.

FDA is thus not convinced that dietary fiber should be excluded from nutrition labels for foods intended for infants and children less than 2 years of age. Most foods included in Table 1 of § 101.12(b) in the final rule entitled "Food Labeling; Serving Sizes," published elsewhere in this issue of the **Federal Register**, contain less than 1 g of fiber per 100 g of edible portion (Ref. 116). Under usual circumstances, these levels would seem to preclude the consumption of high-fiber, low-calorie diets by infants or children under 2 years of age who consume such foods. Also, because dietary fiber has a natural laxative effect, the label declaration of fiber content may be useful information to the purchasers of these foods.

206. A comment to the format proposal objected to the inclusion of DRV's on foods for infants and toddlers because DRV's were not proposed for infants or children less than 4 years of age, and labels on jars of baby food are too small to allow for the additional information. The comment argued that DRV's for adults and children 4 or more years of age are not appropriate for infants and toddlers, and that there could be serious health consequences if a parent tried to adapt an infant's diet to the proposed DRV's.

FDA agrees with the comment for the reasons presented therein. In addition,

the agency believes that it is inappropriate and unnecessary to include the caloric conversion information required by § 101.9(d)(10) on foods intended for children less than 4 years of age because DRV's for this group have not been established and calculation related to such values may be misleading. Accordingly, for foods for infants and children less than 4 years of age, the agency is adding an exemption in § 101.9(j)(5)(ii) that excludes the declaration of Percent Daily Values for nutrients other than vitamins and minerals for which there are RDI's specifically established for infants and children less than 4 years of age. The exemption also applies to the footnote and caloric conversion information. Except for the omission of this information, which is otherwise required in § 101.9(d)(2)(ii), and the footnote and caloric conversion information required in (d)(9) and (d)(10), the format of the nutrition labels on such products should comply with the requirements of § 101.9 (d), (e), or (f), as appropriate. Examples of labels for foods for children less than 4 years of age and less than 2 years of age are given in appendix G.

E. Medical Foods

207. All comments received supported this exemption. In addition, several comments expressed support for the agency's intention, stated in the supplementary proposal (56 FR 60366 at 60377), to develop specific regulations for medical foods in the near future. Some comments suggested that nutrition labeling, intended for use by the general population, does not provide the kind of information needed by health care professionals or patients selecting or using medical foods. The comments noted that, in light of this exemption, there is little guidance for labeling of medical foods, other than general food labeling regulations, citing the need for labeling of nutrient content and purported uses and adequate and appropriate directions for use. In addition to the need for specific labeling requirements, some comments identified the need for quality control and good manufacturing practices specific for medical foods.

Section 403(q)(5)(iv) of the act exempts medical foods from nutrition labeling requirements. The agency agrees with the comments that the exemption for medical foods from nutrition labeling is appropriate considering that these products are not intended for use by the general population but rather are intended for use under the supervision of a physician for specific dietary management of a disease or condition. However, the agency also recognizes that the exemption creates a void in terms of specific labeling regulations suitable for these products. FDA believes, as noted in some comments, that the proper labeling of the nutrient content and purported uses of medical foods, perhaps in a different manner or in more detail than is required for other, more traditional foods, and adequate and appropriate directions for use, as well as assurances of the quality of medical food products, are all of vital public health interest. While these issues are beyond the scope of this rulemaking, the agency intends to develop regulations covering these aspects of medical foods in a future **Federal Register** document.

208. The comments support incorporation into the nutrition labeling regulations the definition of medical foods from section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)). Section 403(q)(5)(iv) of the act incorporated this definition by reference into the statute, and FDA in proposed § 101.9(j)(7) to incorporate the statutory definition of "medical food" into the nutrition labeling regulations. Some clarification of this definition was included in the preamble and codified sections of the proposal, providing some guidance in regard to the intended use of a medical food. However, several comments cited particular products and asked whether the products would be regulated as medical foods.

FDA considers the statutory definition of medical foods, from section 5(b) of the Orphan Drug Act, to delineate the principal characteristics of medical foods. Additional clarification of this definition, contained in the preamble of the proposal, gives guidance on some of the types of products that the term "medical foods" pertains to by identifying a variety of foods that the agency regards as medical foods and some that are not presently regarded as medical foods. Criteria that product must meet to be considered a medical food are stated in the preamble of the proposal, as well as in proposed § 101.9(j)(7), redesignated as § 101.9(j)(8) in the final rule. FDA believes that this definition and the information clarifying the definition in the proposal are reasonable guides for use by industry in determining the characteristics of a medical food at present.

However, following review of the comments generated by this proposal, FDA acknowledges that further clarification of the types of products that are considered to be medical foods by the agency would be helpful to manufacturers. While these comments go beyond the scope of this rulemaking, the agency intends to address this issue in a future **Federal Register** document.

209. One comment suggested that in proposed § 101.9(j)(7)(v), the words "* * * provided only to a patient receiving active and ongoing medical supervision * * *" be changed to read "* * * intended only for a patient receiving active and ongoing medical supervision * * *." The comment stated that manufacturers can label products in a manner that gives a clear indication of the intended level of supervision, but that the word "provided" in this section might require a distribution system beyond the control of the manufacturer, restricting availability of medical foods to prescription status or distribution through an institution.

The agency agrees with this recommended change for the reasons stated in the comment and has modified new § 101.9(j)(8)(v) accordingly.

210. One comment suggested that the word "seeks" in proposed § 101.9(j)(7)(v) be changed to "require." The comment noted that while some patients receiving a medical food under the supervision of a physician are capable of seeking "medical care on a recurring basis," others receiving a medical food under the supervision of a physician are not able to actually "seek medical care" on their own (e.g., a comatose patient).

FDA agrees with the suggested change. The agency acknowledges that a medical food, under the supervision of a physician, may be consumed by, or be administered enterally to, some patients capable of seeking medical care and may be administered enterally to other patients who may be too ill to actively seek medical care. In both instances, the patient may require a medical food for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. FDA has modified § 101.9(j)(8)(v) accordingly.

F. Foods Shipped in Bulk Form

211. FDA received many comments that supported proposed § 101.9(j)(8) that exempts foods shipped in bulk form. A few comments sought clarification of this exemption, requesting that new § 101.9(j)(8) include a statement that flavors and other food ingredients (as opposed to processed foods) shipped in bulk form from one manufacturer to another for use in the manufacture of other foods are exempt.

FDA intended the term "processed" in § 101.9(j)(8) (redesignated as

§ 101.9(j)(9)) to indicate that food ingredients used in the manufacture of other foods were exempt, maintaining the scope of current § 101.9(h)(8). However, for further clarification, FDA is modifying § 101.9(j)(9) as requested to state:

Food products shipped in bulk form that are not for distribution to consumers in such form and that are *for use solely in the manufacture of other foods or that are* to be processed, labeled, or repacked at a site other than where originally processed or packed. (Emphasis added).

G. Foods for Institutional Food Service Use

212. Several comments objected to proposed § 101.9(j)(9) that would require manufacturers or distributors of foods for institutional food service use (i.e., for use by hospitals, schools, prisons) to provide nutrition information required by this section directly to the institutions on a current basis. The comments stated that this requirement was in conflict with section 403(q)(5)(A)(i) of the act, which exempts food that is sold for sale or use in restaurants or other establishments in which food is served for immediate human consumption. The act does not differentiate between food served in institutional and noninstitutional settings. In fact, the comments pointed out that the legislative history specifies that similar food service establishments include cafeterias and hospitals.

FDA agrees with the comments and has deleted proposed § 101.9(j)(9) to bring the final rule into compliance with the 1990 amendments. To clarify that institutional food service establishments are included under the exemption for restaurants and other establishments, FDA has added them as examples in § 101.9(j)(2)(ii).

However, the agency finds merit in other comments that supported nutrition labeling of foods sold to restaurants and other food service establishments in order to enable food service operators to become more aware of the nutritional content of foods they serve, to offer more healthful menu options, and to use more accurate descriptors on their menus. The agency, therefore, encourages manufacturers, packers, and distributors to make nutrition information available to food service operators whenever possible.

H. Single-Ingredient Packaged Fish Products

213. Comments received from the fish industry objected to the inconsistencies between the voluntary nutrition labeling program for raw fish and the mandatory nutrition labeling program. They pointed to the potential for confusion when raw fish under the voluntary program are labeled on an "as consumed" (i.e., "as proposed") basis, and the same fish, when frozen and packaged by a manufacturer, are labeled on an "as packaged" basis. They also pointed to the inconsistency with the USDA proposal that allows single-ingredient raw meat and poultry items, whether frozen or unfrozen, to be under a voluntary program with nutrition information reported on either an "as packaged" or "as consumed" basis.

FDA agrees that consumers may be confused to find inconsistent nutrition labeling on two packages of the identical fish (e.g., fillet of flounder) when one is under the voluntary program for raw fish, and the other is under the mandatory program for frozen packaged fish. According to the final rule for the voluntary program (November 27, 1991, 56 FR 60880; corrected at, March 6, 1992, 57 FR 8174), nutrition information for raw fish is to be reported for a 3 ounce, cooked edible portion (see appendix B, 57 FR 8174 at 8175). The final rule on serving size, published elsewhere in this issue of the **Federal Register**, provides that under the mandatory nutrition labeling program, nutrition information for frozen packaged fish is to be reported for that amount required to prepare 85 g (approximately 3 ounces) of cooked fish (§ 101.12 (b) and (c)) but is to be based on the product "as packaged" (§ 101.9(b)(9)).

To reduce the inconsistencies in nutrition labeling between raw versus frozen packaged single-ingredient fish, and between single-ingredient fish versus single-ingredient meat and poultry, FDA is adding a special labeling provision for fish in § 101.9(j)(11) that allows single-ingredient fish to be labeled on a cooked (i.e., "as prepared") basis consistent with the voluntary program for fish and with USDA's rules for single-ingredient meat and poultry products. Packaged fish that contain added ingredients such as water, salt, or additives such as sodium tripolyphosphate are considered multi-ingredient processed packaged fish products and must continue to be labeled on an "as packaged" basis.

However, in the companion document on nutrient content claims published elsewhere in this issue of the **Federal Register**, claims such as "lean," "extra lean," and "low fat" are based on as packaged values. Therefore, single ingredient packaged fish products that make such claims must provide nutrition information on an "as packaged" basis.

I. Raw Fish in Voluntary Nutrition Labeling Program

214. One comment objected to the manner in which FDA defined "raw" for the purpose of determining what fish products are covered by the exemption in proposed § 101.9(j)(10) that subjects the food to the voluntary nutrition labeling program. The comment stated that "absent a definition in the NLEA, the term "raw" means "uncooked" regardless of whether or not the product is frozen and, therefore, packaged frozen raw fish should not be subject to mandatory nutrition labeling.

FDA discussed its interpretation of the word "raw" as it pertains to fish in its proposed rule (July 2, 1991, 56 FR 30468 at 30470) and final rule (56 FR 60880 at 60886) implementing the voluntary nutrition labeling program for raw fruit, vegetables, and fish. Lacking legislative guidance, the agency chose to draw a practical line in terms of retail selling practices and program implementation rather than one based on a strict definition of the term "raw." While the agency included in the voluntary program those fish that are generally sold raw (i.e., not heat treated), it also included thermally processed shelled or unshelled lobster, crab, and shrimp. The intent was to allow for voluntary nutrition labeling of fish that are generally sold refrigerated, or on ice, or are alive at purchase in fish stores or in the fresh fish section of grocery stores and that are not packaged or are packaged by the retailer or by a packer. These are the types of products for which mandatory nutrition labeling is most impractical. In contrast, providing nutrition labeling for raw, frozen fish that are packaged by a manufacturer (usually in a box with a printed label and brand name) and sold in the frozen food case of a grocery store is no more difficult for a manufacturer than providing nutrition labeling of other packaged foods. Thus, these products appropriately come under the mandatory nutrition labeling program.

The agency has made a similar distinction with frozen packaged raw fruit and vegetables and has received no comment on it. It is likely that the greater concern on the part of the fish industry was a result of the inconsistency between nutrient values to be declared in the voluntary versus mandatory programs (i.e., nutrient values based on "as prepared" versus "as packaged" levels, respectively). The agency believes the exemption in new § 101.9(j)(11) should eliminate this concern. Accordingly, FDA sees no need to amend its interpretation of the term "raw."

The agency would like to clarify, however, a misinterpretation of the above definition of raw fish that appeared in comments. FDA considers raw shellfish in or out of the shell to be under the voluntary program, whether they are sold bagged in plastic containers or displayed loosely in trays or bowls. In addition, pasteurized crab meat that is not shelf-stable and is sold on ice or refrigerated would be included under the voluntary program, whereas canned pasteurized crab meat that is shelf-stable would be subject to mandatory nutrition labeling regulations. As discussed above, the agency considers nutrition labeling of the refrigerated product that may not have gone through a manufacturing plant impractical. However, the processing of the canned product is standardized, and nutrition labeling can be easily accomplished and is required.

J. Meat Products Regulated by FDA

215. Several comments recommended that nutrition labeling of game meat should be on a voluntary rather than mandatory basis. One game meat association stated that because buffalo is a red meat, it should be exempt from FDA regulations and should be allowed the option of voluntary labeling under USDA guidelines. The comment also requested that any required nutrition information should be allowed to be displayed at the point of purchase to reduce costs associated with nutrition labeling.

A number of comments expressed concern that the cost of analytical testing and nutrition labeling would be prohibitive for the small game meat producer. A request was made that an economic impact study be conducted of the effect of the proposed regulations on the buffalo industry before any final rule is issued. Comments suggested small business exemptions for producers marketing less than from 100,000 to 150,000 pounds per year per each product label. A few comments also requested that introductory test market, seasonal, short run, and experimental products should be exempt from nutrition labeling.

FDA is responsible for the regulation of all meats not covered by USDA under the Federal Meat Inspection Act and the Poultry Products Inspection Act (e.g., deer, bison, rabbit, wild turkey, or ostrich, hereinafter identified as "game meats"). Therefore, the law does not provide an option for such products to be covered by USDA guidelines. However, FDA appreciates the fact that game meat producers have had little, if any, experience with nutrition labeling, and that analytical data base information is scarce. Accordingly, the agency will give game meats as much latitude as possible under the 1990 amendments.

Because many game meat producers are small enterprises, it is possible that some will fall under the current small business exemption. Many of those that do not may do so in the future if a legislative amendment is passed to increase the exemption. However, if an amendment is not forthcoming, all nonexempt producers must provide the required nutrition information when the regulations become effective.

While the statute does not allow FDA to include raw game meats under the voluntary nutrition labeling program for raw fruit, vegetables, or fish, for consistency among all animal flesh products, single-ingredient game meat products (frozen or unfrozen, packaged or unpackaged) will also be included in § 101.9(j)(11) that permits the information to be declared on either an "as purchased" or "as prepared" basis (see comment 213 of this document).

Also, in response to a comment, FDA is adding § 101.9(j)(12) to the final regulations to allow nutrition information to be provided in accordance with paragraph (a)(2) of this section which allows the required information to be placed on labeling, that is on signs, posters, tags, or in binders or booklets displayed at the point-of-purchase. FDA believes that this action will allow game meat producers to give first priority to nutrient analyses and data collection and to update nutrient declarations more frequently than would be possible if the information were printed on food labels.

216. One comment requested the use of a data base to reduce the cost of nutrition labeling for game meat. It was noted that the nutrient composition of buffalo meat varies widely according to whether the animal was grain fed or range fed and according to age at slaughter. Another comment recommended that nutrient information for buffalo meat come from actual sample testing and not computer composites. The comment requested that FDA/USDA "do the same complete nutritional study for the buffalo industry as it does for other industries enveloped by the proposal."

FDA acknowledges that there is limited nutrient data available on game meats. The agency advises that it does not conduct nutrient analyses for any commodities; however, it is willing to work cooperatively with game meat producers to produce a valid nutrient data base. To this end, the Agriculture Research Service of USDA has experience in working collaboratively with industry in developing food composition data (Ref. 117).

217. Many game meat processors requested exemption from nutrition labeling for custom services. Custom processed meat includes wild game or domestic stock that is butchered to the specifications of the customer. The meat may have been sold to the customer or brought in by the customer for butchering. Comments stated that because the customer owns the animal at the time of butchering, the nutritional aspect of the meat product is the responsibility of the customer.

Consistent with similar regulations being issued simultaneously by USDA for nutrition labeling of meat and poultry products, FDA is exempting custom processed fish and game meats from mandatory nutrition labeling. This exemption is found in new § 101.9(j)(11)(ii). Legal authority for this is that what is being sold is not the food but the processing. Thus, the food is not subject to section 403(q) of the act.

K. Small Packages

218. A number of comments supported the small package exemption proposed in § 101.9(j)(11). While a few comments supported the provision that nutrition labeling be provided for foods in small packages at the point of purchase in accordance with paragraph § 101.9(a)(2), many other comments objected to this requirement. Several of these comments objected on the grounds that the 1990 amendments did not include a requirement for point of purchase disclosure for small packages, or that point of purchase displays of nutrition information would create "unnecessary clutter" and "place an undue burden on retailers" to find space for the information. One comment stressed the economic impact the proposal would have on supermarkets, especially those with front-end operations and checkout lanes where a wide variety of small package items are offered for sale. The comment stated that such areas would have to be reconfigured with fewer items available because of space lost to signage and fewer inventory changes made throughout the year. A comment raised a question about who would be held responsible if the information was not available at the point of purchase. Comments recommended that manufacturers, not retailers, should be responsible for nutrition information on all packaged foods. A suggestion was also made that interested consumers could refer to larger retail packages of the same product or could write or call the manufacturer for the nutrition

information by using an address or telephone number given on the package label.

FDA is persuaded by the comments that it is impracticable to require point of purchase display of nutrition information for small packages. However, because section 403 (q)(5)(B) of the act states only that the nutrition labeling requirements shall not apply to the label of the food, not the labeling as is included in section 403(q)(5)(C) and (q)(5)(D), the agency concludes that nutrition information about food in small packages must be provided to consumers through alternative means. The agency agrees with the comments that manufacturers should bear the responsibility for nutrition labeling of packaged foods and finds merit in the suggestion that manufacturers provide an address or telephone number on the package for consumers to write or call for nutrition information. FDA believes that almost all small packages should be able to add a short phrase, such as "For nutrition information, call 1-800-123-4567" to the label. In fact, many packages currently give an address or telephone number for consumer use in obtaining additional information about the product.

Therefore, FDA has modified § 101.9(j)(11), redesignated as § 101.9(j)(13)(i), to delete the requirement that foods in small packages that bear no nutrition claims or other nutrition information provide the required nutrition labeling in accordance with § 101.9(a)(2). The agency replaced it with a requirement that the manufacturer clearly state on the package label where a consumer may write or call to obtain the required nutrition information. If a manufacturer finds that it is impracticable to comply with even this requirement on a particular product, the manufacturer should write to the agency in accordance with § 101.9(g)(9) (see section VI.P.3. of this document).

219. A few comments from health professional organizations expressed the belief that the 12 square inch standard for "small packages" was too large, and that consumers should have as much information as possible about what they purchase and consume. One comment stated that "with the increase in fabricated foods and single serving size packaging, [they were] convinced that nutrition information can and should go on less space," adding that by using an abbreviated format, nutrition labeling is possible on smaller packages, down to 8 square inches.

However, several other comments objected to the 12 square inch definition for small packages, stating that it would not allow enough space for all the required information on the label, especially on a product with a lengthy ingredient list. The comments stated that the 12 square inch standard for exempting small packages was established years ago when much less information was required on food labels (i.e., before mandatory nutrition labeling). The comments also expressed concern that attempting to include all of the required information in 12 square inches would result in a label that would not be legible, making it difficult for sight-impaired or elderly persons to read. Comments also said that such a presentation would discourage use of the nutrition information, thereby undermining the purposes of the 1990 amendments.

Two manufacturers commented on the unique space problems arising when more than one language is used on small packages inasmuch as § 101.15(c)(2) requires that if a language other than English is used, all information on the label must be printed in both English and the other language. One comment pointed to the fact that the United States has become an increasingly bilingual nation, making Spanish-language labeling a "necessity in many parts of the country."

Several comments requested a more flexible rule based on "practically available space" or "usable surface space" on labels. One comment stated that the term "surface area available to bear labeling" is newly coined and unfamiliar and likely to be confusing. The comment recommended that the exemption be couched in terms of "total square inches on the information and alternate panels," which are familiar terms to manufacturers.

Other suggestions included: (1) Using a 20 square inch surface area, (2) excluding the principal display panel from the 12 square inch requirement, (3) excluding odd shaped parts of packages from the total surface area available for nutritional labeling, (4) allowing a linear (i.e., string) format for the nutrition information, (5) making the nutrition profile optional, (6) allowing for abbreviations of nutrients, (7) deleting the requirement for declaration of "Servings per container" on single-serving containers, and (8) allowing required nutrition information to appear anywhere on the package expected to be read by consumers rather than just on the information panel as required by § 101.2. In regard to the latter comment, one comment suggested that § 101.2 be modified to allow required information to be placed on other label panels adjoining the principal display panel or the information panel when there was insufficient space on a single panel.

A few comments stated that no manufacturer should be required to change its existing label style or container size to accommodate nutrition labeling. The comments urged that areas of a package not traditionally used for labeling should be excluded from the total surface area (e.g., many companies do not use lids of jars, necks of bottles, or bottoms of cans for labels). One comment recommended that current company practices be grandfathered until the company changes its packaging or container.

The agency received additional comments regarding small package limitations in response to the format proposal. Several comments from manufacturers of smaller size products such as candy rolls and bars, chewing gum, canned fish, and cookies stated that such labels could accommodate only the CONTROL format. Two comments suggested raising the minimum 12 square inch requirement for "small packages" to 13 square inches.

A number of comments addressed the inclusion of the DRV's on the labels of small packages. These comments apply to inclusion of the footnote providing calorie-specific recommended nutrient amount information specified in § 101.9(d)(8)(i).

The majority of comments asserted that it would be difficult to accommodate the DRV's without a relaxation of the minimum requirement of 12 square inches of printable label space. Most of those seeking relief suggested the option of listing DRV's in linear rather than column array over an intermediate range of printable package area. Alternate upper limits suggested were 20 and 26 square inches or no more than 30 percent of printable package area devoted to the nutrition label. One manufacturer provided support for 20 square inches as a minimum area below which DRV's could not be accommodated without violating minimum type size or principal display panel size requirements. It submitted executions of the proposed and alternate formats for several existing products. One comment suggested several principles to be followed by FDA in establishing a range within which the DRV listing could be modified or deleted while preserving legibility and remaining in conformance with existing labeling requirements concerning type size and area devoted to the principal display panel.

FDA acknowledges the need to give consumers as much information as possible. The agency is persuaded,

however, that with requirements for more nutrition-related information, it may be difficult to get all of the required information on packages that just meet or slightly exceed 12 square inches of surface area available to bear labeling, particularly for products that do not qualify for the simplified format. However, in light of the exemption from nutrition labeling on the package label for products with less than this amount of usable surface space, provided that no nutrition claim is made (see preceding comment), the agency believes that exempting a larger number of foods by increasing the definition of "small package" size would undermine the intent of the 1990 amendments.

However, based on the comments, FDA has concluded that justification exists for developing a graduated system that would allow added flexibility for foods in an intermediate package size group. To select the dimensions of such an intermediate sized package, FDA reviewed comment suggestions, examined the space requirements of the required label with the calorie-specific daily values, and reviewed data on available label area for a sample of packaged foods (Ref. 117a). The agency is rejecting suggestions such as the use of only "practically available space" or "usable surface space" or the exclusion of "oddly shaped parts of packages" because there is a significant potential for differences of opinion about what is "practically available," "usable," or "oddly shaped." The remaining suggestions are to exclude the principal display panel, to use an upper limit of 20 or 26 square inches of surface area available to bear labeling, or to require that no more than 30 percent of the surface area available to bear labeling be devoted to the information panel.

The agency believes that the suggestion to apply the 30 percent criterion to space requirements necessary to comply with FDA regulations has merit. Based on current requirements (see § 101.1(b) and (c)), the principal display panel can be considered to cover 40 percent of the total surface area available to bear labeling. On the assumption that no more than half of the remaining 60 percent of the label should be required to be devoted to FDA-required information (i.e., the nutrition label and ingredient list), 30 percent of the total surface area would be used for such information. This is consistent with the comment.

Based on the data examined, FDA believes an upper limit of 40 square inches of surface available to bear labeling is appropriate to define an intermediate sized package. The smallest legal sized execution of the format required under § 101.9(d) is approximately 7 square inches. For many processed foods, the addition of the ingredient list could bring the space needed for presenting this FDA-required information to 11 square inches. Using the 30 percent factor, this information could be accommodated on packages with 37 square inches available to bear labeling. In order to provide incentive to allow sufficient space to make the label readily observable and easily comprehensible, the agency has decided to round this number up to 40 square inches. The agency is providing for this upper limit in § 101.9(j)(13)(ii).

The agency does not agree with the comment that the term "surface area available to bear labeling" is newly coined and unfamiliar, inasmuch as it has been used in § 101.2(c)(3)(i) for 17 years.

FDA looked to the comments for suggestions of added flexibility for the labeling of foods in intermediate sized packages available to bear labeling. Suggestions in the comments included: Allowing a linear (i.e., string) format for nutrition information (including the DRV listing), making DRV's optional, allowing for abbreviations, deleting the requirement for declaration of "Servings per container" on single-serving containers, and allowing required nutrition information to appear in other places than those required by § 101.2 (i.e., the information panel). Dependent upon the circumstances of a particular package size and shape, the agency is not opposed to the use of any of these suggested methods. In addition, as provided for in § 101.9(g)(9), manufacturers may request special allowances for provision of the required information on tags affixed to the product according to § 101.9(a)(2) as discussed in section VI.P.3. of this document, Foods For Which Labeling Is Impracticable.

In regard to the request to delete the requirement for declaration of "Servings per container" on single serving containers, FDA finds that inasmuch as the declaration of "Serving size" on such products will specify that the serving is the entire unit (e.g., 1 can or 1 bar), it would be needlessly repetitive to state that there is one serving per container. Therefore, FDA has modified § 101.9(d)(3)(ii) that pertains to all container sizes to state that "Servings per container" is not required on single serving containers as defined in § 101.9(b)(6).

While the provisions being made to increase flexibility are for the purpose of making it easier for manufacturers to place mandatory nutrition labeling on packages of an intermediate size, they may also be used on "small packages" (i.e., packages with less than 12 square inches of surface area available to bear labeling) whose labels are exempt under § 101.9(j)(13)(i) when manufacturers elect to provide a nutrition label on those foods.

FDA is providing in § 101.9(j)(13)(ii)(A) that the required nutrition information may be presented in a tabular fashion when the package shape or size cannot accommodate a column display on any label panel. This form of presentation is currently used on many foods in long rectangular or round packages, such as candy bars and is shown in Appendix H. In addition, to facilitate the provision of information on small packages, § 101.9(j)(13)(ii)(A) provides for the use of a tabular presentation on all products with less than 12 square inches of surface area available to bear labeling, regardless of the package shape. Further, if the label will not accommodate a tabular display, § 101.9(j)(13)(ii)(A) also provides that the required nutrition information may be presented in a linear (i.e., string) fashion.

In regard to abbreviations, one comment stated that the design limits of their company's printers for labels to be affixed to foods packaged in retail stores limited the description of nutrients to 10 characters. While the agency is concerned about the use of abbreviations and any possible consumer confusion they may cause, FDA believes their use under limited and controlled conditions may be preferable to overcrowding within the nutrition label. Therefore, based on this comment, the agency is providing the following abbreviations in § 101.9(j)(13)(ii)(B) for those mandatory nutrients whose names exceed 10 characters.

Serving size: Serv. size
Servings per container: Servings
Calories from fat: Fat cal
Saturated fat: Sat fat
Cholesterol: Cholest
Total carbohydrate: Total carb
Dietary fiber: Fiber

Section 101.9(d)(9)(iv) allows these abbreviations to also be used in a footnote within the nutrition label.

As discussed above in section V. of this document on the format of the nutrition label, FDA is providing in § 101.9(j)(13)(ii)(C) that the footnote and caloric conversion information required in § 101.9(d)(9) and (d)(10) may be omitted on intermediate sized packages. When the footnote required by § 101.9(d)(8) is omitted, an alternate footnote must be used that states:

"Percent Daily Values are based on a 2,000 calorie diet."

The agency believes that concerns expressed in comments requesting that the nutrition information be allowed to appear elsewhere on the package rather than just on the information panel as required by § 101.2 (see § 101.9(i)) are generally addressed by § 101.2(a)(1). This section states that if the information panel is too small to accommodate the necessary information or is otherwise unusable label space, e.g., folded flaps or can ends, the panel adjoining to the right may be used. However, in recognition of the increased need for this flexibility in packages with less than 40 square inches available to bear labeling, FDA is providing in § 101.9(j)(13)(ii)(D) that nutrition labeling on intermediate sized packages may appear on any label panel.

As a conforming change, § 101.9(c), (d), and (i) have been modified to reflect the provisions of § 101.9(j)(13).

In regard to the comments requesting an exemption or postponement based on current company labeling practices, FDA advises that Congress did not provide in the 1990 amendments for any such actions. The agency recognizes the possible economic burdens associated with changing labeling practices and has tried to incorporate sufficient flexibility to minimize the need for such changes but has no authority to prevent them. FDA advises that in § 101.1 the agency stated that, in determining the area of the principal display panel, tops, bottoms, flanges at tops and bottoms of cans, and shoulders and necks of bottles and jars were to be excluded. Therefore, it is reasonable to conclude that the agency will not include these areas in determining the "surface area available to bear labeling."

220. A comment requested clarification as to whether manufacturers of products that are sold in small packages that qualify for the small package exemption are required to omit nutrition information from the label and then present it through other means as required in proposed § 101.9(a)(2), or whether they may attempt to provide the nutrition labeling.

While comment 218 of this document addressed the underlying concern in this comment about the mandatory inclusion of required nutrition information in labeling at the point of purchase, FDA does not view this or any other exemption under § 101.9(j) (except for infant formula which is subject to other labeling requirements) as prohibiting a manufacturer from including nutrition labeling on the label of a food product. The agency encourages the inclusion of nutrition information on the label of exempted products whenever possible. To clarify the situation, § 101.9(j)(13)(i) has been modified to state that the new requirement for an address or telephone number for consumer use in obtaining nutrition information is to apply to products that qualify and use this exemption.

L. Shell Eggs

221. One manufacturer commented on the labeling of egg cartons, stating that proposed § 101.9(j)(12) allowing for the presentation of the required nutrition information immediately beneath the carton lid is as impractical for many egg cartons as requiring its display on the upper surface of the lid because both surfaces conform to the shape of the eggs. The comment suggested that packaging of this kind may not be readily imprinted at all. The comment further stated that eggs are a largely homogeneous agricultural commodity, and eggs sold at retail in their shells should all be treated alike with respect to nutrition labeling, whether the eggs are in bulk, on trays without cartons, or in cartons. The comment requested that eggs be exempt under 21 U.S.C. 343(q)(3) that allows the Secretary to provide that nutrition labeling be displayed at the point of purchase for foods received in bulk containers.

FDA is persuaded by the comment that it may be impractical for egg cartons that conform to the shape of the eggs to bear nutrition labeling. Accordingly, FDA is modifying § 101.9(j)(12) (redesignated as § 101.9(j)(14)) to allow the required nutrition information to appear on the inside or the outside of the carton, or on an insert that can be clearly seen when the carton is opened. By doing this, FDA is greatly expanding the total surface area available to bear labeling.

FDA rejects the suggestion that, because some eggs are sold in bulk, all eggs should be allowed to be labeled at the point of purchase according to the exemption for bulk foods (§ 101.9(j)(9)). As discussed above, nutrition labeling for eggs may appear on the egg carton or on a package insert. FDA concludes that there is no need to modify § 101.9(j)(14) to allow for further special conditions for shell eggs packed in cartons. If, in fact, a manufacturer finds it impossible to label a particular egg carton or to include a package insert, it may request a special allowance from the agency, as discussed in comment 223 of this document.

M. Multi Unit Packages

222. A few comments disagreed with the requirement in proposed § 101.9(j)(13)(iii) that each unit within a multipack state "this unit not labeled for retail sale." Comments stated that this requirement is redundant because § 101.9(j)(13)(i) and (j)(13)(ii) adequately prevent the product from being sold without nutrition labeling.

The agency does not agree that the requirement is redundant. Although multiunit containers may be enclosed and are not intended to be separated from the retail package under normal conditions of sale, occasionally the individual units are separated from the multiunit container and purchased separately. Proposed §§ 101.9(j)(13)(i) and (j)(13)(ii), redesignated as §§ 101.9(j)(15)(i) and (j)(15)(ii), state: "The multiunit retail food package labeling contains all nutrition information in accordance with this section;" and "The unit containers are securely enclosed within and not intended to be separated from the retail package under conditions of retail sale." These sections cannot guarantee that the units in a multiunit package will not be separated; e.g., frozen juice bars, soft drink bottles, and sticks of butter are sometimes separated from an enclosed multiunit package by consumers prior to purchase at the retail level. Therefore, FDA is not modifying the regulation.

223. A soft drink trade association requested a provision in the final rule to exempt from nutrition labeling glass bottles with lithographed labeling that are marketed in multi-unit packages. These bottles, the comment pointed out, are often loosely packed rather than securely enclosed. The comment made reference to the technical limitations of labeling glass by the lithograph method, and the impracticality of placing nutrition labeling on the individual bottles or "unit containers." The comment requested that the agency clarify the proposal to ensure the continued availability of lithographed bottle multiunit packages and suggested that the nutrition labeling information appear on the information panels of the multiunit retail package.

The agency acknowledges that there will be some circumstances in which strict adherence to the regulations (in this case the requirement that units be securely enclosed in the retail package) is not technologically feasible, or some other circumstance makes it impracticable. Proposed § 101.9(g)(8) would have allowed for alternative means of compliance or additional exemptions to deal with the situation when firms were unable to develop

adequate nutrient profiles. The agency concludes based on this comment that this latitude should be available for additional circumstances. Accordingly, FDA is modifying § 101.9(g)(8), redesignated as § 101.9(g)(9), to broaden its scope by stating "When it is not technologically feasible, or some other circumstance makes it impracticable, for firms to comply with the requirements of this section (e.g., to develop adequate nutrient profiles to comply with paragraph (c)), * * *."

Additionally, FDA believes that actions taken to address technological or other problems on a case-by-case basis do not need to be established by regulation in response to a petition to initiate rulemaking. Therefore, the agency is replacing "establish by regulation" with "permit" in § 101.9(g)(9) and is deleting the reference to a petition, stating instead that firms in need of such special allowances shall make their request in writing to the Food and Drug Administration, Office of Nutrition and Food Sciences (HFF-200), 200 C St., SW., Washington, DC 20204. However, FDA concludes that no change is necessary in § 101.9(j)(15) in response to this comment.

N. Foods Sold from Bulk Containers

224. A food retailer wrote in support of the requirement in proposed § 101.9(j)(14) that nutrition labeling information for bulk foods be provided at the point of purchase. However, the comment took exception to the agency's intention to include within the requirement individually wrapped bulk food items such as candies, arguing that the exemption for small packages should apply to small individually wrapped food items that are sold in bulk.

FDA disagrees with this comment. The labels of individually wrapped small food items, such as bite size pieces of candy, are exempt from nutrition labeling under the small package exemption (§ 101.9(j)(13)) because of the lack of space needed to print the required information. However, under section 403(q) of the act, foods sold from bulk containers must be nutrition labeled whether or not they are individually wrapped. Nutrition labeling can, and should, be presented on the labeling of the bulk container or on a counter card, sign, or other appropriate device as identified in § 101.100(a)(2). Moreover, as discussed above, the exemption for small packages only applies to the label and not to a product's labeling. The agency reiterates its position as stated in the **Federal Register** of July 19, 1990 55 FR 29487 at 29505, and 56 FR 60366 at 60379:

> * * * Many foods, such as candies, cookies, and pasta, are offered for sale from large containers such as barrels or bins. FDA has traditionally required that these foods be labeled in accordance with section 403(i)(2) of the act through the use of a counter sign or card on the labeling of the bulk container [21 CFR 101.100(a)(2)]. The agency believes that nutrition labeling can be provided in a similar manner. Therefore, the agency will require nutrition information for such foods.

Accordingly, no changes are being made to § 101.9(j)(14), redesignated as § 101.9(j)(16).

225. Several other comments were received in support of the requirement in the proposed version of § 101.9(j)(16) that nutrition labeling information for bulk foods be provided at the point of purchase. Two comments recommended that nutrition information be provided in the form of brochures or "tear-off" sheets at the point of purchase, so that consumers can have the information available at home.

FDA agrees that tear-off sheets or brochures with the required nutrition information would be useful to consumers and encourages manufacturers to provide retailers with the required nutrition information in such form. Section 403(q)(3) of the act states: "For food that is received in bulk containers at a retail establishment, the Secretary may, by regulation, provide that the nutrition information required * * * be displayed at the point of sale." Thus, the statute does not specify the form in which this information is to be provided. Accordingly, FDA has not made the recommended change.

226. A retail ice cream manufacturer requested that the proposed version of § 101.9(j)(16) be clarified so that scoops of ice cream that are dispensed by store employees from bulk ice cream containers are clearly not subject to the "sold from bulk containers" requirement.

FDA advises that it is not necessary to exempt ice cream from the requirements of § 101.9(j)(16). Ice cream that is dispensed by store employees from bulk ice cream containers at an ice cream store is for immediate human consumption and would therefore be exempt from mandatory nutrition labeling under revised § 101.9(j)(2)(ii).

227. A retail grocery chain stated that popular bulk food items sold from bins and barrels but packaged by clerks for customer convenience should not be required to have nutrition labeling on each package.

FDA advises that § 101.9(j)(16) allows food products sold from bulk food containers to display the required nutrition information "either on the labeling of the bulk container plainly in view or in accordance with provisions of paragraph (a)(2) of this section." Section 101.9(a)(2) allows use of counter cards, signs, tags affixed to the product, or other appropriate devices. Accordingly, the containers such foods are put into when sold to the consumer need not bear nutrition labeling as long as the required nutrition information is plainly in view, regardless of whether it is the consumer or a store employee that packages the product. However, if the foods are packaged in an area that is off-limits to customers, and the information is not plainly in view, the required nutrition information must be available on the package label or in labeling adjacent to the packages accordingly to the provisions of § 101.9(a)(2).

O. Foods Used as the Sole Item of the Diet

228. One professional organization and one consumer interest group wrote in support of FDA's tentative decision to delete the exemption in current § 101.9(h)(3) for foods promoted as the sole item in a diet (such as formulated weight-loss products) and to have the same labeling requirements for those products as all other foods. The consumer interest group stated that "considering the minimal long-term benefit from these products and the potential for harm from the unsupervised use of these products, FDA should consider greater labeling requirements for these products."

FDA intends to monitor the use and labeling of foods used as the sole item of the diet and, as discussed in the supplementary proposal (56 FR 60366 at 60378), will consider at a later date whether there should be additional or different requirements for the nutrition labeling of these products.

P. Other Requests for Exemption

1. Donated Foods

229. Two comments from food banks requested an exemption from mandatory nutrition labeling, citing that food banks are nonprofit charitable organizations, and as such, it would be "unreasonably costly and unduly burdensome for (food banks) to be required to apply complete nutrition labeling to repacked food products." The comments stated that the exemption is necessary to ensure that mandatory nutrition labeling rules do not hamper the ability of charitable organizations to receive and distribute foods to needy individuals.

Section 403(q)(1) of the act requires nutrition labeling on food that "is intended for human consumption and is

offered for sale." Accordingly, donated foods that are given without charge to the ultimate consumer are not subject to mandatory nutrition labeling. This provision of the 1990 amendments was not included in the proposed implementing regulations. To correct this omission, the agency is modifying § 101.9(a) to state that "Nutrition information relating to food shall be provided for all products intended for human consumption and offered for sale * * *."

230. A second request from these foods banks was that food companies having inventories of foods not in compliance with new labeling rules after the effective date of section 403(q) of the act be permitted to donate those products to charitable organizations.

Section 10(a)(2) of the 1990 amendments states that the new nutrition labeling requirements shall not apply to foods labeled before the effective date. Therefore, companies will be able to continue to sell all foods that are labeled in compliance with current regulations before the effective date of section 403(q) of the act, May 8, 1993. As a result, there should be no inventories of labeled food that cannot be sold to consumers. The agency wishes to state, however, that it has long been the agency's policy that misbranded foods, such as those that have been the subject of a seizure or recall, can be donated to charitable organizations rather than being destroyed if they do not present a safety concern, and the recipient is fully informed as to the problem with the food (e.g., short weight).

231. Two comments expressed concern that if donated foods are exempted from nutrition labeling, the goals of nutrition labeling will not be met for individuals who rely on such foods.

In passing the 1990 amendments, Congress intended to require that consumers have the necessary information at their disposal to select diets that are consistent with dietary recommendations aimed at improving the health status of Americans. However, by requiring nutrition labeling only on foods offered for sale, Congress limited the coverage of the nutrition labeling requirements. Therefore, while the agency would encourage nutrition labeling on any foods repackaged or relabeled by charitable organizations, the statute does not require such labeling.

The agency is pleased to note, however, that in conversations with the Food and Nutrition Service, USDA, which administers the Food Distribution Program, the Food and Nutrition Service has stated that it plans to incorporate nutrition labeling on all foods that it distributes to individuals. The Food Distribution Program purchases surplus foods from American markets and distributes them to State agencies for further distribution to individuals and eligible local outlets.

2. Exported Foods

232. Comments from a trade association and a manufacturer requested that products intended for export be exempt from U.S. nutrition labeling regulations because they will necessarily be required to comply with the importing country's labeling criteria.

FDA advises that under section 801(e) of the act, foods intended for export will not be deemed misbranded under section 403 of the act under certain circumstances. Section 801(e) states that:

> A food, drug, device or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this Act if it:
> (A) Accords to the specifications of the foreign purchaser,
> (B) Is not in conflict with the laws of the country to which it is intended for export,
> (C) Is labeled on the outside of the shipping package that it is intended for export, and
> (D) Is not sold or offered for sale in domestic commerce.

Thus, if a company complies with the requirements of section 801(e) of the act, it need not be concerned about misbranding the food by failing to comply with section 403(q) of the act.

3. Foods for Which Labeling Is Impracticable

233. Two dairy companies requested that returnable glass milk bottles be exempt from nutrition labeling because the total surface area available for labeling is much less than 12 square inches. The labeling surface is the closure on the top of the bottle. If the label were placed on the side of the bottle it would be impossible to recycle the bottle for milk use because of problems with washing and disinfecting the bottle after each use. The comments stated that the returnable glass bottle is important for the environment, and that many of their customers purchase it for that reason. They suggested the nutrition labeling for milk in returnable glass bottles be placed on placards at the point of purchase.

Other comments requested special allowances for uniquely shaped package containers (such as containers of honey in the shape of a bear, individual juice containers in the shape of a hand grenade, or cheese balls) or packaging materials that do not allow for fine printing (e.g., styrofoam ice cream cups).

FDA is willing to consider allowing the required nutrition information for returnable glass milk bottles to be available in labeling, as provided for in § 101.9(a)(2). As discussed in comment 223 of this document, § 101.9(g)(9) of this final rule allows that when it is not technologically feasible, or some other circumstance makes it impracticable, for firms to comply with the requirements of nutrition labeling, FDA may permit alternative means of compliance or additional exemptions to deal with the situation.

4. Foods Purchased Under Government Contract

234. One trade association and one manufacturer requested exemptions for products produced for Government contracts (e.g., the National School Lunch Program, military feeding operations), using the reasoning that any products sold would be offered to the final consumer as part of a total meal/diet, and nutrition information on the meal must be supplied by the facility offering the meal.

FDA advises that products of the type discussed in the comment that are sold for use in restaurants and institutional food service operations are exempt under § 101.9(j)(2)(iii). As long as it is not reasonably possible that they will be sold directly to consumers, they need not be nutrition labeled. Therefore, no further exemption is necessary.

VII. Other Issues

A. Assortments of Food

235. A few comments requested clarification on whether assortments of foods, such as a box of assorted chocolates or nuts, would have to bear nutrient information on each type of chocolate (or nuts), or whether an average nutrient value would suffice.

The agency advises that in the preamble to the mandatory nutrition labeling proposal (55 FR 29487 at 29505), it stated that "where assortments of food are packaged, firms will be required to express nutrient content based on the package as a whole (e.g., the entire product contents may be combined for a nutrient analysis)." FDA recognizes that the terms "will be required" and "may be combined" appear inconsistent. Therefore, to clarify the regulation and in accordance with the agency's intent to offer flexibility in the labeling of assortments of foods, FDA has modified § 101.9(e)(1), recodified as § 101.9(h)(1), by deleting "of the total product" and adding a new sentence that states that when

separately packaged ingredients or assortments of the same type of foods are intended to be eaten at the same time, the nutrition information may be specified for each component or as a composite value. In developing a composite nutrient value, the entire product contents would be combined for a nutrient analysis.

In addition, to clarify the term "assortments of food" FDA has modified § 101.9(h)(1) by adding "assortments of the same type of food" and including the example of assorted nuts.

236. A few comments addressed the labeling of variety packs containing an assortment of individually packaged products (e.g., assorted ready-to-eat breakfast cereals or snack foods such as corn chips, cheese puffs, and potato chips). A food manufacturer marketing variety packages stated that they currently label each of the single-serving packages placed in a multi-serving container separately. The comment stated that the outer wrapping is generally transparent, making extensive labeling on the outer wrapping infeasible. Another comment suggested that the outer label contain the statement "Individual inner units carry nutrition information" where each of the single-serving packages in the variety pack bears nutrition labeling. The comment also stated that larger sizes of the individual packages of foods in the variety pack are invariably available to consumers at the same location, and the nutrition labels on those larger packages may be reviewed if desired.

FDA points out that a primary purpose of the 1990 amendments is to allow consumers to maintain healthy dietary practices. To do this, consumers must have access to nutrition information at the point of purchase. In many situations, consumers can look at the nutrition labels of larger packages of the individual foods for nutrition information. However, the agency does not agree that it is always possible to do so.

With respect to the transparent nature of the outer wrapping, FDA does not believe this makes labeling on that wrapping infeasible. Many bakery products are packaged in transparent wrappers and these products provide nutrition and other label information.

Inasmuch as many variety packs are currently printing the required nutrition information for each of the products contained in the variety pack in a table on the outer package, and because the outer packages are generally large, the agency concludes that a special allowance is not required for variety packs. Accordingly, FDA rejects the suggestion that the outer label merely state that the individual units within the package provide nutrition information.

However, the agency has no objection to manufacturers labeling only the individual inner packages if the information is provided in such a way that consumers can clearly see it at the time of purchase. Examples of this type of packaging can be found currently in the marketplace where nutrition labeling is provided on the tops of single-serving packages of breakfast cereals. Accordingly, FDA is adding a new paragraph § 101.9(h)(2) to specify that nutrition labeling of single-serving packages within variety packs must be clearly visible at the point of purchase. Proposed § 101.9(e)(2) is redesignated as § 101.9(h)(4).

237. FDA received comments from companies that sell food products by mail order, particularly varieties of foods and food assortments that are marketed as gifts. The comments requested special provisions in the regulations to provide some flexibility for packaged gift assortments because these packages are assembled from several thousand separately labeled food items, many of which are similar, differing only in size or flavor, and which are used in many different assortments. Because of the unique characteristics of the mail order gift food industry, caused, in part, by rapidly changing selections of gift packages offered, the comments contended that nutrition labeling would have a devastating effect on the industry, unless alternative means of compliance are allowed.

The comments requested that a new paragraph be added under proposed § 101.9(e) for assortments of foods intended to be used as gifts, allowing for nutrition information on such foods to: (1) Be included on labeling, (2) be based on uniform serving sizes, (3) omit reference to "servings per container," (4) be calculated as averages for categories of foods having similar dietary uses or similar significant nutritional characteristics for characterizing nutrients, (5) be based on calculations from nutrient data bases, and (6) omit foods meeting the definition of "small package" in § 101.9(j)(13) from determinations of nutrient content. A subsequent comment on behalf of the mail order gift food companies modified the last provision to state that foods in small packages only be omitted if they are not listed in promotional catalogues and are "optical garnishes" used to enhance the appearance of the gift package, or bonus items included as a free gift or promotional item.

FDA is persuaded that special allowances are justified for gift packages containing a variety of foods (e.g., cheese, jams, and crackers packed together in one gift box) or of food assortments (e.g., several different types of jam in one box). Accordingly, the agency is adding a new paragraph § 101.9(h)(3) to address gift packages.

New § 101.9(h)(3)(i) allows the required nutrition information to appear on the label or in labeling that is within or attached to the outer gift package. This provision allows the information to be consolidated in a single document that could accompany several different gift food packages that contain the same assortment of foods, although not necessarily in consistent size packages, as are identified in the document. This action is in recognition of the fact that the person who buys the gift package is generally not the person who will use the information. According to the comments, on average, 65 percent of company sales are shipped to recipients other than the purchaser. Moreover, many packages shipped to purchasers are subsequently offered as gifts to other persons.

The "outer package" is intended to mean the container directly within which component items are packed. It does not mean the shipping carton, unless component items are packed directly within the shipping carton instead of being packed in a separate inner container.

Comments also have persuaded the agency that standardizing the serving sizes for foods included in gift packages will simplify the simultaneous presentation of information on a variety of different types of foods by putting the information for all products on a comparable weight basis and, thereby, increase the likelihood that consumers will use and understand the information. The comments requested that, where there is no uniform household measure that is either a common multiple or fraction of the quantity of an individual food in an assortment, one ounce (fluid or solid as appropriate) be used as the standard serving size. Rather than leaving open the possibility of the use of any "uniform household measure," however, FDA believes that an allowable exemption from the serving size requirements would be permissible only when all of the foods in a particular gift package are not subject to the same reference amount customarily consumed, as specified in § 101.12(b).

FDA has no objection to the suggestion of a one ounce serving size

for solid foods in such circumstances. The selection of one ounce is acceptable based on the fact that it is the simplest value for use in calculations, many of the foods are packaged in multiples of one ounce, and it is the same as the reference amounts customarily consumed for many of the types of foods used in gift packages (e.g., many cheeses, crackers, and nuts) specified in § 101.12 in the companion document on serving sizes published elsewhere in this issue of the **Federal Register**.

In the case of liquids, the agency believes a larger serving size is needed because of the extra weight of water, and because there are no reference amounts specified in § 101.12 for liquids at only one fluid ounce. Based on the reference amounts in § 101.12, FDA believes a serving size of 2 fluid ounces is more appropriate for nonbeverage liquids such as syrups, and 8 fluid ounces is appropriate for beverages. These are the reference amounts in § 101.12(b) for maple syrup and for all beverages, respectively. The agency does not believe that it is reasonable to collapse the number of categories of foods any further than these three groups for the purpose of nutrition labeling of gift packages. Therefore, in response to the comments and in an effort to minimize the number of different serving sizes required in the nutrition labeling of gift packages, § 101.9(h)(3)(ii) allows for a serving size of 1 ounce for all solid foods, 2 fluid ounces for nonbeverage liquids, and 8 fluid ounces for beverages where there is no uniform reference amount customarily consumed for each individual food used in an assortment or variety of foods within a gift package.

However, the agency believes it would be misleading to allow nutrient content or health claims based on these serving sizes for foods packaged in gift packs where they differ from reference amounts specified in § 101.12(b) that are used as criteria for the claims. Therefore, § 101.9(h)(3)(ii) states that the reference amounts customarily consumed that are listed in § 101.12 must continue to be used for purposes of evaluating whether individual foods in a gift package qualify for nutrient content claims or health claims.

Inasmuch as section 403(q)(1)(B) of the act requires that the number of servings per container be included on the nutrition label, FDA does not believe that it has the authority to permit this information to be deleted. However in § 101.9(h)(3)(iii), FDA is allowing for the number of servings per container to be stated in the nutrition label as "varied" in recognition of the fact that each type of gift package will furnish a different number of servings. This action is consistent with § 101.9(b)(8) in the companion document on serving size published elsewhere in this issue of the **Federal Register**, which allows a manufacturer to declare "varied" for the number of servings per container for random weight products. The assembling of gift packs has a random quality. FDA is persuaded that requiring more specific information on labeling would necessitate a unique label or labeling for each package, negating the usefulness of these special provisions.

Section 101.9(h)(3)(iv) provides that average, composite nutrient values may be declared in nutrition labeling for reasonable categories of foods having similar dietary uses and similar significant nutritional characteristics. While the comments requested that composite values be allowed for reasonable categories of foods having similar dietary uses or similar significant nutritional characteristics, FDA believes that both criteria are necessary. Many forms of cheese and peanut butter have similar dietary uses in that they are used to make sandwiches or are eaten on crackers, yet they have far different nutritional characteristics and should not be composited.

The comments suggested, and FDA concurs, that companies should submit to FDA their determinations of "reasonable categories" for review and acceptance. FDA's decision on the companies' determinations will be based, in large part, on whether the values of the characterizing nutrients for foods in the category meet the compliance criteria set forth in § 101.9(g)(3) through (g)(6). To that end, companies should also submit a list of proposed characterizing nutrients for each "reasonable category" of foods.

For example, assuming total calories, total fat, saturated fat, and cholesterol are the categorizing nutrients for a group of cheeses, each cheese's content of these 4 nutrients would have to be no greater than 20 percent in excess of the declared values in the nutrition label, in accordance with § 101.9(g)(5), or reasonably less than the declared values, in accordance with § 101.9(g)(6). Nutrients other than the characterizing nutrients could be stated as an average, or composite, for the category, without having to meet the standards of § 101.9(g)(3) through (g)(6).

While the comments requested that FDA specifically permit the use of data bases for calculating the nutrition information for foods in gift packages, the agency does not believe a separate policy from that which the agency is establishing for other packaged foods (see section VII.B.2. of this document) is necessary or appropriate.

Section 101.9(h)(3)(v) allows foods that meet the definition for small packages under § 101.9(j)(13)(i) that are included in a gift package to be omitted in determining the nutrition information if they are not specifically listed in a promotional catalogue, and they are used in small quantities as "optical garnishes" to enhance the appearance of the gift package or are included as a free gift or promotional item. According to the comment, these items are used in very small quantities and may vary greatly from package to package. On the understanding that the "optical garnishes" are generally small plain candies wrapped in bright colored paper, the agency believes that the small amount used will make an insignificant nutrient contribution to the total package. Free gifts or promotional items, by definition, are not "offered for sale" and are therefore exempt under § 101.9(a).

B. Compliance (§ 101.9(g))

1. Compliance Procedures

In discussing the agency's rationale for requiring a single nutrient value on the label in lieu of permitting ranges of values, FDA tentatively concluded that its current compliance policy with respect to nutrient variability satisfied the requirements of the 1990 amendments (56 FR 60366 at 60373).

The compliance policy in current § 101.9(e) (proposed § 101.9(g)) requires that the nutrient content of the composite of 12 subsamples be at least equal to the labeled value for Class I nutrients (i.e., added nutrients in fortified and fabricated foods) and at least 80 percent of the labeled value for Class II nutrients (naturally occurring or indigenous nutrients). Proposed § 101.9(g)(4) specified that these requirements are applicable for vitamins, minerals, protein, total carbohydrate, complex carbohydrate, dietary fiber, unsaturated fat, and potassium content. Likewise, in proposed § 101.9(g)(5), the nutrient content of the composite is required to be no more than 20 percent above the labeled value for calories, sugars, total fat, saturated fat, cholesterol, and sodium.

238. The agency received a number of comments regarding its compliance policy as stated in proposed in § 101.9(g) (56 FR 60366 at 60391). A few comments agreed with allowing an 80 to 120 percent leeway in the compliance of foods. One comment noted that while the nutrient values may not be absolute,

they are more consistent for the consumer. Also, the present system makes it easier for manufacturers to obtain compliance. However, the majority of comments disagreed with FDA's compliance policy, requesting that either a tighter or looser standard be used.

Consumers were strongly opposed to the so-called "80-120 rule." They felt the range was too lenient and stated that they would like to see a tighter standard adopted, especially for calories. Fat, carbohydrate, and cholesterol were also identified as nutrients that should have very accurate or exact label declarations. Some suggested other limits of acceptance, such as a plus or minus 5 to 10 percent range. Several comments supported a more accurate declaration of nutrients in consideration of the needs of persons with medical conditions requiring adherence to specialized or restricted diets. Other consumers considered the 20 percent margin of error as being inaccurate and misleading. Some comments considered that with today's available technology, food manufacturers could and should more accurately declare nutrients, notably calories, on the labels and meet more stringent standards.

Several comments included suggestions as how to better declare nutrient content on the label. Suggestions included the declaration of a tolerance standard on all product labels and an example of what the tolerance could mean. For example, the label of a product having a 10 percent tolerance for calories would state the declaration as "100 calories--could be 90 or 110 calories." One comment suggested that a statement be required adjacent to the calorie value declaring that it is "only an approximate figure." Another suggested that all food labels carry a warning of the 20 percent margin of error permitted for calories.

Comments from industry and trade associations considered the 80/120 percent range unduly restrictive. They supported more flexible compliance standards that would provide "representative values" of a product's nutrient content. Representative data in one comment was defined as the mean or the mean plus or minus one standard deviation. Their contention was that, because of the natural variation of foods, application of FDA's compliance procedures result in gross under-representation of some nutrients, such as vitamin A in carrots, and gross over-representation of other nutrients, such as sodium in soft drinks (because of variability in water sources). The comments took exception to FDA's assertion in the discussion on fresh produce and seafood, in the mandatory nutrition labeling proposal (55 FR 29487 at 29506) that nutrient content can largely be controlled in most manufactured foods. In fact, they stated there is greater variability in processed foods because of the complexity of prepared foods, the further processing that is required, the need to total the variability for each ingredient for prepared foods, the flexibility needed for obtaining ingredients from various sources or suppliers, and the analytical variability for required nutrients. One comment recommended that an 80 to 120 percent compliance range be used for nutrients with a low degree of natural or analytical variability. For nutrients with a high degree of natural or analytical variability, a less stringent 65 to 135 percent compliance range was suggested.

Another comment endorsed a more flexible compliance standard whereby micronutrient levels need only be present at a minimum level of 80 percent of declared levels. They recommended that no maximum compliance level be set. This comment was particularly in reference to the difficulty of achieving compliance for a product that has a standard of identity, such as pasta, where maximum and minimum levels of enrichment are specified by the standard. The comment stated that levels of added nutrients may vary depending upon the method of enrichment, indigenous nutrient levels in the wheat, analytical error, rounding of values declared on the label, and loss of nutrients during the drying process.

The agency disagrees with establishing more stringent requirements for label values. FDA shares concerns about individuals with very specific health problems where diets must be closely monitored and controlled. However, no data have been presented, and FDA is not aware of any such data, to suggest that health problems have been created because of the allowable variances. Therefore, the agency considers health management under professional guidance satisfactory using the nutrient values on the labels based on current regulations. In addition, it should be noted that the natural variability of foods may lead to both under- and over-reporting within the allowable variances for individual foods. These variances will tend to balance out over the entire day's diet.

While it is highly desirable to have a precise nutrient value on the label, it is impractical. The natural variability of a food is dependent upon a number of factors. Among them are the season of the year, soil type, variety (cultivar), and weather conditions. The processing that a food undergoes also alters its nutrient content. In addition to these variables, the agency places restrictions on the label declarations in regard to the rounding of nutrient values. These rounding rules are to avoid the impression of unwarranted accuracy as well as to make a label easier for a consumer to review and understand. To declare nutrient values more accurately or precisely than is presently required would place an onerous burden on the manufacturer. The costs associated with the excessive controls to provide more exact label declarations are unreasonable and would not be commensurate with any possible additional health benefit.

The agency rejects the suggestions that declared values be qualified by statements that they reflect tolerance levels or margins of error. Such statements on the label informing consumers of the possible variation between labeled and analytical values would cause great confusion with no real benefit.

Similarly, FDA disagrees with the comments that suggested establishing less stringent requirements for determining compliance with declared label values. As seen in comments, consumers rely on the declared values, and the accuracy of those values is important. FDA does not believe larger suggested ranges, such as 65 to 135, would give consumers the information that they need to adequately evaluate their nutrition intake. Therefore, the agency is not making requested changes in § 101.9(g).

FDA advises that it has not set maximum compliance levels in § 101.9(g) for Class I and Class II nutrients, nor has it set minimum compliance levels for nutrients specified in § 101.9(g)(5) (i.e., calories, sugars, total fat, saturated fat, cholesterol, and sodium). The 20 percent variability permitted is not a range but rather a lower or upper limit, depending on the nutrient. The only regulatory limit on overages of Class I and II nutrients is given in § 101.9(g)(6), which states that "reasonable excesses" are acceptable within current good manufacturing practice. Likewise, § 101.9(g)(6) also states that "reasonable deficiencies" of calories, sugars, total fat, saturated fat, cholesterol, and sodium under labeled amounts are acceptable within current good manufacturing practice. FDA anticipates that manufacturers will be diligent in their own behalf in not underdeclaring Class I and II nutrients, such as vitamins and minerals, and in not overdeclaring nutrients such as calories and fat.

Regarding maximum levels of micronutrients in standardized enriched pasta products, regulatory relief cannot be achieved through modifications of § 101.9 but require changes in the standards of identity of such products.

239. Several comments suggested that the 80 and 120 percent criteria should only be a guideline or screening tool. A few comments expressed the position that FDA should not declare a product misbranded until the manufacturer has had an opportunity to establish that the variations are reasonable under the circumstances.

Other comments suggested that the 80 and 120 percent criteria be waived when there are small quantities. (The quantity limits suggested were 10 and 20 or fewer "units." "Units" were interpreted to be units of measurements, such as 10 or 20 calories or 10 or 20 mg of sodium.) The comments noted that small numbers combined with rounding rules and analytical variability result in inequities for label compliance (i.e., the analytical variance for some low levels of nutrients is greater than the allowed regulatory variance). For example, the comment stated that if a mean value of 1.3 units was rounded for label declaration to the nearest whole unit (i.e., 1 unit), then the acceptable range would be 0.8 to 1.2 units when applying the 80 and 120 percent criteria. The range would be below the true mean value which could result in many products being found out of compliance. Furthermore, these small differences of 0.2 units may not be within the accuracy of many methods, so that the analytical variance could be greater than the allowed regulatory variance. For these small quantities of 20 or fewer units, the comments recommended that a 50 to 150 percent rule be applied. One comment recommended that FDA clarify in the final rule that the rounding of nutrient values, as required by the proposal, would not disadvantage a manufacturer when making nutrient content claims to meet compliance criteria as well as standards of identity.

An alternative suggestion in another comment to avoid an extreme over- or under-declaration when the value is small is to declare the nutrient content to the nearest whole unit with compliance based on a fixed percentage (e.g., within 80 percent) or a fixed unit amount (e.g., one unit or 2 percent U.S. RDA, the basic increment of rounding). The regulation would then require that declared amounts be within 80 percent or one unit (such as a g) for Class II nutrients or within 120 percent or one unit for nutrients such as calories, fat, or sodium.

The agency is not persuaded that the current or proposed acceptance criteria for compliance evaluation should be changed. The compliance criteria permit reasonable excesses over labeled amounts or deficiencies under labeled amounts, dependent upon the nutrient being evaluated, (current § 101.9(e)(6), redesignated as § 101.9(g)(6)) within current good manufacturing practices. As discussed in section IV.A. of this document, the level of "reasonable" is not specified.

It is the manufacturer's responsibility to target labeled values to correspond to actual nutrient levels so that products will meet compliance requirements. This responsibility includes taking into consideration the effects of rounding. Any effect caused by the rounding of labeled values to meet the agency's requirements in § 101.9(c) should be accounted for by the manufacturer in developing a label value and would be included in the evaluation of a "reasonable" level by the agency. Analytical variance is also one of the factors in determining compliance acceptance. This fact is stated in § 101.9(g) (4) and (5) in this final rule.

Manufacturers should perform shelf-life stability studies to substantiate the declared nutrient levels of the product and to demonstrate that a product can meet label claims over the shelf life of the product. FDA does not believe that incorporation into the regulations of any additional explicit provision or compliance position for low level nutrients or small labeling increments would provide added protection for manufacturers.

240. One comment strongly recommended that FDA address sampling issues. It suggested that the current procedure in § 101.9(e)(2) (and in proposed § 101.9(g)(2)) of preparing a composite of 12 subsamples taken from a single lot be changed. Instead, it was suggested that a sample composite for analysis represent 12 different lots.

The agency disagrees with the suggested change in sampling procedures. The comment's suggestion reflects a sampling objective that appears to focus on estimating the nutrient content of product for a specified quantity (e.g., a company's production). FDA's sampling objective is to determine whether the average, within a given lot (a quantity that is defined in current § 101.9(e)(1)), meets label claims. From a compliance evaluation standpoint, the suggested sampling scheme is not a feasible alternative because the results obtained would not be traceable to a specific lot should an overage or deficiency be encountered. Instead of a compliance action against a smaller quantity (a single lot), it might be necessary to take a compliance action against a larger quantity (e.g., a company's production for a larger specified point in time). Therefore, FDA is making no change in § 101.9(g)(2) in response to this comment.

241. Several comments that disagreed with the agency's compliance policy provided suggestions to clarify the codified language. One comment recommended the elimination of total carbohydrate, complex carbohydrate, and unsaturated fat from the Class I category of nutrients at § 101.9(g)(4)(i). It maintained that these three nutrients are unlikely to be "added" but are the result of having used ingredients that inherently have these nutrients.

FDA agrees with the recommendation. Therefore, the agency is amending § 101.9(g)(4)(i) to delete total carbohydrate, complex carbohydrate, and unsaturated fat from the Class I category. This deletion should allay the concerns of having the cited nutrients meet Class I nutrition labeling requirements. These nutrients remain in the Class II category (§ 101.9(g)(4)(ii)), although in accordance with the changes made in section III. of this document, complex carbohydrate is changed to other carbohydrate and unsaturated fat to poly- and monounsaturated fat.

To clarify the compliance policy concerning variability because of analytical methodology for Class I and Class II nutrients, FDA is modifying § 101.9(g)(4) by making a new paragraph out of the last sentence which begins with the word "Provided." This change should make clear that the proviso information regarding consideration of regulatory action is applicable to both Class I and Class II nutrients. This qualifying information was inadvertently moved under the paragraph on Class II nutrients in the July 19, 1990 mandatory nutrition labeling proposal, and the error was carried forward in the supplementary proposal.

242. One comment stated that manufacturers should be able to use mean values in all cases, except that statistical outliers should be ignored. The comment also urged the agency to codify its compliance policy to the extent that if a nutrient is found out of the 80 to 120 range of the labeled amount, the product would not be deemed out of compliance as long as the manufacturer can demonstrate that the label declarations represent mean values based on reasonable and adequate sampling and analyses.

FDA disagrees with the comment. The agency's position on the use of mean values is summarized in the preamble of the supplementary proposal (56 FR 60366 at 60373). This position is discussed in more detail in the "FDA Nutrition Labeling Manual: A Guide for Developing and Using Databases" and in section VII.B. of this document. In short, FDA will allow the use of mean values derived from satisfactory data bases if the coefficient of variation is equal to or less than the maximum coefficient of variation specified in the above manual. The coefficient of variation is the standard of deviation (a measure of variability) expressed as a percentage of the mean.

243. A recommendation was made in one comment to amend § 101.9(g)(5) by adding: "Provided, that no regulatory action will be based on a determination of a nutrient value which falls above this level by a factor less than the variability generally recognized for the analytical method used in that product at the level involved." The comment noted this addition would extend the allowance for analytical variability permitted for vitamins, minerals, protein, total carbohydrate, complex carbohydrate, dietary fiber, unsaturated fat, and potassium, as given in proposed § 101.9(g)(4) to the nutrient declarations for calories, sugars, total fat, saturated fat, cholesterol, and sodium.

The agency agrees that analytical variance is a valid consideration when contemplating regulatory action for all nutrients. Accordingly, the proviso stated in § 101.9(g)(4), which is applicable for Class I and Class II nutrients, is added to § 101.9(g)(5).

244. One comment recommended a two-stage enforcement procedure. The first stage would involve analysis of a single 12-sample composite to determine whether the product passes the compliance standard of 80 to 120. If it passed, the agency would have no enforcement issue. If it did not pass, the agency would collect and measure the nutrient content in three other lots. The average of all four lots tested would be evaluated for compliance purposes.

The agency is not making the change in its procedures that was suggested by this comment. As recognized in several comments from manufacturers, it is the manufacturer's responsibility to accurately declare the nutrient content of a product. As discussed above, the interpretation of results obtained from more than one lot (same ingredients, same processing conditions) cannot be translated to other lots. Factors that could have altered the nutrient content of one lot may not be present for subsequent lots. Through quality control programs and careful consideration of declared nutrient amounts according to the guidelines in "FDA Nutrition Labeling Manual: A Guide for Developing and Using Databases," manufacturers can help to ensure that each lot meets compliance standards. The suggestion made in this comment or in comment 240 of this document in regard to evaluating results representing the analysis of a composite from 12 different lots or an average of results from four composites could be implemented in a manufacturer's quality control procedures to assure compliance with § 101.9(g).

It should be noted that the analyzed nutrient content is not the sole factor in determining whether the agency will bring a particular enforcement action. Other factors that it considers include the effect of matrix upon the analyte, the level of the analyte in the food, information obtained during an establishment inspection of a firm, consumer complaints, past compliance history of the firm, and the firm's demonstrated ability to adequately perform the analysis for a nutrient.

245. A comment recommended that a new section be added to the codified language to the effect that "The metric declaration of the serving size shall be used to determine compliance under this section." The comment said that this change would eliminate any confusion about which of the dual declarations required for serving size would be the determining factor for nutrient declaration.

FDA agrees with the comment. In its serving size proposal (56 FR 60394 at 60410), the agency stated that in addition to the more approximate household measure, it needed a precise weight statement for serving size for compliance purposes. Accordingly, the agency proposed in § 101.9(b)(7) that the serving size in common household measures must be followed by the equivalent metric quantity. However, FDA did not specifically state that this metric measure would be used for compliance purposes. Therefore, for purposes of clarity, the agency is adding a new section, § 101.9(g)(7), to correct this oversight. Consequently, the remaining paragraphs in § 101.9(g) are redesignated.

246. One comment expressed concern that net weight regulations must be considered when evaluating a product against the 80 to 120 rule for compliance. The comment stated that manufacturers are required to sell products at levels above the declared label weight. The comment concluded that this resulted in a discrepancy between labeled nutrition information and actual nutrition values.

The agency does not consider this issue to be a valid concern. Because of the economic considerations of manufacturing, most products are close to label claims for net weight. Additionally, while an overage or underage of the net weight may slightly alter the nutrient content of the container (and particularly if the container is a single serving size), the serving size is the factor by which the nutrients are evaluated. As discussed in the preceding comment, FDA will composite samples and then use the metric weight declared as the label serving size to evaluate the accuracy of declared nutrient values.

2. Data Bases

247. FDA received a large number of comments regarding the use of data bases as sources of nutrient information for nutrition labeling. Most comments supported the use of data bases, giving as reasons that the use of data bases would reduce costs to industry (especially to small businesses), moderate food cost increases to be passed on to consumers, promote fair competition, save time, reduce the use of laboratory chemicals, provide sufficient accuracy, and ease compliance verification procedures. Comments requested the opportunity to use nutrient composition data in commercially available or published data bases directly or through calculation of ingredient values to yield the final composition of formulated products.

FDA appreciates the important role data bases can play in nutrition labeling. Industry-wide data bases were first suggested in 1979 as a possible means of reducing the cost of developing nutrition labeling for individual companies. FDA, USDA, and the Federal Trade Commission encouraged this concept in a notice of proposed rulemaking published in the **Federal Register** of December 21, 1979 (44 FR 75990) describing the agencies' policies and intentions with respect to numerous food labeling issues. In that notice, FDA, while not agreeing to approve data bases, stated that it would work with industry to resolve any compliance problems that might arise for food labeled on the basis of a data base that the agency had accepted.

FDA is concerned about the reliability of data bases to meet compliance requirements for nutrition labeling. Nutrient data may be valid for some purposes and not for others. For example, data bases that were developed largely for determining

average daily dietary intakes generally serve that purpose well. However, such data bases are usually not adequate to determine natural variability of a particular food or to develop labeling values that are in compliance with FDA nutrition labeling regulations.

Despite these concerns, FDA continues to acknowledge the potential usefulness of data bases to reduce costs associated with nutrition labeling. The agency set out its general policy on the use of data bases most recently in the proposed and final rules on the voluntary nutrition labeling program for raw produce and fish (56 FR 30468 at 30474, July 2, 1991 and 56 FR 60880 at 60884, November 27, 1991, respectively) and the supplementary nutrition labeling proposal (56 FR 60366 at 60373). In addition, the agency announced in the **Federal Register** of July 23, 1992 (57 FR 32796) the availability of a draft manual entitled "FDA Nutrition Labeling Manual: A Guide for Developing and Using Databases." The manual, which replaces the former guide "Compliance Procedures for Nutrition Labeling," is intended to aid companies and trade organizations in developing and using a data base for nutrition labeling that would meet the regulations proposed as a result of the 1990 amendments. It also discusses the conditions under which the mean value derived from a satisfactory data base may be used for nutrition labeling. Comments were requested on the draft manual. These comments have been considered, and the agency is hereby announcing the availability of the final manual. The manual may be obtained from the Division of Nutrition (HFF-260), Office of Nutrition and Food Sciences, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

FDA anticipates that this manual will be of assistance in identifying a data base that is of a quality to provide an adequate basis for nutrition labeling. The use of such a data base to calculate the final composition of a product formulated from several ingredients presents additional problems, however, in that there are no allowances or determinations of the loss of nutrients that may occur during further processing. Depending on the type and amount of processing, significant amounts of nutrients may be lost. The agency is willing to work with manufacturers and trade associations to determine if successful models can be developed showing the relationship between ingredient composition and final product composition that account for losses during processing. While extensive analyses of ingredients and final products would be required to develop and validate a successful model, such action could lead to an acceptable data base.

If a manufacturer wishes to use a data base for nutrition labeling, it is advantageous to follow the statistical procedures outlined in the manual and have the data base accepted by FDA. If the agency finds that the nutrition label of a product which is based on a data base that has been accepted by FDA is not in compliance with § 101.9, FDA will not take immediate action against the product, provided that the company has followed good manufacturing practices in producing the food. Instead, the agency would work with the manufacturer to resolve the compliance issue. Action would be taken only if noncompliance was the result of failure to follow good manufacturing practices.

It must be noted that submission of a data base to FDA for review and acceptance is voluntary. The agency has not prescribed how an individual company is to determine nutrient content for labeling purposes. The choice of a data source is the prerogative of the manufacturer. The manufacturer needs to be judicious in this selection, however, to ensure that the product labeling is in compliance with the regulations. The compliance policy of the agency remains unchanged from current § 101.9(e). An FDA investigator/inspector will collect random units of food (e.g., consumer packages, items of product) from each of 12 different randomly chosen shipping cases of the same code/lot, and an FDA laboratory will prepare a single composite from the 12 units of food. Analysis of the composite will be performed using methods of the AOAC or other reliable and appropriate methods. FDA will then compare the values declared in the nutrition label and labeling with the results from the laboratory analyses. Section 101.9(g)(8) provides for the use of an approved data base.

248. Many comments were received expressing support for use of data bases because they can be used by a company one time, and there would be only a one time cost to determine the nutritional values for the label without regard to future changes in the product.

The agency is concerned that there is a misunderstanding regarding the use of data bases. Data bases are not static but dynamic because of changes in products. Those data bases submitted to the agency or used by companies are expected to reflect the nutritional content of products being offered for sale. Changes in variety, supplier, recipe, or manner of processing could lead to very different nutritional values for the product than those in the original data base. The agency, in monitoring products for compliance, will also review the maintenance of these data bases to ensure that the information in the data bases reflects the nutritional content of the products being offered for sale. Maintenance of a data base means that laboratory analyses of the product are done on a periodic basis to ensure that the nutritional values of the product are within the limits of the data base values. Proper maintenance of the data base is left to the originators of the data base. Frequency and type of maintenance are determined by the data base holders based on their knowledge of the changes in the products. Satisfactory data bases could be useful for periods of up to 10 years based on the size of the data base, plan for maintenance, and the complexity of the product. FDA reviews will be based on the amount of supplementation of the data bases with additional laboratory data (maintenance) during the period of use and the changes in the products covered by the data base.

3. "Nutrition Labeling Manual: A Guide for Developing and Using Data Bases"

FDA announced in the **Federal Register** (57 FR 32796) on July 23, 1992, the availability of a draft manual entitled "Nutrition Labeling Manual: A Guide for Developing and Using Data Bases" (the manual). This manual is intended to aid companies and trade organizations in developing and using a data base for nutrition labeling that meets the regulations resulting from the 1990 amendments. Comments on the manual were accepted until September 8, 1992. This manual provides generic instructions on how to develop and use a data base in preparing nutrition labeling for a food product. Eighteen comments were received from companies or trade associations. The following summarizes the comments and provides the agency response to those comments.

249. Almost all of the comments were opposed to the limit of 80 percent of the label claim for Class II (indigenous) nutrients and 120 percent for calories, sugars, total fat, saturated fat, cholesterol or sodium. The comments argued that these limits were overly restrictive and should be widened or average values should be used with no consideration of limits.

The use of 80 percent or 120 percent as limits for regulatory purposes is established in § 101.9(g) and has been addressed above in section VI. of this document. The manual was developed to aid in the calculation and

construction of data or data bases to meet the regulatory requirements of the agency. Should the agency change its regulations, it will reflect those changes in the manual. Until such changes are made, however, the manual must reflect the applicable regulatory limits.

250. All but one of the comments addressed the use of recipe data bases to calculate final composition of mixed products. The comments cited the savings in money to small businesses, the constant changes in recipes that make it too costly to do analytical testing of products, and the cost of analyzing a large number of products for which the volume is low. The expressed belief was that calculated values better represent the nutrient content over time. Several comments suggested criteria for a good recipe data base. One comment offered the following four proposed principles of good ingredient composition data bases:

(1) Confidence in the quality of data, supported by documentation of data sources. Companies maintaining or using ingredient composition data bases must be able to demonstrate the data source used for each type of product and each nutrient for which ingredient composition data bases are utilized.

(2) Proper maintenance of the data base. Companies developing or using ingredient composition data bases must have procedures in place to ensure that the values in the ingredient composition data bases are reviewed and updated as needed and on a regular basis.

(3) Specificity with respect to ingredients, product formulations, and processes. Companies using ingredient composition data bases must have procedures in place to ensure that the nutrient values are used only for specific applications. For example, a company should have a procedure to ensure that nutrient data specific for one product formulation or process are not used to prepare nutrient declarations for similar product formulations or processes, without assurance that the data are applicable to those products or processes.

(4) Validation of the data base. Companies developing or using ingredient composition databases must have procedures in place to ensure that nutrient values receive reviews, audits, and confirmation through nutrient analyses as often as necessary.

Other comments suggested that manufacturers should be required to substantiate any nutrient content or health claims with analytical data.

The agency agrees that the principles suggested by the comment are worthwhile and necessary for construction of a proper ingredient composition data base. This was the intent of the statement in the manual that calculation of the final composition of a mixed product using data bases of the nutrient composition of ingredients might be acceptable if properly modelled. The agency wanted to assure itself that the ingredient composition information was adequate, and that the calculation of the final nutrient value of the finished product reflected any possible loss of nutrients during processing. In addition, a successful mathematical model used for this purpose should be augmented over time with a review of its applicability by laboratory analysis of the nutrient content of both ingredients and final products. Models constructed with the features described above, and applied to a limited range of appropriate products, would receive serious consideration from the agency. The above features of an appropriate data base will be included in the manual.

The agency believes that in time the calculation of the final composition of mixed products from ingredient data bases may be acceptable for a range of food products. At this time, however, the agency believes that the data that make up ingredient data bases are of mixed quality and, therefore, of limited value. Companies that wish to use ingredient data bases must look at the individual analytical values of each ingredient to evaluate the data to assure themselves that the data are sufficient, meet the requirements expressed in the manual for representativeness, are valid from an analytical standard, and are sufficient to account for any variation in the ingredient.

The agency has stated that the company bears the final responsibility for the accuracy of the label. This principle has not changed and was repeated and supported by several of the comments.

251. Comments were received on changing various aspects of the agency's regulatory policy such as larger number of lots sampled and the average taken, composite samples consisting of several lots, exemption from compliance procedures when data bases are used regardless of whether the agency has accepted them or not, exemption from compliance procedures for nutrients that have a low concentration, and exemption from compliance procedures for companies/associations that have submitted basic data and a plan for data base development over time.

The manual is intended to aid manufacturers/associations in meeting the compliance regulations of the agency. The manual does not set compliance policy but rather offers some explanation for the compliance policy and provide different means of complying with the nutrition labeling regulations. Should the compliance policy of the agency change, the manual will also be changed to reflect those changes.

252. Many comments were received regarding the confidentiality of the submitted data bases. Developers of data bases did not want to see the information gained through analyses of products and ingredients released through freedom of information requests or used in unacceptable ways or for inappropriate products. In addition, development of data bases is a program with costs shared among the participating companies. The comments sought assurance that the data would not be available at no cost to companies that did not participate in its development. Formulations that are used to produce mixed products are also regarded as confidential company information, and the comments sought assurance that they would not be available to anyone who requests the information.

The agency is aware that the development of a data base is costly, and that it may contain information that is of a confidential nature. The agency agrees that release of a data base could vitiate substantial proprietary interests in valuable documents submitted to the agency. Furthermore, it has never been the agency's intent, nor does it have the resources, to maintain and manage data bases that are developed by manufacturers or associations. The agency believes that the availability of a data base is therefore the primary responsibility of the developer. The agency will continue with the policy of assisting the developers of data bases, providing guidance to those who ask for it, and accepting adequate data bases for the products submitted for review. Only those data sufficient to support the agency's decision to accept or not accept a data base will be retained. Confidentiality of such data will be determined and maintained in accord with regulations in part 20 (21 CFR part 20).

Those data base developers who choose to do so are encouraged to make their information available through such compilations as the USDA Handbook No. 8 so that all may benefit from the additional analytical information.

C. Proposed § 101.9(h)

253. A few comments objected to the requirement in proposed § 101.9(h) that nutrition information provided by manufacturers or distributors directly to professionals (e.g., physicians,

dietitians, educators) must contain or have attached to it the nutrition information exactly as required by § 101.9. The comments stated that it was inappropriate for a Federal agency to regulate the transfer of information in this manner.

FDA notes that this section of the regulation has been carried unchanged since 1973 (49 FR 6961, March 14, 1973). At that time, the agency stated that it did not want to restrict the flow of information from food manufacturers to professionals (such as more precise amounts rather than the increments used in nutrition labeling) but rather wanted nutrition information included or attached to it in the form it would be provided to consumers. Inasmuch as nutrition labeling is now mandatory, so that consumers will have the required information available to them on food product labels, FDA has decided to delete this requirement and is doing so in this final rule.

D. Section 101.9(k)

254. Many comments objected to proposed 21 CFR 101.9(k) which details types of nutrition-related claims that cause a food to be misbranded. Most of these comments asserted that the provisions of § 101.9(k) are contrary to the intent of the 1990 amendments and contrary to the will of Congress.

Many comments offered specific objection to proposed § 101.9(k) (3) and (4) and asserted that manufacturers should be allowed to provide information about the effects of soil, storage, transportation, or cooking on the nutrient content of foods. Some comments maintained that the restriction of such information is unconstitutional. A number of comments felt that labels should be required to provide information as to the exact identity of the contents (including substances of no nutritional value), the source of the contents, the amounts of all ingredients, and the techniques and dates of processing. One comment proposed that manufacturers should be required to put toll-free telephone numbers on all of their products so that consumers could call for information about those products.

Many comments asserted that proposed § 101.9(k)(5) is arbitrary and restrictive and expressed a belief that certain naturally-occurring food constituents will be rendered unavailable by this provision. A number of comments maintained that there is no legitimate reason for prohibiting substances found in nature from being incorporated into nutritional products and listed on the label. Some comments suggested amending proposed § 101.9(k) to allow the use of naturally-occurring constituents of foods and herbs, unless there is sufficient evidence that any specific such substance is harmful to human health.

Some comments also objected to proposed § 101.9(k)(6), maintaining that vitamins that are naturally present are better than added synthetic vitamins. These comments expressed a strong desire to know whether vitamins contained in any specific product are naturally-occurring or synthetic.

FDA regrets that its publication of § 101.9(k)(2) through (6) in the November 27, 1991 (56 FR 60393) proposal has created confusion. The publication of § 101.9(k)(2) through (k)(6) did not constitute a proposal of new regulations. It merely represented a proposed redesignation and republication of existing regulations for clarity and completeness.

The provisions embodied in current § 101.9(i)(2) through (i)(6), redesignated in the November 27, 1991, supplementary proposal as § 101.9(k)(2) through (k)(6), to which the comments directed their objections, were first proposed in the **Federal Register** of March 30, 1972 (37 FR 6493), and were promulgated and published in the **Federal Register** of January 19, 1973 (38 FR 2125), as § 1.17(i)(2) through (i)(6). Following an appropriate comment period, these regulations were modified and published as final regulations in the **Federal Register** of March 14, 1973 (38 FR 6961). The regulations were subsequently applied, with certain exemptions, to all food labeling ordered after December 31, 1973, and all labeling used for food products shipped in interstate commerce after June 30, 1975. In the reorganization and republication of section 21 of the Code of Federal Regulations that appeared in the **Federal Register** of March 15, 1977 (42 FR 14308), § 1.17(i) was renumbered as § 101.9(i). No changes were made to the original codified language of the subject paragraphs during any of these renumberings, and those regulations remain as adopted in 1973.

The only change in § 101.9(k) in the supplementary proposal was in the document entitled "Labeling; General Requirements for Health Claims for Food" (56 FR 60537, November 27, 1991). This document proposed to amend current § 101.9(i)(1), redesignated as § 101.9(k)(1), by adding a second sentence that reads "Information about the relationship of a dietary property to a disease or health-related condition may only be provided in conformance with the requirements of § 101.14 and subpart E of part 101." No comments voiced specific objection to this proposed change.

FDA notes that the provisions of current § 101.9(i) had long been in effect at the time Congress drafted the 1990 amendments. While Congress did enact provisions under the 1990 amendments that allow for health claims on foods, nothing in the act or in the legislative history of the act suggests that Congress intended that current § 101.9(i) should be changed. The agency therefore finds no basis for the assertion that the provisions of current § 101.9(i), redesignated as § 101.9(k), are now contrary to the intent of the 1990 amendments.

FDA has reconsidered the requirements of § 101.9(k)(5), however, in light of the comments. The agency concludes that there is no reason to prohibit safe substances from being incorporated into conventional foods or dietary supplements of vitamins and minerals as long as their presence is noted in the ingredient list, and the product's label or labeling does not state or imply that the food has special dietary properties because of the presence of the substance when, in fact, its usefulness has not been established. Section 411(b)(2) of the act provides that vitamin and mineral products may contain substances that are not vitamins or minerals as long as the substances are only identified as a part of the ingredient list. Therefore, proposed § 101.9(k)(5) is amended by deleting the second and third sentences.

Questions have been raised as to whether the amounts of these substances that are not vitamins or minerals can be included on the food label. Such information can be included in the ingredient list if, in addition to listing the ingredients in order of predominance by weight, quantitative information on each of the ingredients in the food is presented. However, information about the ingredients that are not vitamins and minerals may not be presented in a way that suggests that the dietary usefulness of these substances has been established.

While the comments raised objections to the other provisions of proposed § 101.9(k) (i.e., (k)(3), (k)(4) and (k)(6)), none provided arguments that convinced the agency that deletion or revision of those provisions was either appropriate or necessary in fulfilling the mandates of the 1990 amendments. The objections that were raised, however, suggest that a clarification of the intent of those provisions would prove helpful to those who voiced the objections. Such a clarification was provided in the **Federal Register** of March 14, 1973 (38 FR 6961). In that document, the agency

noted that § 1.17 (i)(3) and (i)(4) (redesignated as § 101.9(k)(3) and (k)(4)) are aimed at prohibiting unsubstantiated generalizations about nutrient losses because of soil, transportation, or processing and do not preclude a producer, manufacturer, or vendor from indicating a higher nutrient retention in a particular product as compared to other similar products. Nor do they preclude an indication that such retention results from special handling of the product, provided that such indications are factual. Further, these provisions do not preclude a manufacturer from suggesting cooking or handling methods that would result in optimum nutrient retention. While the agency recognizes that such information may be useful to consumers, it does not believe that it would be appropriate to require manufacturers to provide such information, either on the labeling or through other media.

Current § 101.9(i)(6), redesignated in the supplementary proposal as § 101.9(k)(6), prohibits any suggestion that a naturally-occurring vitamin is superior to an added vitamin. The agency finds no basis for such an assertion, and the comment offered no data in support of such an assertion. As the agency clarified in the repromulgation of March 14, 1973 (38 FR 6950 at 6958), this section (then § 1.17(i)(6)) "forbids any suggestion that a natural vitamin is superior to an added vitamin, but permits any truthful designation of any nutrient as natural in origin."

FDA acknowledges its inadvertent oversight in not including a reference to proposed § 101.36, Nutrition Labeling of Dietary Supplements of Vitamins and Minerals, in proposed § 101.9(k). The inclusion of this reference is a logical outgrowth of the agency's stated intention that "nutrition labeling of vitamin and mineral supplements appear as similar as possible to the nutrition labeling of other foods" (56 FR 60366 at 60382). Section 101.9(k) applies to all foods, including dietary supplements of vitamins and minerals, and the agency did not intend to narrow its scope. Therefore, FDA tentatively concluded that it should correct this oversight by including an appropriate cross reference to § 101.36 in the final rule. However, the agency will propose its position on this issue following the DS Act. For completeness, FDA is inserting the word "label" in the first paragraph of § 101.9(k) to clarify that this section pertains to food labels as well as labeling.

255. One comment asserted that the phrase "represents, suggests, or implies" in the opening sentence of § 101.9(k) is unconstitutionally vague.

FDA disagrees with the comment's assertion that the phrase "represents, suggests, or implies" is unconstitutionally vague. The agency notes that the vagueness doctrine is generally applied to strike down prohibitions on speech that leave individuals without clear guidance on the type of speech that is prohibited. See, e.g., *Village of Hoffman Estates* v. *Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498-99 (1982); *Grayned* v. *City of Rockford*, 408 U.S. 104, 108 (1972). The provisions of § 101.9(k) are narrowly tailored and clearly delineate the types of statements about nutrients that will render a food misbranded. Thus, § 101.9(k) provides clear and precise guidance on the type of speech that is prohibited.

E. Conforming Amendments

256. A trade association wrote in support of the multiunit retail exemption in § 101.9(j)(15) and requested that § 1.24(a)(14) be amended to reflect the change by including a reference to section 403(q) and (r) of the act. The comment stated "we submit that this amendment is fully consistent with the requirements of the 1990 amendments and the provisions of the proposed § 101.9(j)(13) in that nutrition labeling will be provided on the outer carton together with the other information required under the referenced sections."

The agency agrees that § 1.24(a)(14) of the General Enforcement Regulations should be amended to reference 403(q) of the act, as amended by the 1990 amendments. This change merely conforms § 1.24(a)(14) to the rule that FDA is adopting in § 101.9(j)(15). Accordingly, the agency is amending § 1.24(a)(14) to read as follows: "The unit containers in a multiunit or multicomponent retail food package shall be exempt from regulations of section 403(e)(1), (g)(2), (i)(2), (k), and (q) of the act with respect to the requirements for label declaration of the name and place of business of the manufacturer, packer, or distributor; label declaration of ingredients; and nutrition information when * * *."

However, FDA cannot grant the comment's request with respect to section 403(r) of the act. Any container that bears a nutrient content claim or a health claim must comply fully with the requirements of that section of the act and of the regulations that implement it.

257. A food trade association requested that FDA amend § 101.100(d) to include section 403(q) and (r) of the act to provide that products shipped in bulk for further processing, labeling, or repacking in substantial quantities at an establishment other than where originally processed or packed, are exempt during the time of introduction into, and movement in, interstate commerce and during the time of holding in such establishment.

FDA agrees that § 101.100(d), Exemptions From Food Labeling Requirements, should be amended to include 403(q) of the act. Again, this modification merely reflects the rule that FDA is adopting in § 101.9(j)(9). However, for the reason explained in response to the previous comment, FDA is not granting the request with respect to section 403(r) of the act. Accordingly, FDA is amending 21 CFR § 101.100(d) to read as follows:

> Except as provided by paragraphs (e) and (f) of this section, a shipment or other delivery of food which is, in accordance with the practice of the trade, to be processed, labeled or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling requirements of section 403 (c), (e), (g), (h), (i), (k), and (q) of the act if: * * *."

Nutrition Labeling of Dietary Supplements of Vitamins and Minerals

258. Most comments, including those from supplement manufacturers and trade associations, supported the general concept of nutrition labeling for dietary supplements of vitamins and minerals. One comment, however, suggested that any decisions on nutrition labeling of vitamin and mineral supplements be deferred until the agency decides how it intends to regulate dietary supplements, in general. This comment is referring to FDA's Task Force on Dietary Supplements. The comment argued that the proposed labeling requirement would create a label with large amounts of information that is of little value to the consumer, particularly for single vitamin and mineral supplements.

As pointed out in the supplementary proposal (56 FR 60366 at 60381), section 403(q)(5)(E) of the act states that if a food to which section 411 of the act applies (i.e., dietary supplements of vitamins and minerals) contains one or more of the nutrients required to be listed in nutrition labeling, "the label or labeling of such food shall comply with the requirements of paragraphs (1) and (2) [of section 403(q) of the act] in a manner which is appropriate for such food and which is specified in regulations of the Secretary." In the supplementary proposal (56 FR 60366 at

60381 through 60382), the agency also stated that vitamin and mineral supplements are required to bear nutrition labeling under section 403(q)(5)(C) of the act even if they do not contain any of the nutrients required to be in nutrition labeling. Section 403(q)(5)(C) of the act provides that nutrition labeling is not required in such circumstances unless a claim is made about the nutritional value of the food. The statement of identity for supplements of vitamins or minerals, including single vitamins or minerals, may be a claim about the nutritional value of the supplement. However, because the DS Act imposes a moratorium on the implementation of the 1990 amendments, FDA is not taking any action to implement section 403(q)(5)(c) of the act at this time.

FDA's Task Force on Dietary Supplements is consequently irrelevant to this issue. Nothing in the Task Force's report would relieve the agency of the obligation to adopt regulations to implement the explicit requirements of the law.

Furthermore, the agency does not agree that nutrition information for vitamin and mineral supplements is of little value to the consumer. These products are represented and sold for their vitamin and mineral content. Thus, nutrition information about them will assist consumers in determining the role that the products can play in maintaining healthy dietary practices. Moreover, the agency notes that most vitamin and mineral supplements already bear nutrition information on their labels.

For the reasons stated, the agency tentatively concluded that it is not necessary to modify its requirement for mandatory nutrition labeling on labels of dietary supplements of vitamins and minerals. However, the agency will propose its position on this issue based on the provisions of the DS Act.

259. In testimony at one of the public meetings held by FDA, there was a comment suggesting that small packages of dietary supplements of vitamins and minerals be exempt from mandatory nutrition labeling.

Section 403(q)(5)(B) of the act provides for an exemption for foods in small packages "if the label of such foods does not contain any nutrition information." This provision is implemented in § 101.9(j)(13)(i). Thus, the question is raised as to whether the statement of identity for supplements of vitamins and minerals is a claim. FDA will address this question and the implementation of section 403(q)(5)(B) with respect to dietary supplements in accordance with the terms of the DS Act.

260. One comment recommended deleting proposed § 101.36(b)(1) that required the number of units recommended per day to be declared in the nutrition label on the basis that it is repetitious of information that is on the label in other places.

Likewise, a few comments were opposed to proposed § 101.36(b)(2) that required declaration of "Units per container" in the nutrition label. These comments asserted that such a requirement is redundant and unnecessary because the number of units per container is already listed on the principal display panel of dietary supplements as part of the net contents declaration.

FDA considered these comments and agrees that, for supplements in which the unit is a discretely defined unit (e.g., tablets or capsules), "Units per day" could be confusing. The agency is concerned that consumers could be confused by a statement that indicates that several units are to be taken per day (e.g., 3 tablets per day) when the nutrient information is given for one unit. If consumers do not look at the column legend that states that the nutrient information is "per unit," they might assume that the nutrient information is for the amount specified for consumption per day. To avoid the possibility for confusion, FDA tentatively concludes that the subheading "Each unit contains:" should be allowed for supplements in which the unit is a discretely defined unit (e.g., tablets or capsules). Directions concerning the number of units to be consumed per day should be given outside of the nutrition label.

The agency also agrees that, since § 101.105(a) requires the net quantity of content declaration to include a numerical count when appropriate, there is little benefit to be derived from information on the number of units per container appearing in two different places on the label. However, when the supplement is in a liquid or powdered form, FDA believes additional information similar to that on conventional foods best informs the consumer about the dosage unit. Therefore, FDA tentatively concludes that for dietary supplements of vitamins and minerals in liquid or powdered form, "Serving size" and "Servings per container" should be stated consistent with § 101.9(d). The agency will propose its position on these issues in the rulemaking required by the DS Act.

261. Several comments, mostly from the dietary supplement industry, opposed the dual labeling of nutrient content "per unit" and "per day" if more than one unit is specified for consumption per day. Comments argued that dual declaration is impractical and will result in overcrowding of already small labels, creating consumer confusion and obfuscating the label's message. Other arguments against dual declaration were that such a requirement may discriminate against supplements that are not in the one-per-day format, and that it would force the industry to reformulate products so that labels can accommodate all of the information. One comment pointed out that the proposed regulation does not address how required information should be presented when the recommended daily dose is a range, e.g., 1 to 3 tablets per day.

Among the comments opposing dual declaration, however, there was disagreement as to which declaration is preferable, "per unit" or "per day." Some comments stated that it was the total amount of nutrients that is important, and therefore, declaration should be on a "per day" basis. These comments pointed out that FDA regulations (§ 105.77) promulgated in 1973 specified that dietary supplements be labeled according to the quantity specified for consumption during one day. The comment stated that although these regulations were withdrawn in 1979, most companies still comply with them.

Other comments stated that consumers may deviate from the recommended dose and should be given credit for being able to multiply quantities of nutrients by the number of units consumed. Therefore, these comments stated that declaration should be on a "per unit" basis. Comments pointed out that the U.S. Pharmacopeia is developing quality standards for dietary supplements in which they propose that nutrient information be presented "per dosage unit."

Other comments suggested that as an alternative to just one form of declaration on the label, the label could reference other labeling such as package inserts that contain all of the required information, or could permit either "per unit" or "per day" listing as long as the label clearly states which type of information is provided. A few comments favored dual declaration. One comment stated that omitting either declaration might confuse people who think that the nutrition information for one unit applies to a day or vice versa.

The agency is persuaded that dual declaration of nutrition information "per unit" and "per day," when a daily dose of more than one unit is recommended, may create a readability

problem for consumers, given the limited label space available on most dietary supplement products. FDA also agrees that recommended daily consumption of other than well defined dosages (e.g., "consume 1 to 3 tablets per day") would pose a problem in terms of labeling on a "per day" basis.

FDA is concerned that consumers have nutrition information available at the point of purchase upon which to base purchase decisions. Therefore, the agency is not considering package inserts which could be viewed only after purchase of the product. Additionally, rather than allowing manufacturers to label on a "per day" or "per unit" basis, the agency favors one consistent method of labeling. A consistent method will allow consumer education programs to explain how nutrition labeling is to always appear and to teach consumers how to calculate their individual consumption levels if their intake differs from the amount specified within the nutrition label. The agency believes labeling "per unit" is more useful in that the product will always be consumed "per unit," however, consumers may not always follow a manufacturer's recommendation to consume a certain number of units per day and therefore may not actually consume the amount indicated "per day."

For these reasons, and to harmonize with the U.S. Pharmacopeia, the agency tentatively concludes that nutrition information should be declared on a "per unit" basis. FDA intends to propose its position in the rulemaking that is required under the DS Act.

262. In the supplementary proposal, FDA proposed that nutrition labels for dietary supplements of vitamins and minerals include a column of quantitative amounts by weight and a second column of percent of RDI's, expressed as "Percent Daily Value." Comments were requested on the usefulness of a list of DRV's and the percent of the DRV for fat, saturated fat, cholesterol, carbohydrate, dietary fiber, and sodium provided by the supplement when they are declared (i.e., when they are present in the supplement in more than insignificant amounts) (56 FR 60366 at 60383). In the format proposal, FDA stated that it anticipated modifying § 101.36, Nutrition Labeling of Dietary Supplements, to be as consistent as possible with the nutrition labeling of other foods and requested comment (57 FR 32058 at 32072).

Several comments to both the supplementary proposal and the format proposal addressed the format for declaring amounts of nutrients present. About half of the comments supported FDA's position. However, one comment argued that the unique characteristics of dietary supplements demand a different approach to their nutrition labeling. Characteristics identified included: (1) The vast majority of supplements are marketed in relatively small packages, (2) the nutrition profiles for these products typically reflect high levels of micronutrients and relatively insignificant amounts of macronutrients, (3) consumers look for and expect nutrition information on supplements that is different from that on conventional foods, and (4) consumers of supplements will already be asked to search through an array of nutrient names and units of measure to find the information they look for most: The percentage of their daily nutritional requirements that the supplement provides.

One comment from a manufacturer stated that there was no need to make significant changes in dietary supplement labels because current labels that have been used for many years are widely accepted and present the necessary data on vitamins and minerals in a logical and readily understandable form. A comment from another manufacturer opposed the required declaration in separate columns of quantitative amounts by weight of nutrients and by the percent RDI or percent DRV (expressed as "Percent of Daily Value"). The comment argued that only percent of daily value should be mandatory, and that listing of quantitative amounts by weight should be voluntary, because there is no congressional mandate to list quantitative amounts on two bases, no agency justification that two bases are useful to consumers, and a potential to confuse consumers with little understood terms, e.g., mg alpha-tocopherol. The comment also asserted that a requirement for too much information is discriminatory against products with larger numbers of nutrients and might discourage use of smaller packages that are less expensive to consumers. The comment also stated that a requirement for declaration of only percent of daily value would be consistent with the requirement for vitamins and minerals on conventional food labels.

A few comments objected to the required inclusion of a list of daily values in addition to the quantitative amounts by weight and the percent of daily value on the label. The comments stated that this additional information will produce an even more cluttered appearance and further contribute to the proliferation of numerical values on dietary supplement labels. One comment argued that "The goal of meeting the supplement consumer's need for relevant, comprehensible nutrition information should not be sacrificed out of a blind concern for consistency." The comment concluded that consumers of supplements are already familiar and comfortable with the concept of percent of daily value and their focus on this information should not be diverted by additional unnecessary and potentially confusing information.

While FDA continues to believe it is helpful to consumers to minimize inconsistencies in the label format between types of foods, the agency is persuaded that the unique characteristics of dietary supplements require a reevaluation of whether the format requirements for conventional foods should be carried over to dietary supplements. For example, the agency believes that the declaration of quantitative amounts on two bases (i.e., both by weight and by percent of daily value) needs to be considered for dietary supplements in terms of its usefulness to consumers. In that regard, the agency considers dietary supplement consumers to have special needs for quantitative nutrition information about the products they use by virtue of the way such products are formulated, marketed, and used. Dietary supplements are often formulated and marketed on the basis of offering specific amounts of certain nutrients to consumers. Dietary supplement product users are often trying to maintain a certain quantitative intake of specific nutrients in their diets and use the product to obtain this quantitative goal. Some of the nutrients contained in dietary supplements and declared on the nutrition label are not well known to many consumers. The quantitative goals that are importantly relevant to consumption of dietary supplement products may be stated in various units including units of weight or of percent of RDI's or DRV's. FDA intends to address this issue in the rulemaking that it will undertake in response to the DS Act.

In its reevaluation of format requirements for dietary supplements, the agency also looked at the requirement in nutrition labeling of conventional foods for a list of daily values for all nutrients declared on the label. After careful consideration of the comments, the agency tentatively concludes that it is not necessary or appropriate to require the inclusion of the DV list on dietary supplements. Because of the small size of most supplement packages and the

duplication of the more complex nomenclature of units for vitamins (e.g., mg alpha-tocopherol) that would be required in a DV list, the agency believes that the added complexity and proliferation of numerical values would interfere with consumers use of the quantitative information by weight and by percent of daily value. FDA will propose its position regarding the format of the nutrition label for dietary supplements based on the provisions of the DS Act.

263. A few comments opposed the requirement for declaration of the quantitative amount and the percent of the DRV of fat, saturated fat, cholesterol, carbohydrate, dietary fiber, sodium, and potassium when these nutrients are present in a supplement in more than insignificant amounts. One comment suggested that the declaration either be optional or be required only when these nutrients are present at levels greater than 10 percent of their respective DRV's. The comment stated that: (1) Excessive and useless information would detract from the importance of a product's vitamin and mineral content; (2) even though the vast majority of supplements lack these substances, all products would have to undergo extensive and expensive testing to determine whether listing of these components is necessary, thus burdening small companies with diverse supplement product lines; and (3) these requirements would hinder product development and increase the cost of bringing innovative products to market. Another comment stated that declaration of fat should be required only for fatty acid supplements of 1 g or more per unit since declaration of smaller amounts would clutter the label and be difficult to read.

As discussed in the preceding comment, FDA agrees that the declaration of the amount of the DRV's (i.e., the DV list) is not necessary on labels of dietary supplements of vitamins and minerals. However, FDA continues to believe that the quantitative amount and the percent of the DRV should be declared for total fat, saturated fat, cholesterol, total carbohydrate, dietary fiber, sodium, and potassium when these nutrients are present in a supplement in more than insignificant amounts. Information about these food components, which are important to the maintenance of good health, is useful for consumers. This view was supported by comments from health professionals, consumer organizations, and the general public. Moreover, supplements are formulated products, and manufacturers should know from the ingredients that they use to make these products whether a supplement contains more than insignificant amounts of any of the nutrients for which DRV's have been established. When such ingredients are not used, laboratory analyses for such nutrients would be unnecessary. As discussed in comment 176 of this document, the definition of insignificant has been modified so that an "insignificant amount" of total carbohydrate, dietary fiber, and protein is an amount that allows a declaration of "less than 1 g" in the nutrition label. The agency will propose its position on this issue in the rulemaking that it does in response to the DS Act.

264. Several comments, predominantly from manufacturers and trade associations, disagreed with FDA's statement in the supplementary proposal that dietary supplements of selenium and chromium are not permitted because there are no regulations declaring these nutrients as approved food additives, GRAS, or prior-sanctioned ingredients. A trade association stated that nutrition labeling regulations are not the appropriate place to announce decisions about the GRAS status of nutrients. Comments argued that selenium and chromium are recognized as essential nutrients for humans. They pointed out that the National Research Council's Food and Nutrition Board has established a Recommended Dietary Allowance for selenium and an ESADDI for chromium (Ref. 23), and that FDA proposed RDI's for these nutrients. Moreover, comments stated that FDA has advised for many years that these trace minerals are "safe and suitable" for use in supplements. The comments argued that, therefore, FDA should adopt a general policy that trace minerals for which a Recommended Dietary Allowance or ESADDI has been established are GRAS, at least at levels not to exceed their respective Recommended Dietary Allowance/ESADDI.

The agency agrees that this rulemaking is not the appropriate place to announce decisions about the GRAS status of nutrients. Therefore, FDA reiterates that there are currently no sources of selenium or chromium that are either affirmed as GRAS or approved food additives for addition to human food. Any direct addition of these trace minerals to a food is based solely on the manufacturer's judgment that the nutrient sources are GRAS and is not sanctioned by the agency.

265. One comment advocated the parenthetical listing of the source of each vitamin or mineral immediately following its declaration on the nutrition information panel in lieu of a separate ingredient list. The comment argued that this listing would avoid confusion by enabling consumers to readily identify the nutrient source and would save limited label space. Furthermore, the comment stated that it is already common practice in the supplement industry. The comment suggested that information about the source of the nutrient would allow the consumer to identify whether the source is the most physiologically desirable, e.g., beta-carotene versus vitamin A palmitate.

FDA advises that dietary supplements, like any food, are required to bear a complete list of ingredients under section 403(l)(2) of the act, and such list should not be confused with the nutrition label. Ingredient listing, moreover, is needed for substances other than vitamins or minerals, e.g., lactose, other fillers, artificial colors, flavors, binders, and excipients. Consumers desiring to know the source of a nutrient can merely look at the list of ingredients just as they would for a conventional food product. Therefore, in accordance with ingredient labeling regulations, the specific source of vitamin A must be shown in the ingredient list.

However, in response to this and another similar comment (see comment 81 of this document), the agency is allowing for the declaration of the percent of vitamin A present as beta-carotene in § 101.9(c)(8)(vi). The agency will propose its position regarding a similar provision in nutrition labeling regulations pertaining to dietary supplements of vitamins and minerals following provisions of the DS Act.

266. One comment objected to the listing of the quantitative amounts of vitamins and minerals to the nearest unit of the same level of significance at which the RDI's are specified in § 101.9(c)(8)(iv). The comment stated that it would be potentially confusing to consumers for thiamin, for example, to be declared to the first decimal place, e.g., 100.0 mg, and niacin to be declared to the nearest whole number, e.g., 100 mg. The comment suggested that decimal places be dropped, and that all nutrients be listed to the nearest whole number when nutrient levels are ten or more times the RDI.

While FDA intends to deal with this issue in its rulemaking that responds to the DS Act, the agency offers the following comments. FDA is not persuaded that consumers would be confused by decimals for some nutrients and not others. In addition, requiring only whole numbers would introduce a large amount of imprecision in the declarations of some nutrients. For

example, it would cause 1.5 mg of thiamin (i.e., 100 percent of the RDI) to be rounded up to 2 mg—a 33 percent increase.

However, when the decimal is followed by a zero, the agency generally has no objection to the zero being dropped. In fact, in the supplementary proposal, this was done in the declaration of the amount of vitamin B12 in the hypothetical sample label for "Daily Vitamins Plus Iron" (56 FR 60366 at 60383). Since RDI's in § 101.9(c)(8)(iv) are established only in whole numbers or in tenths of a unit, allowing zeros following decimals to be dropped, in effect, allows all nutrients to be declared to the nearest whole number when nutrient levels are ten times the RDI.

267. A couple of comments objected to FDA's proposal that compliance with the requirements for labeling of dietary supplements be determined in accordance with § 101.9(g), i.e., 100 percent of label claim for Class I nutrients. Comments argued that the 100 percent requirement is unreasonable in that it is more stringent than United States Pharmacopeia (USP) requirements for certain vitamin and mineral products, which generally allow lower limits of 90 percent to 95 percent of label claim.

FDA intends to deal with this issue in the rulemaking that responds to the DS Act. However, the agency notes that dietary supplements are fabricated products. Therefore, the question is raised why they should not be held to the same Class I nutrient standards as conventional foods that are fortified or enriched. Based on the agency's current compliance policy it has informed USP that anything less than 100 percent of the label claim for vitamin and mineral products is not acceptable to FDA, and that the only permissible deviation from this requirement would be the variability of the analytical method (Ref. 118).

The agency notes that, contrary to the statement in the comments, the General Notices of the USP state that a dosage should be formulated to provide 100 percent of the labeled amount (Ref. 119). The limits in the monographs allow for overages of ingredients known to decrease with time, for analytical error, for manufacturing and compounding variations, and for deterioration to an extent considered insignificant under practical conditions (Ref. 119).

268. One comment asserted that manufacturers should be prohibited from labeling a supplement in such a way as to confuse the weight of a unit of supplement with its nutrient content. For example, a calcium supplement that contains 250 mg of elemental calcium as calcium chloride should not be labeled as "calcium—625 mg" anywhere on the label.

FDA concurs that such labeling is potentially misleading to consumers. Section 403(a) of the act provides that a food will be deemed to be misbranded if its labeling is false or misleading in any particular. FDA concludes that existing statutory authority is sufficient for taking regulatory action if the weight of a product is specified on the label in a manner that is likely to mislead consumers into thinking that that is the weight of the nutrient contained in the product if those amounts are different.

IX. Consumer Education Program

Section 2(c) of the 1990 amendments directs the Secretary (and FDA, by delegation) to carry out activities that educate consumers about nutrition information on the food label and the importance of that information in maintaining healthy dietary practices. To achieve this purpose, FDA and USDA have jointly initiated a multi-year food labeling education campaign. The major goals of this campaign are to increase consumers' knowledge and effective use of the new food label to make accurate and sound dietary choices; to integrate food labeling education into existing and new nutrition and health education programs; and to build extensive partnerships capable of developing and evaluating labeling education targeted to the dietary needs of diverse populations, such as low literacy consumers, minorities, older Americans, children, and people with dietary restrictions.

As part of this effort, the agencies have established the National Exchange on Food Labeling Education which includes an information center housed in the Food and Nutrition Information Center at the National Agricultural Library. The National Exchange on Food Labeling Education provides the general public and professionals with access to information about food labeling research and educational activities (projects, programs, and materials) from both the public and private sector.

FDA and USDA have also worked to establish cooperative projects with diverse organizations and to facilitate the communication of information that targets various subpopulations as well as the general public. The agencies have thus developed extensive food label education networks that include consumers, health professionals and organizations, educators, trade associations, Federal and local government, and many others to assist in the dissemination and development of information and activities.

To ensure that consumers have accurate and adequate resource materials and information, the agencies have begun, and will continue, to conduct and report on existing and planned food labeling research; to develop education initiatives at the national and local level; to hold regularly-scheduled meetings to build labeling education exchanges; to produce videos; and to produce an array of public education materials, including a special edition of FDA Consumer magazine that summarizes the final food labeling regulations, and brochures (in English and other languages) on the new label and how to use it to meet the Dietary Guidelines for Americans (Ref. 4). These materials will be targeted to the general public, nutritionists, such special groups as ethnic minorities, and others. Organizations will also be able to use these resource materials to develop educational materials of their own.

X. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule

as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

XI. Environmental Impact

The agency previously considered the environmental effects of the action being taken in this final rule. As announced in its nutrition labeling proposed rules published in the **Federal Register** of November 27, 1991 (56 FR 60366 et al.), the agency determined that under 21 CFR 25.24(a)(11), these actions are of a type that do not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

In its November 1991 nutrition labeling proposed rules, the agency proposed that the final rules for these actions would become effective 6 months following their publication in the **Federal Register**. Several comments on the nutrition labeling proposed rules suggested that there would be significant adverse environmental effects from the final rules unless the agency allowed more time between the publication of the final rules and their effective dates. The concern in these comments was that, if the agency did not allow firms more time between the publication of the final rules and their effective dates to use up existing label inventories, large stocks of labels and labeled packaging would have to be discarded. These comments questioned whether the agency had sufficiently examined the impact of disposing of obsolete labels and labeled packaging on this country's solid waste disposal capabilities. Two comments estimated the amounts of labeling from their respective industries, i.e., dairy and confectionery, that would need to be discarded following publication of FDA's final rules on several food labeling actions, including this action. However, these comments did not: (1) Provide details on how these estimates were derived, (2) identify what portion of the estimated amounts are attributable to these two actions, or (3) describe what impact the discarded labels and packaging would have on the disposal of solid waste.

Based on its review of available data and comments received, the agency has decided to allow additional time for companies to use up their old labels. Thus, the nutrition labeling final rules will not be effective until May 8, 1994. FDA believes there will thus be ample time for food companies to use up most of the existing labeling and packaging stocks and to incorporate labeling language that complies with FDA's regulations into their food labels. Consequently, the comments on the potential for adverse environmental effects do not affect the agency's previous determination that no significant impact on the human environment is expected and that an environmental impact statement is not required.

XII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1 and 101 are amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for 21 CFR part 1 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 403, 502, 512, 602, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 343, 352, 355, 360, 362, 371); sec. 215 of the Public Health Service Act (42 U.S.C. 216).

2. Section 1.24 is amended by revising paragraph (a)(14) to read as follows:

§ 1.24 Exemptions from required label statements.

* * * * *

(a) * * *

(14) The unit containers in a multiunit or multicomponent retail food package shall be exempt from regulations of section 403 (e)(1), (g)(2), (i)(2), (k), and (q) of the act with respect to the requirements for label declaration

of the name and place of business of the manufacturer, packer, or distributor; label declaration of ingredients; and nutrition information when:

(i) The multiunit or multicomponent retail food package labeling meets all the requirements of this part;

(ii) The unit containers are securely enclosed within and not intended to be separated from the retail package under conditions of retail sale; and

(iii) Each unit container is labeled with the statement "This Unit Not Labeled For Retail Sale" in type size not less than one-sixteenth of an inch in height. The word "Individual" may be used in lieu of or immediately preceding the word "Retail" in the statement.

* * * * *

PART 101—FOOD LABELING

3. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

4. Section 101.9 is revised to read as follows:

§ 101.9 Nutrition labeling of food.

(a) Nutrition information relating to food shall be provided for all products intended for human consumption and offered for sale unless an exemption is provided for the product in paragraph (j) of this section. A nutrition claim or any other nutrition information on the label or in labeling or advertising in any context, and in any form of expression, implicit, as well as explicit, shall negate any exemption and subject a food to the provisions of this section.

(1) When food is in package form, the required nutrition labeling information shall appear on the label in the format specified in this section.

(2) When food is not in package form, the required nutrition labeling information shall be displayed clearly at the point of purchase (e.g., on a counter card, sign, tag affixed to the product, or some other appropriate device). Alternatively, the required information may be placed in a booklet, looseleaf binder, or other appropriate format that is available at the point of purchase.

(3) Solicitation of requests for nutrition information by a statement "For nutrition information write to _____" on the label or in the labeling or advertising for a food, or providing such information in a direct written reply to a solicited or unsolicited request, does not subject the label or the labeling of a food exempted under paragraph (j) of this section to the requirements of this section if the reply to the request conforms to the requirements of this section.

(4) If any vitamin or mineral is added to a food so that a single serving provides 50 percent or more of the Reference Daily Intake (RDI) for the age group for which the product is intended, as specified in paragraph (c)(8)(iv) of this section, of any one of the added vitamins or minerals, unless such addition is permitted or required in other regulations, e.g., a standard of identity or nutritional quality guideline, or is otherwise exempted by the Commissioner, the food shall be considered a food for special dietary use within the meaning of § 105.3(a)(1)(iii) of this chapter.

(b) [Reserved]

(c) The declaration of nutrition information on the label and in labeling of a food shall contain information about the level of the following nutrients, except for those nutrients whose inclusion, and the declaration of amounts, is voluntary as set forth in this paragraph. No nutrients or food components other than those listed in this paragraph as either mandatory or voluntary may be included within the nutrition label. Except as provided for in paragraphs (f) or (j) of this section, nutrient information shall be presented using the nutrient names specified and in the following order in the formats specified in paragraphs (d) or (e) of this section.

(1) "Calories, total," "Total calories," or "Calories": A statement of the caloric content per serving, expressed to the nearest 5-calorie increment up to and including 50 calories, and 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero. Energy content per serving may also be expressed in kilojoule units, added in parentheses immediately following the statement of the caloric content.

(i) Caloric content may be calculated by:

(A) Using specific Atwater factors (i.e., the Atwater method) given in Table 13, "Energy Value of Foods—Basis and Derivation," by A. L. Merrill and B. K. Watt, United States Department of Agriculture (USDA) Handbook No. 74 (slightly revised, 1973), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 and is available from the Division of Nutrition, Center for Food Safety and Applied Nutrition (HFF-260), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or may be inspected at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.;

(B) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate, and total fat, respectively, as described in USDA Handbook No. 74 (slightly revised 1973) pp. 9–11, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 (the availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section);

(C) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate less the amount of insoluble dietary fiber, and total fat, respectively, as described in USDA Handbook No. 74 (slightly revised 1973) pp. 9–11, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 (the availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section);

(D) Using data for specific food factors for particular foods or ingredients approved by the Food and Drug Administration (FDA) and provided in parts 172 or 184 of this chapter, or by other means, as appropriate; or

(E) Using bomb calorimetry data and subtracting 1.25 calories per gram protein to correct for incomplete digestibility, as described in USDA Handbook No. 74 (slightly revised 1973) p. 10, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 (the availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section).

(ii) "Calories from fat": A statement of the caloric content derived from total fat as defined in paragraph (c)(2) of this section in a serving, expressed to the nearest 5-calorie increment, up to and including 50 calories, and the nearest 10-calorie increment above 50 calories, except that label declaration of "calories from fat" is not required on products that contain less than 0.5 gram of fat in a serving and amounts less than 5 calories may be expressed as zero. This statement shall be declared as provided in paragraph (d)(5) of this section. Except as provided for in paragraph (f) of this section, if "Calories from fat" is not required and, as a result, not declared, the statement "Not a significant source of calories from fat" shall be placed at the bottom of the table of nutrient values in the same type size.

(iii) "Calories from saturated fat" or "Calories from saturated" (VOLUNTARY): A statement of the caloric content derived from saturated fat as defined in paragraph (c)(2)(i) of this section in a serving may be declared voluntarily, expressed to the nearest 5-

calorie increment, up to and including 50 calories, and the nearest 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero. This statement shall be indented under the statement of calories from fat as provided in paragraph (d)(5) of this section.

(2) "Fat, total" or "Total fat": A statement of the number of grams of total fat in a serving defined as total lipid fatty acids and expressed as triglycerides. Amounts shall be expressed to the nearest 0.5 (½) gram increment below 3 grams and to the nearest gram increment above 3 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(i) "Saturated fat," or "Saturated": A statement of the number of grams of saturated fat in a serving defined as the sum of all fatty acids containing no double bonds, except that label declaration of saturated fat content information is not required for products that contain less than 0.5 gram of total fat in a serving if no claims are made about fat or cholesterol content, and if "calories from saturated fat" is not declared. Except as provided for in paragraph (f) of this section, if a statement of the saturated fat content is not required and, as a result, not declared, the statement "Not a significant source of saturated fat" shall be placed at the bottom of the table of nutrient values in the same type size. Saturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½) gram increment below 3 grams and to the nearest gram increment above 3 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(ii) "Polyunsaturated fat" or "Polyunsaturated" (VOLUNTARY): A statement of the number of grams of polyunsaturated fat in a serving defined as *cis,cis*-methylene-interrupted polyunsaturated fatty acids may be declared voluntarily, except that when monounsaturated fat is declared or when a claim is made on the label or in labeling about fatty acids or cholesterol, label declaration of polyunsaturated fat is required. Polyunsaturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½) gram increment below 3 grams and to the nearest gram increment above 3 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(iii) "Monounsaturated fat" or "Monounsaturated" (VOLUNTARY): A statement of the number of grams of monounsaturated fat in a serving defined as *cis*-monounsaturated fatty acids may be declared voluntarily except that when polyunsaturated fat is declared or when a claim is made on the label or in labeling about fatty acids or cholesterol, label declaration of monounsaturated fat is required. Monounsaturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½) gram increment below 3 grams and to the nearest gram increment above 3 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(3) "Cholesterol": A statement of the cholesterol content in a serving expressed in milligrams to the nearest 5-milligram increment, except that label declaration of cholesterol information is not required for products that contain less than 2 milligrams cholesterol in a serving and make no claim about fat, fatty acids, or cholesterol content, or such products may state the cholesterol content as zero. Except as provided for in paragraph (f) of this section, if cholesterol content is not required and, as a result, not declared, the statement "Not a significant source of cholesterol" shall be placed at the bottom of the table of nutrient values in the same type size. If the food contains 2 to 5 milligrams of cholesterol per serving, the content may be stated as "less than 5 milligrams."

(4) "Sodium": A statement of the number of milligrams of sodium in a specified serving of food expressed as zero when the serving contains less than 5 milligrams of sodium, to the nearest 5-milligram increment when the serving contains 5 to 140 milligrams of sodium, and to the nearest 10-milligram increment when the serving contains greater than 140 milligrams.

(5) "Potassium" (VOLUNTARY): A statement of the number of milligrams of potassium in a specified serving of food may be declared voluntarily, except that when a claim is made about potassium content, label declaration shall be required. Potassium content shall be expressed as zero when the serving contains less than 5 milligrams of potassium, to the nearest 5-milligram increment when the serving contains less than or equal to 140 milligrams of potassium, and to the nearest 10-milligram increment when the serving contains more than 140 milligrams.

(6) "Carbohydrate, total" or "Total carbohydrate": A statement of the number of grams of total carbohydrate in a serving expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, or if the serving contains less than 0.5 gram, the content may be expressed as zero. Total carbohydrate content shall be calculated by subtraction of the sum of the crude protein, total fat, moisture, and ash from the total weight of the food. This calculation method is described in A. L. Merrill and B. K. Watt, "Energy Value of Foods—Basis and Derivation," USDA Handbook 74 (slightly revised 1973) pp. 2 and 3, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 (the availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section).

(i) "Dietary fiber": A statement of the number of grams of total dietary fiber in a serving, indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, declaration of dietary fiber is not required or, alternatively, the statement "Contains less than 1 gram" or "less than 1 gram" may be used, and if the serving contains less than 0.5 gram, the content may be expressed as zero. Except as provided for in paragraph (f) of this section, if dietary fiber content is not required and as a result, not declared, the statement "Not a significant source of dietary fiber" shall be placed at the bottom of the table of nutrient values in the same type size.

(A) "Soluble fiber" (VOLUNTARY): A statement of the number of grams of soluble dietary fiber in a serving may be declared voluntarily except when a claim is made on the label or in labeling about soluble fiber, label declaration shall be required. Soluble fiber content shall be indented under dietary fiber and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(B) "Insoluble fiber" (VOLUNTARY): A statement of the number of grams of insoluble dietary fiber in a serving may be declared voluntarily except that when a claim is made on the label or in labeling about insoluble fiber, label declaration shall be required. Insoluble fiber content shall be indented under dietary fiber and expressed to the nearest gram except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(ii) "Sugars": A statement of the number of grams of sugars in a serving, except that label declaration of sugars content is not required for products that contain less than 1 gram of sugars in a

serving if no claims are made about sweeteners, sugars, or sugar alcohol content. Except as provided for in paragraph (f) of this section, if a statement of the sugars content is not required and, as a result, not declared, the statement "Not a significant source of sugars" shall be placed at the bottom of the table of nutrient values in the same type size. Sugars shall be defined as the sum of all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose). Sugars content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less then 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(iii) "Sugar alcohol" (VOLUNTARY): A statement of the number of grams of sugar alcohols in a serving may be declared voluntarily on the label, except that when a claim is made on the label or in labeling about sugar alcohol or sugars when sugar alcohols are present in the food, sugar alcohol content shall be declared. For nutrition labeling purposes, sugar alcohols are defined as the sum of saccharide derivatives in which a hydroxyl group replaces a ketone or aldehyde group and whose use in the food is listed by FDA (e.g., mannitol) or is generally recognized as safe (e.g., xylitol, sorbitol). In lieu of the term "sugar alcohol," the name of the specific sugar alcohol (e.g., "xylitol") present in the food may be used in the nutrition label provided that only one sugar alcohol is present in the food. Sugar alcohol content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less then 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(iv) "Other carbohydrate" (VOLUNTARY): A statement of the number of grams of other carbohydrates may be declared voluntarily. Other carbohydrates shall be defined as the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol, except that if sugar alcohol is not declared (even if present), it shall be defined as the difference between total carbohydrate and the sum of dietary fiber and sugars. Other carbohydrate content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(7) "Protein": A statement of the number of grams of protein in a serving, expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero. When the protein in foods represented or purported to be for adults and children 4 or more years of age has a protein quality value that is a protein digestibility-corrected amino acid score of less than 20 expressed as a percent, or when the protein in a food represented or purported to be for children greater than 1 but less than 4 years of age has a protein quality value that is a protein digestibility-corrected amino acid score of less than 40 expressed as a percent, either of the following shall be placed adjacent to the declaration of protein content by weight: The statement "not a significant source of protein," or a listing aligned under the column headed "Percent Daily Value" of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the Daily Reference Value (DRV) or Reference Daily Intake (RDI), as appropriate, for protein and expressed as Percent of Daily Value. When the protein quality in a food as measured by the Protein Efficiency Ratio (PER) is less than 40 percent of the reference standard (casein) for a food represented or purported to be for infants, the statement "not a significant source of protein" shall be placed adjacent to the declaration of protein content. Protein content may be calculated on the basis of the factor of 6.25 times the nitrogen content of the food as determined by the appropriate method of analysis as given in the "Official Methods of Analysis of the AOAC International" (formerly the Association of Official Analytical Chemists), 15th Ed. (1990), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, except when the official procedure for a specific food requires another factor. Copies may be obtained from AOAC, 2200 Wilson Blvd., suite 400, Arlington, VA 22201-3301, or may be inspected at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(i) A statement of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the RDI or DRV for protein, as appropriate, and expressed as Percent of Daily Value, may be placed on the label, except that such a statement shall be given if a protein claim is made for the product, or if the product is represented or purported to be for use by infants or children under 4 years of age. When such a declaration is provided, it shall be placed on the label adjacent to the statement of grams of protein and aligned under the column headed "Percent Daily Value," and expressed to the nearest whole percent. However, the percentage of the RDI for protein shall not be declared if the food is represented or purported to be for use by infants and the protein quality value is less than 40 percent of the reference standard.

(ii) The "corrected amount of protein (gram) per serving" for foods represented or purported for adults and children 1 or more years of age is equal to the actual amount of protein (gram) per serving multiplied by the amino acid score corrected for protein digestibility. If the corrected score is above 1.00, then it shall be set at 1.00. The protein digestibility-corrected amino acid score shall be determined by methods given in sections 5.4.1, 7.2.1, and 8.00 in "Protein Quality Evaluation, Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation," Rome, 1990, except that when official AOAC procedures described in section (c)(7) of this paragraph require a specific food factor other than 6.25, that specific factor shall be used. The "Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation" as published by the Food and Agriculture Organization of the United Nations/World Health Organization is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Division of Nutrition, Center for Food Safety and Applied Nutrition (HFF-260), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or may be inspected at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC. For foods represented or purported for infants, the corrected amount of protein (grams) per serving is equal to the actual amount of protein (grams) per serving multiplied by the relative protein quality value The relative protein quality value shall be determined by dividing the subject food protein PER value by the PER value for casein. If the relative protein value is above 1.00, it shall be set at 1.00.

(iii) [Reserved]

(8) Vitamins and minerals: A statement of the amount per serving of the vitamins and minerals as described in this paragraph, calculated as a

percent of the RDI and expressed as percent of Daily Value.

(i) For purposes of declaration of percent of Daily Value as provided for in paragraphs (d), (e), and (f) of this section, foods represented or purported to be for use by infants, children less than 4 years of age, pregnant women, or lactating women shall use the RDI's in paragraph (c)(8)(iv) of this section that are specified for the intended group. For foods represented or purported to be for use by both infants and children under 4 years of age, the percent of Daily Value shall be presented by separate declarations according to paragraph (e) of this section based on the RDI values for infants from birth to 12 months of age and for children under 4 years of age. Similarly, the percent of Daily Value based on both the RDI values for pregnant women and for lactating women shall be declared separately on foods represented or purported to be for use by both pregnant and lactating women. When such dual declaration is used on any label, it shall be included in all labeling, and equal prominence shall be given to both values in all such labeling. All other foods shall use the RDI for adults and children 4 or more years of age.

(ii) The declaration of vitamins and minerals as a percent of the RDI shall include vitamin A, vitamin C, calcium, and iron, in that order, and shall include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are added as a nutrient supplement, or when a claim is made about them. Other vitamins and minerals that are:

(A) Required or permitted in a standardized food (e.g., thiamin, riboflavin, and niacin in enriched flour) and that standardized food is included as an ingredient (i.e., component) in another food; or

(B) Included in a food solely for technological purposes and declared only in the ingredient statement need not be declared if neither the nutrient nor the component is otherwise referred to on the label or in labeling or advertising. The declaration may also include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are naturally occurring in the food. The additional vitamins and minerals shall be listed in the order established in paragraph (c)(8)(iv) of this section.

(iii) The percentages for vitamins and minerals shall be expressed to the nearest 2-percent increment up to and including the 10-percent level, the nearest 5-percent increment above 10 percent and up to and including the 50-percent level, and the nearest 10-percent increment above the 50-percent level. Amounts of vitamins and minerals present at less than 2 percent of the RDI are not required to be declared in nutrition labeling but may be declared by a zero or by the use of an asterisk (or other symbol) that refers to another asterisk (or symbol) that is placed at the bottom of the table and that is followed by the statement "Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients)." Alternatively, except as provided for in paragraph (f) of this section, if vitamin A, vitamin C, calcium, or iron is present in amounts less than 2 percent of the RDI, label declaration of the nutrient(s) is not required if the statement "Not a significant source of _____ (listing the vitamins or minerals omitted)" is placed at the bottom of the table of nutrient values. Either statement shall be in the same type size as nutrients that are indented.

(iv) [Reserved]

(v) The following synonyms may be added in parentheses immediately following the name of the nutrient or dietary component:

Vitamin C—Ascorbic acid
Thiamin—Vitamin B_1
Riboflavin—Vitamin B_2
Folate—Folacin
Calories—Energy

(vi) The percent of vitamin A that is present as beta-carotene may be declared to the nearest 10-percent increment immediately adjacent to or beneath the nutrient name (e.g., "Vitamin A (90 percent as beta-carotene)").

(9) [Reserved]

(d)(1) Nutrient information specified in paragraph (c) of this section shall be presented on foods in the following format, as shown in paragraph (d)(12) of this section, except on foods on which dual columns of nutrition information are declared as provided for in paragraph (e) of this section, on those food products on which the simplified format is required to be used as provided for in paragraph (f) of this section, on foods for infants and children less than 4 years of age as provided for in paragraph (j)(5) of this section, and on foods in small or intermediate-sized packages as provided for in paragraph (j)(13) of this section. In the interest of uniformity of presentation, FDA urges that the nutrition information be presented using the graphic specifications set forth in Appendix B to Part 101.

(i) The nutrition information shall be set off in a box by use of hairlines and shall be all black or one color type, printed on a white or other neutral contrasting background whenever practical.

(ii) All information within the nutrition label shall utilize:

(A) A single easy-to-read type style,

(B) Upper and lower case letters,

(C) At least one point leading (i.e., space between two lines of text) except that at least four points leading shall be utilized for the information required by paragraphs (d)(7) and (d)(8) of this section as shown in paragraph (d)(12), and

(D) Type that is kerned (i.e., has proximity of placement) no tighter than −4 setting.

(iii) All information except for the information required in paragraphs (d)(4), (d)(6), (d)(9), and (d)(10) of this section shall be in type size no smaller than 8 point. The information required in paragraphs (d)(4), (d)(6), (d)(9), and (d)(10) of this section shall be in type size no smaller than 6 point.

(iv) The headings required by paragraphs (d)(2), (d)(4), and (d)(6) of this section (i.e., "Nutrition Facts," "Amount per Serving," and "% Daily Value*"), the names of all nutrients that are not indented according to requirements of paragraph (c) of this section (i.e., "Calories," "Total Fat," "Cholesterol," "Sodium," "Total Carbohydrate," and "Protein"), and the percentage amounts required by paragraph (d)(7)(ii) of this section shall be highlighted by bold or extra bold type or other highlighting (reverse printing is not permitted as a form of highlighting) that prominently distinguishes it from other information. No other information shall be highlighted.

(v) A hairline rule that is centered between the lines of text shall separate "Amount Per Serving" from the calorie statements required in paragraph (d)(5) of this section and shall separate each nutrient and its corresponding percent Daily Value required in paragraphs (d)(7)(i) and (d)(7)(ii) of this section from the nutrient and percent Daily Value above and below it, as shown in paragraph (d)(12) of this section.

(2) The information shall be presented under the identifying heading of "Nutrition Facts" which shall be set in a type size larger than all other print size in the nutrition label and, except for labels presented according to the format provided for in paragraph (d)(11) of this section, unless impractical, shall be set the full width of the information provided under paragraph (d)(7) of this section, as shown in paragraph (d)(12) of this section.

(3) Information on serving size shall immediately follow the heading as

shown in paragraph (d)(12) of this section. Such information shall include:

(i) "Serving Size": A statement of the serving size as specified in paragraph (b)(7) of this section.

(ii) "Servings Per Container": The number of servings per container, except that this statement is not required on single serving containers as defined in paragraph (b)(6) of this section.

(4) A subheading "Amount Per Serving" shall be separated from serving size information by a bar as shown in paragraph (d)(12) of this section.

(5) Information on calories shall immediately follow the heading "Amount Per Serving" and shall be declared in one line, leaving sufficient space between the declaration of "Calories" and "Calories from fat" to allow clear differentiation, or, if "Calories from saturated fat" is declared, in a column with total "Calories" at the top, followed by "Calories from fat" (indented), and "Calories from saturated fat" (indented).

(6) The column heading "% Daily Value," followed by an asterisk (e.g., "% Daily Value*"), shall be separated from information on calories by a bar as shown in paragraph (d)(12) of this section. The position of this column heading shall allow for a list of nutrient names and amounts as described in paragraph (d)(7) of this section to be to the left of, and below, this column heading. The column headings "Percent Daily Value," "Percent DV," or "% DV" may be substituted for "% Daily Value."

(7) Except as provided for in paragraph (j)(13) of this section, nutrient information for all nutrients required by paragraph (c) of this section, except vitamins and minerals, shall be declared as follows:

(i) The name of each nutrient specified in paragraph (c) of this section shall be given in a column and followed immediately by the quantitative amount by weight for that nutrient appended with a "g" for grams or "mg" for milligrams as shown in paragraph (d)(12) of this section.

(ii) A listing of the percent of the DRV as established in paragraphs (c)(7)(iii) and (c)(9) of this section shall be given in a column aligned under the heading "% Daily Value" established in paragraph (d)(6) of this section with the percent expressed to the nearest whole percent for each nutrient declared in the column described in paragraph (d)(7)(i) of this section for which a DRV has been established, except that the percent for protein may be omitted as provided in paragraph (c)(7) of this section. The percent shall be calculated by dividing the actual amount (i.e., before rounding) for each nutrient by the DRV for the nutrient, except that the percent for protein shall be calculated as specified in paragraph (c)(7)(ii) of this section. The numerical value shall be followed by the symbol for percent (i.e., %),

(8) Nutrient information for vitamins and minerals shall be separated from information on other nutrients by a bar and shall be arrayed horizontally (e.g., Vitamin A 4%, Vitamin C 2%, Calcium 15%, Iron 4%) as shown in paragraph (d)(12) of this section, except that when more than four vitamins and minerals are declared, they may be declared vertically with percentages listed under the column headed "% Daily Value."

(9) A footnote, preceded by an asterisk, shall be placed beneath the list of vitamins and minerals and shall be separated from that list by a hairline.

(i) The footnote shall state:

Percent Daily Values are based on a 2,000 calorie diet.

Your daily value may be higher or lower depending on your calorie needs.

	Calories:	2,000	2,500
Total fat	Less than	65 g	80 g
Saturated fat.	Less than	20 g	25 g
Cholesterol	Less than	300 mg	300 mg
Sodium	Less than	2,400 mg	2,400 mg
Total carbohydrate.	.....	300 g	375 g
Dietary fiber	.....	25 g	30 g

(ii) If the percent of Daily Value is given for protein in the Percent of Daily Value column as provided in paragraph (d)(5)(ii) of this section, protein shall be listed under dietary fiber, and the DRV established in paragraph (c)(7)(iii) of this section shall be inserted on the same line in the numeric columns.

(iii) If potassium is declared in the column described in paragraph (d)(5)(i) of this section, potassium shall be listed under sodium and the DRV established in paragraph (c)(9) of this section shall be inserted on the same line in the numeric columns.

(iv) The abbreviations established in paragraph (j)(13)(ii)(B) of this section may be used within the footnote.

(10) Caloric conversion information on a per gram basis for fat, carbohydrate, and protein shall be presented beneath the information required in paragraph (d)(9) and shall be separated from that information by a hairline. This information may be presented horizontally as shown in paragraph (d)(12) of this section (i.e., "Calories per gram: fat 9, carbohydrate 4, protein 4") or vertically in columns.

(11) If the space beneath the information on vitamins and minerals is not adequate to accommodate the information required in paragraphs (d)(9) and (d)(10) of this section, the information required in paragraph (d)(9) may be moved to the right of the column required in paragraph (d)(7)(ii) and set off by a line that distinguishes it and sets it apart from the percent daily value information. The caloric conversion information required in paragraph (d)(10) of this section may be presented beneath either side or along the full length of the nutrition label.

(12) The following sample label illustrates the provisions of paragraph (d) of this section.

BILLING CODE 4160-01-m

Nutrition Facts

Serving Size 1/12 cup (45g)
Servings Per Container 12

Amount Per Serving	Mix	Baked
Calories	190	280
Calories from Fat	45	135
	% Daily Value**	
Total Fat 5g*	**13%**	**36%**
Saturated Fat 2g	**10%**	**13%**
Cholesterol 0mg	**0%**	**23%**
Sodium 300mg	**8%**	**9%**
Total Carbohydrate 34g	**9%**	**9%**
Dietary Fiber 0g	**0%**	**0%**
Sugars 18g		
Protein 2g		
Vitamin A	0%	0%
Vitamin C	0%	0%
Calcium	6%	8%
Iron	2%	4%

*Amount in Mix

**Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

(e) Nutrition information may be presented for two or more forms of the same food (e.g., both "as purchased" and "as prepared") or for common combinations of food as provided for in paragraph (h)(4) of this section, for different units (e.g., slices of bread or per 100 grams) as provided for in paragraph (b) of this section, or for two or more groups for which RDI's are established in paragraph (c)(8)(iv) of this section (e.g., both infants and children less than 4 years of age) as shown in paragraph (e)(5) of this section. When such dual labeling is provided, equal prominence shall be given to both sets of values. Information shall be presented in a format consistent with paragraph (d) of this section, except that:

(1) Following the subheading of "Amount Per Serving," there shall be two or more column headings accurately describing the forms of the same food (e.g., "Mix" and "Baked"), the combinations of food, the units, or the RDI groups that are being declared. The column representing the product as packaged and according to the label serving size based on the reference amount in § 101.12(b) shall be to the left of the numeric columns.

(2) When the dual labeling is presented for two or more forms of the same food, for combinations of food, or for different units, total calories and calories from fat (and calories from saturated fat, when declared) shall be listed in a column and indented as specified in paragraph (d)(5) of this section with quantitative amounts declared in columns aligned under the column headings set forth in paragraph (e)(1) of this section.

(3) Quantitative information by weight required in paragraph (d)(7)(i) of this section shall be specified for the form of the product as packaged and according to the label serving size based on the reference amount in § 101.12(b).

(i) Quantitative information by weight may be included for other forms of the product represented by the additional column(s) either immediately adjacent to the required quantitative information by weight for the product as packaged and according to the label serving size based on the reference amount in § 101.12(b) or as a footnote.

(A) If such additional quantitative information is given immediately adjacent to the required quantitative information, it shall be declared for all nutrients listed and placed immediately following and differentiated from the required quantitative information (e.g., separated by a comma). Such information shall not be put in a separate column.

(B) If such additional quantitative information is given in a footnote, it shall be declared in the same order as the nutrients are listed in the nutrition label. The additional quantitative information may state the total nutrient content of the product identified in the second column or the nutrient amounts added to the product as packaged for only those nutrients that are present in different amounts than the amounts declared in the required quantitative information. The footnote shall clearly identify which amounts are declared. Any subcomponents declared shall be listed parenthetically after principal components (e.g., 1/2 cup skim milk contributes an additional 40 calories, 65 mg sodium, 6 g total carbohydrate (6 g sugars), and 4 g protein).

(ii) Total fat and its quantitative amount by weight shall be followed by an asterisk (or other symbol) (e.g., "Total fat (2 g)*") referring to another asterisk (or symbol) at the bottom of the nutrition label identifying the form(s) of the product for which quantitative information is presented.

(4) Information required in paragraphs (d)(7)(ii) and (d)(8) of this section shall be presented under the subheading "% DAILY VALUE" and in columns directly under the column headings set forth in paragraph (e)(1) of this section.

(5) The following sample label illustrates the provisions of paragraph (e) of this section:

BILLING CODE 4160-01-M

Nutrition Facts

Serving Size 1/2 cup (114g)
Servings Per Container 4

Amount Per Serving

Calories 260 Calories from Fat 120

	% Daily Value*
Total Fat 13g	**20%**
Saturated Fat 5g	**25%**
Cholesterol 30mg	**10%**
Sodium 660mg	**28%**
Total Carbohydrate 31g	**11%**
Dietary Fiber 0g	**0%**
Sugars 5g	
Protein 5g	

Vitamin A 4%	•	Vitamin C 2%
Calcium 15%	•	Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

(f) The declaration of nutrition information may be presented in the simplified format set forth herein when a food product contains insignificant amounts of seven or more of the following: Calories, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron; except that for foods intended for children less than 2 years of age to which § 101.9(j)(5)(i) applies, nutrition information may be presented in the simplified format when a food product contains insignificant amounts of six or more of the following: Calories, total fat, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron.

(1) An "insignificant amount" shall be defined as that amount that allows a declaration of zero in nutrition labeling, except that for total carbohydrate, dietary fiber, and protein, it shall be an amount that allows a declaration of "less than 1 gram."

(2) The simplified format shall include information on the following nutrients:

(i) Total calories, total fat, total carbohydrate, protein, and sodium;

(ii) Calories from fat and any other nutrients identified in paragraph (f)(1) of this section that are present in the food in more than insignificant amounts; and

(iii) Any vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are required to be added as a nutrient supplement to foods for which a standard of identity exists.

(iv) Any vitamins or minerals that are voluntarily added to the food as nutrient supplements.

(3) Other nutrients that are naturally present in the food in more than insignificant amounts may be voluntarily declared as part of the simplified format.

(4) If any nutrients are declared as provided in paragraphs (f)(2)(iii), (f)(2)(iv), or (f)(3) of this section as part of the simplified format, the statement "Not a significant source of _____" (with the blank filled in with the name(s) of any nutrient(s) identified in § 101.9(f) and calories from fat that are present in insignificant amounts) shall be included at the bottom of the nutrition label.

(5) Except as provided for in paragraphs (j)(5) and (j)(13) of this section, nutrient information declared in the simplified format shall be presented in the same manner as specified in paragraphs (d) or (e) of this section, except that the footnote and caloric conversion information required in paragraphs (d)(9) and (d)(10) of this section are not required. When the footnote and caloric conversion information are omitted, an asterisk shall be placed at the bottom of the label followed by the statement "Percent Daily Values are based on a 2,000 calorie diet" and, if the term "Daily Value" is not spelled out in the heading, a statement that "DV" represents "Daily Value."

(g) Compliance with this section shall be determined as follows:

(1) A collection of primary containers or units of the same size, type, and style produced under conditions as nearly uniform as possible, designated by a common container code or marking, or in the absence of any common container code or marking, a day's production, constitutes a "lot."

(2) The sample for nutrient analysis shall consist of a composite of 12 subsamples (consumer units), taken 1 from each of 12 different randomly chosen shipping cases, to be representative of a lot. Unless a particular method of analysis is specified in paragraph (c) of this section, composites shall be analyzed by appropriate methods as given in the "Official Methods of Analysis of the AOAC International," 15th Ed. (1990), which is incorporated by reference in accordance with 5 U.S.C. 552(a) or 1 CFR part 51 or, if no AOAC method is available or appropriate, by other reliable and appropriate analytical procedures. The availability of this incorporation by reference is given in paragraph (c)(7) of this section.

(3) Two classes of nutrients are defined for purposes of compliance:

(i) *Class I.* Added nutrients in fortified or fabricated foods; and

(ii) *Class II.* Naturally occurring (indigenous) nutrients. If any ingredient which contains a naturally occurring (indigenous) nutrient is added to a food, the total amount of such nutrient in the final food product is subject to class II requirements unless the same nutrient is also added.

(4) A food with a label declaration of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium shall be deemed to be misbranded under section 403(a) of the Federal Food, Drug, and Cosmetic Act (the act) unless it meets the following requirements:

(i) *Class I vitamin, mineral, protein, dietary fiber, or potassium.* The nutrient content of the composite is at least equal to the value for that nutrient declared on the label.

(ii) *Class II vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium.* The nutrient content of the composite is at least equal to 80 percent of the value for that nutrient declared on the label.

Provided, That no regulatory action will be based on a determination of a nutrient value that falls below this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved.

(5) A food with a label declaration of calories, sugars, total fat, saturated fat, cholesterol, or sodium shall be deemed to be misbranded under section 403(a) of the act if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label. *Provided,* That no regulatory action will be based on a determination of a nutrient value that falls above this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved.

(6) Reasonable excesses of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium over labeled amounts are acceptable within current good manufacturing practice. Reasonable deficiencies of calories, sugars, total fat, saturated fat, cholesterol, or sodium under labeled amounts are acceptable within current good manufacturing practice.

(7) Compliance will be based on the metric measure specified in the label statement of serving size.

(8) Compliance with the provisions set forth in paragraphs (g)(1) through (g)(6) of this section may be provided by use of an FDA approved data base that has been computed following FDA guideline procedures and where food samples have been handled in accordance with current good manufacturing practice to prevent nutrition loss. FDA approval of a data base shall not be considered granted until the Center for Food Safety and Applied Nutrition has agreed to all aspects of the data base in writing. The approval will be granted where a clear need is presented (e.g., raw produce and seafood). Approvals will be in effect for a limited time, e.g., 10 years, and will be eligible for renewal in the absence of significant changes in agricultural or industry practices. Approval requests shall be submitted in accordance with the provisions of § 10.30 of this chapter. Guidance in the use of data bases may be found in the "FDA Nutrition Labeling Manual—A Guide for Developing and Using Data Bases," available from the Division of Nutrition, Center for Food Safety and Applied

Nutrition (HFF-260), Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

(9) When it is not technologically feasible, or some other circumstance makes it impracticable, for firms to comply with the requirements of this section (e.g., to develop adequate nutrient profiles to comply with the requirements of paragraph (c) of this section), FDA may permit alternative means of compliance or additional exemptions to deal with the situation. Firms in need of such special allowances shall make their request in writing to the Office of Nutrition and Food Sciences (HFF-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

(h) Products with separately packaged ingredients or foods, with assortments of food, or to which other ingredients are added by the user may be labeled as follows:

(1) If a product consists of two or more separately packaged ingredients enclosed in an outer container or of assortments of the same type of food (e.g., assorted nuts or candy mixtures) in the same retail package, nutrition labeling shall be located on the outer container or retail package (as the case may be) to provide information for the consumer at the point of purchase. However, when two or more food products are simply combined together in such a manner that no outer container is used, or no outer label is available, each product shall have its own nutrition information, e.g., two boxes taped together or two cans combined in a clear plastic overwrap. When separately packaged ingredients or assortments of the same type of food are intended to be eaten at the same time, the nutrition information may be specified per serving for each component or as a composite value.

(2) If a product consists of two or more separately packaged foods that are intended to be eaten individually and that are enclosed in an outer container (e.g., variety packs of cereals or snack foods), the nutrition information shall be specified per serving for each food in a location that is clearly visible to the consumer at the point of purchase.

(3) If a package contains a variety of foods, or an assortment of foods, and is in a form intended to be used as a gift, the nutrition labeling shall be in the form required by paragraphs (a) through (f) of this section, but it may be modified as follows:

(i) Nutrition information may be presented on the label of the outer package or in labeling within or attached to the outer package.

(ii) In the absence of a reference amount customarily consumed in § 101.12(b) that is appropriate for the variety or assortment of foods in a gift package, 1 ounce for solid foods, 2 fluid ounces for nonbeverage liquids (e.g., syrups), and 8 fluid ounces for beverages may be used as the standard serving size for purposes of nutrition labeling of foods subject to this paragraph. However, the reference amounts customarily consumed in § 101.12(b) shall be used for purposes of evaluating whether individual foods in a gift package qualify for nutrient content claims or health claims.

(iii) The number of servings per container may be stated as "varied."

(iv) Nutrition information may be provided per serving for individual foods in the package, or, alternatively, as a composite per serving for reasonable categories of foods in the package having similar dietary uses and similar significant nutritional characteristics. Reasonable categories of foods may be used only if accepted by FDA. In determining whether a proposed category is reasonable, FDA will consider whether the values of the characterizing nutrients in the foods proposed to be in the category meet the compliance criteria set forth in paragraphs (g)(3) through (g)(6) of this section. Proposals for such categories may be submitted in writing to the Office of Nutrition and Food Sciences (HFF-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

(v) If a food subject to paragraph (j)(13) of this section because of its small size is contained in a gift package, the food need not be included in the determination of nutrition information under paragraph (h) of this section if it is not specifically listed in a promotional catalogue as being present in the gift package, and:

(A) It is used in small quantities primarily to enhance the appearance of the gift package; or

(B) It is included in the gift package as a free gift or promotional item.

(4) If a food is commonly combined with other ingredients or is cooked or otherwise prepared before eating, and directions for such combination or preparations are provided, another column of figures may be used to declare nutrition information on the basis of the food as consumed in the format required in paragraph (e) of this section (e.g., a dry ready-to-eat cereal may be described with one set of Percent Daily Values for the cereal as sold (e.g., per ounce), and another set for the cereal and milk as suggested in the label (e.g., per ounce of cereal and 1/2 cup of vitamin D fortified skim milk); and a cake mix may be labeled with one set of Percent Daily Values for the dry mix (per serving) and another set for the serving of the final cake when prepared): *Provided*, That, the type and quantity of the other ingredients to be added to the product by the user and the specific method of cooking and other preparation shall be specified prominently on the label.

(i) Except as provided in paragraph (j)(13) of this section, the location of nutrition information on a label shall be in compliance with § 101.2.

(j) The following foods are exempt from this section or are subject to special labeling requirements:

(1)(i) Food offered for sale by a manufacturer, packer, or distributor who has annual gross sales made or business done in sales to consumers that is not more than $500,000 or has annual gross sales made or business done in sales of food to consumers of not more than $50,000, *Provided*, That the food bears no nutrition claims or information on a label or labeling or in advertising.

(ii) For purposes of this paragraph, calculation of the amount of sales shall be based on the most recent 2-year average of business activity. Where firms have been in business less than 2 years, reasonable estimates must indicate that annual sales will not exceed the amounts specified. For foreign firms that ship foods into the United States, the business activities to be included shall be the total amount of food sales, as well as other sales to consumers, by the firm in the United States.

(2) Food products which are:

(i) Served in restaurants;

(ii) Served in other establishments in which food is served for immediate human consumption (e.g., institutional food service establishments, such as schools, hospitals, and cafeterias; transportation carriers, such as trains and airplanes; bakeries, delicatessens, and retail confectionery stores where there are facilities for immediate consumption on the premises; food service vendors, such as lunch wagons, ice cream shops, mall cookie counters, vending machines, and side-walk carts where foods are generally consumed immediately where purchased or while the consumer is walking away, including similar foods sold from convenience stores; and food delivery systems or establishments where ready-to-eat foods are delivered to homes or offices);

(iii) Sold for sale or use only in such facilities; or

(iv) Sold by a distributor who principally sells food to such facilities: *Provided*, That:

(A) This exemption shall not be available for those foods that are manufactured, processed, or repackaged by that distributor for sale to any persons other than restaurants or other establishments that serve food for immediate human consumption, and

(B) The manufacturer of such products is responsible for providing the nutrition information on the products if there is a reasonable possibility that the product will be purchased directly by consumers.

(3) Food products that are:

(i) Of the type of food described in paragraphs (j)(2)(i) and (j)(2)(ii) of this section,

(ii) Ready for human consumption,

(iii) Offered for sale to consumers but not for immediate human consumption,

(iv) Processed and prepared primarily in a retail establishment, and

(v) Not offered for sale outside of that establishment (e.g., ready-to-eat foods that are portioned and packaged on-site and sold by independent delicatessens, bakeries, and retail confectionery stores where there are no facilities for immediate human consumption, by in-store delicatessen, bakery, or candy departments, or at self-service food bars such as salad bars).

(4) Foods that contain insignificant amounts of all of the nutrients and food components required to be included in the declaration of nutrition information under paragraph (c) of this section. An insignificant amount of a nutrient or food component shall be that amount that allows a declaration of zero in nutrition labeling, except that for total carbohydrate, dietary fiber, and protein, it shall be an amount that allows a declaration of "less than 1 gram." Foods that are exempt under this paragraph include coffee beans (whole or ground), tea leaves, plain unsweetened instant coffee and tea, condiment-type dehydrated vegetables, flavor extracts, and food colors.

(5)(i) Foods, other than infant formula, represented or purported to be specifically for infants and children less than 2 years of age shall bear nutrition labeling, except as provided in paragraph (j)(5)(ii) and except that such labeling shall not include calories from fat (paragraph (c)(1)(ii) of this section), calories from saturated fat ((c)(1)(iii)), saturated fat ((c)(2)(i)), polyunsaturated fat ((c)(2)(ii)), monounsaturated fat ((c)(2)(iii)), and cholesterol ((c)(3)).

(ii) Foods, other than infant formula, represented or purported to be specifically for infants and children less than 4 years or age shall bear nutrition labeling, except that such labeling shall not include listings of percent of Daily Value and the footnote required in paragraphs (d)(7), (d)(9), and (d)(10) of this section. Nutrient names and quantitative amounts by weight shall be presented in two separate columns.

(6) Dietary supplements of vitamins and minerals except that the labeling of a dietary supplement of vitamins and minerals in conventional food form, e.g., a breakfast cereal, shall conform to the labeling established in this section.

(7) Infant formula subject to section 412 of the act, as amended, except that such foods shall be labeled in compliance with part 107 of this chapter.

(8) Medical foods as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)). A medical food is a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. A food is subject to this exemption only if:

(i) It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube;

(ii) It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone;

(iii) It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation;

(iv) It is intended to be used under medical supervision; and

(v) It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.

(9) Food products shipped in bulk form that are not for distribution to consumers in such form and that are for use solely in the manufacture of other foods or that are to be processed, labeled, or repacked at a site other than where originally processed or packed.

(10) Raw fruits, vegetables, and fish subject to section 403(q)(4) of the act, except that the labeling of such foods should adhere to guidelines in § 101.45. The term "fish" includes freshwater or marine fin fish, crustaceans, and mollusks, including shellfish, amphibians, and other forms of aquatic animal life.

(11) Packaged single-ingredient products that consist of fish or game meat (i.e., animal products not covered under the Federal Meat Inspection Act or the Poultry Products Inspection Act, such as flesh products from deer, bison, rabbit, quail, wild turkey, or ostrich) subject to this section may provide required nutrition information for a 3-ounce cooked edible portion (i.e., on an "as prepared" basis), except that:

(i) Such products that make claims that are based on values as packaged must provide nutrition information on an as packaged basis, and

(ii) Nutrition information is not required for custom processed fish or game meats.

(12) Game meats (i.e., animal products not covered under the Federal Meat Inspection Act or the Poultry Products Inspection Act, such as flesh products from deer, bison, rabbit, quail, wild turkey, or ostrich) may provide required nutrition information on labeling in accordance with the provisions of paragraph (a)(2) of this section.

(13)(i) Foods in small packages that have a total surface area available to bear labeling of less than 12 square inches, *Provided*, That the labels for these foods bear no nutrition claims or other nutrition information. The manufacturer, packer, or distributor shall provide on the label of packages that qualify for and use this exemption an address or telephone number that a consumer can use to obtain the required nutrition information (e.g., "For nutrition information, call 1–800–123–4567").

(ii) Foods in packages that have a total surface area available to bear labeling of 40 or less square inches may modify the requirements of paragraphs (c) through (f) and (i) of this section by one or more of the following means:

(A) Presenting the required nutrition information in a tabular or, as provided below, linear (i.e., string) fashion rather than in vertical columns if the product has a total surface area available to bear labeling of less than 12 square inches or if the package shape or size cannot accommodate a column display on any label panel. Nutrition information may be given in a linear fashion, only if the label will not accommodate a tabular display, and, in that case, any subcomponents declared shall be listed

parenthetically after principal components (e.g., saturated fat shall be declared in parentheses after total fat).

The following sample label illustrates a tabular display.

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Nutrition Facts

Serv. Size 1/3 cup (56g)
Servings about 3
Calories 80
Fat Cal. 10
*Percent Daily Values (DV) are based on a 2,000 calorie diet.

Amount/serving	% DV*	Amount/serving	% DV*
Total Fat 1g	2%	**Total Carb.** 0g	0%
Sat.Fat 0g	0%	Fiber 0g	0%
Cholest. 10mg	3%	Sugars 0g	
Sodium 200mg	8%	**Protein** 17g	

Vitamin A 0% • Vitamin C 0% • Calcium 0% • Iron 6%

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(B) Using any of the following abbreviations:
Serving size—Serv. size
Servings per container—Servings
Calories from fat—Fat cal
Saturated fat—Sat fat
Cholesterol—Cholest
Total carbohydrate—Total carb
Dietary fiber—Fiber

(C) Omitting the footnote and caloric conversion information required in paragraphs (d)(9) and (d)(10) of this section and placing another asterisk at the bottom of the label followed by the statement "Percent Daily Values are based on a 2,000 calorie diet" and, if the term "Daily Value" is not spelled out in the heading, a statement that "DV" represents "Daily Value."

(D) Presenting the required nutrition information on any label panel.

(14) Shell eggs packaged in a carton that has a top lid designed to conform to the shape of the eggs are exempt from outer carton label requirements where the required nutrition information is clearly presented in no less than 1/16-inch type size immediately beneath the carton lid or in an insert that can be clearly seen when the carton is opened.

(15) The unit containers in a multiunit retail food package where:

(i) The multiunit retail food package labeling contains all nutrition information in accordance with the requirements of this section;

(ii) The unit containers are securely enclosed within and not intended to be separated from the retail package under conditions of retail sale; and

(iii) Each unit container is labeled with the statement "This Unit Not Labeled For Retail Sale" in type size not less than 1/16-inch in height. The word "individual" may be used in lieu of or immediately preceding the word "Retail" in the statement.

(16) Food products sold from bulk containers: *Provided*, That nutrition information required by this section be displayed to consumers either on the labeling of the bulk container plainly in view or in accordance with the provisions of paragraph (a)(2) of this section.

(k) A food labeled under the provisions of this section shall be deemed to be misbranded under sections 201(n) and 403(a) of the act if its label or labeling represents, suggests, or implies:

(1) [Reserved]

(2) That a balanced diet of ordinary foods cannot supply adequate amounts of nutrients.

(3) That the lack of optimum nutritive quality of a food, by reason of the soil on which that food was grown, is or may be responsible for an inadequacy or deficiency in the quality of the daily diet.

(4) That the storage, transportation, processing, or cooking of a food is or may be responsible for an inadequacy or deficiency in the quality of the daily diet.

(5) That the food has dietary properties when such properties are of no significant value or need in human nutrition.

(6) That a natural vitamin in a food is superior to an added or synthetic vitamin or to differentiate in any way between vitamins naturally present from those added.

5. Section 101.100 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 101.100 Food; exemptions from labeling.

* * * * *

(d) Except as provided by paragraphs (e) and (f) of this section, a shipment or other delivery of a food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling requirements of section 403 (c), (e), (g), (h), (i), (k), and (q) of the act if:

* * * * *

6. Appendix B to Part 101 is added to read as follows:

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Appendix B to Part 101

Graphic Enhancements used by the FDA

A.Overall

1. Nutrition Facts Label is boxed with all black or one color type printed on a white or neutral ground.

B. Typeface and size

1. The "Nutrition Facts" label uses 6 point or larger Helvetica Black and/or Helvetica Regular type. In order to fit some formats the typography may be kerned as much as -4, (tighter kerning reduces legibility).
2. Key nutrients & their % Daily Value are set in 8 point Helvetica Black (but "%" should be set in Helvetica Regular).
3. "Nutrition Facts" is set in either Franklin Gothic Heavy or Helvetica Black to fit the width of the label flush left and flush right.
4. "Serving Size" and "Servings per container" are set in 8 point Helvetica Regular with 1 point of leading.
5. The table labels (for example; "Amount per Serving") are set 6 point Helvetica Black.
6. Absolute measures of nutrient content (for example; "1g") and nutrient subgroups are set in 8 point Helvetica Regular with 4 points of leading.
7. Vitamins and minerals are set in 8 point Helvetica Regular, with 4 points of leading, separated by 10 point bullets.
8. All type that appears under vitamins and minerals is set in 6 point Helvetica regular with 1 point of leading.

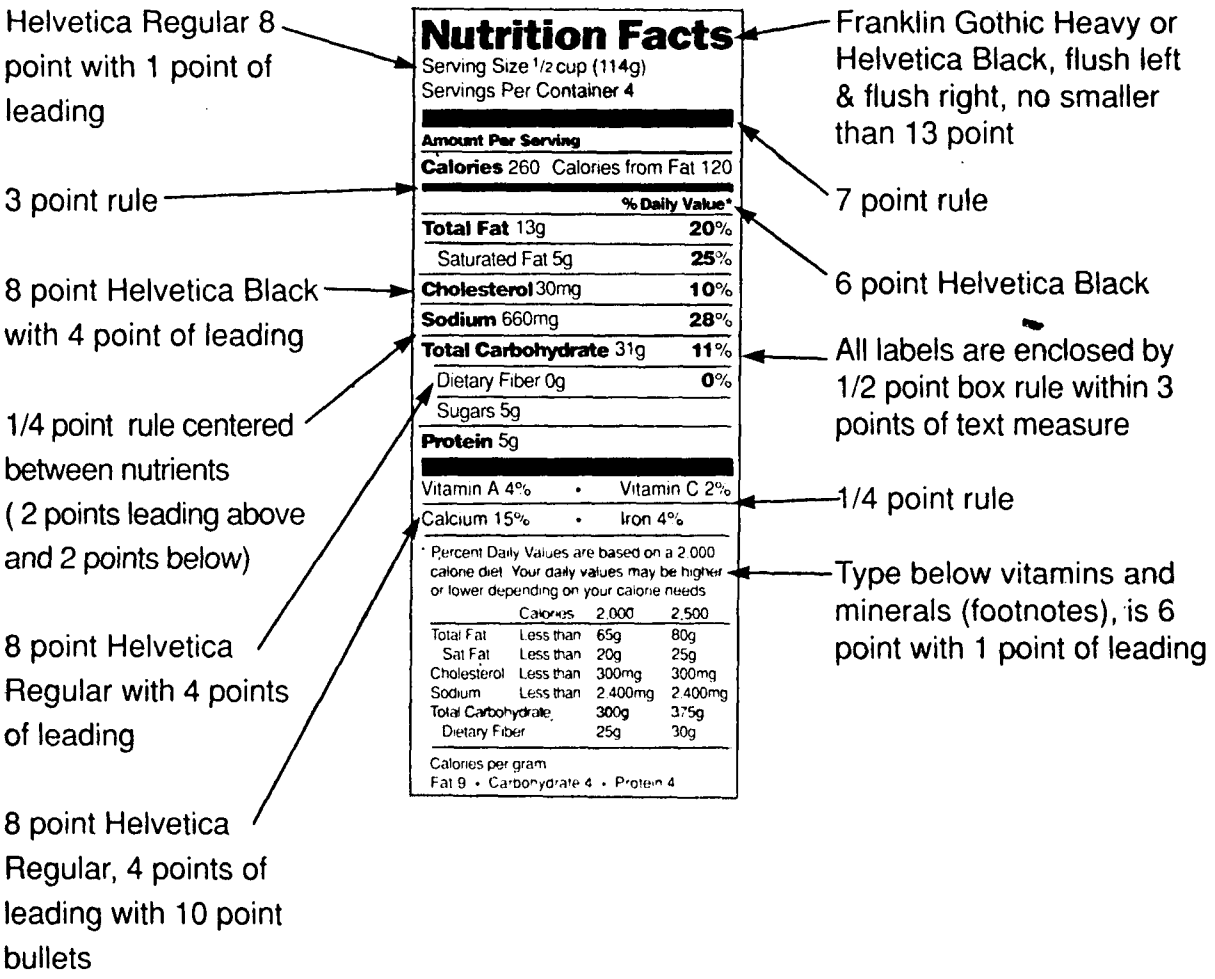
C. Rules

1. A 7 point rule separates large groupings as shown in example. A 3 point rule separates calorie information from the nutrient information.
2. A hairline rule or 1/4 point rule separates individual nutrients, as shown in the example. Descenders should not touch rule. The top half of the label (nutrient information) has 2 points of leading between the type and the rules, the bottom half of the label (footnotes) has 1 point of leading between the type and the rules.

D. Box

1. All labels are enclosed by 1/2 point box rule within 3 points of text measure.

Appendix B to Part 101



BILLING CODE 4160-01-C

Dated: December 17, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

Editorial Note: The following appendixes will not appear in the annual Code of Federal Regulations.

BILLING CODE 4160-01-M

Appendix A:
Shortened Format (See comment 8)—Vegetable Soup

Nutrition Facts

Serving Size 1cup (245g)
Servings Per Container 2

Amount Per Serving

Calories 55 Calories from Fat 20

	% Daily Value*
Total Fat 1g	**2**%
Sodium 800mg	**33**%
Total Carbohydrate 31g	**11**%
Dietary Fiber 4g	**16**%
Sugars 0g	
Protein 2g	

Vitamin A 20% • Vitamin C 4% • Iron 2%

Not a significant source of saturated fat, cholesterol, and calcium.

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

BILLING CODE 4160-01-C

APPENDIX B.—TRUE PROTEIN DIGESTIBILITY VALUE OF COMMON FOODS

Major product group	Subgroup	Product	True digestibility	References
Cereals and grains	Barley	Barley	90	1
	Corn and Corn Products	Corn, Extruded Cereal	62	2
		Corn, Corn Flake	70	2
		Corn, Degerminated Opaque 2	94	2
		Corn, Puffed Cereal	76	2
		Corn, Whole	89	2
		Corn, Whole Opaque 2	92	2
		Corn meal	84	2
	Millet	Millet	79	2
	Oats and Oat products	Oat, Sugared Flakes	67	2
		Oat Flakes	70	2
		Oat, Extruded Oat/Wheat	76	2
		Cereal	89	2
		Oat, Quick Oatmeal	82	2
		Oat, Oatmeal	90	3
		Oats, Rolled	.....	.....
	Rice and Rice Products	Rice	91	2
		Rice, Germ	87	4
		Rice, Brown, Cooked	72	5
		Rice, High Protein	85	2
		Rice, Milled, Cooked	86	6
		Rice, Polished	87	2, 5
		Rice, Crisped Rice Cereal	77	2
		Rice, Flakes	63	2
	Sorghum	Sorghum, Cooked	73	6
	Triticale	Triticale	90	2
	Wheat and Wheat Products	Bread	96	2
		Bread, Coarse, Brown	91	2
		Bread, White	9	2
		Bread, Whole Wheat	92	2
		Wheat, Bran	5	15
		Wheat, Brown, Cooked	93	6
		Wheat Endosperm (Farina)	98	2
		Wheat, Flour, 90% extracted	89	2
		White, Flour, 80% extracted	92	2
		Wheat Germ	81	2
	Wheat and Wheat Products	Wheat Gluten	98	2
		Wheat, Hard Spring	86	2
		Wheat, Meat Analogue	95	2
		Wheat, Puffed Wheat	84	2
		Wheat, Shredded	73	2
		Wheat, Wheaties	80	2
		Wheat, White Flour	97	2
		Wheat, Whole	87	2
		Wheat, Whole, Hot Cereal	85	2
		Wheat, 40% Bran Flakes	69	2
Dairy Products	Casein	Acid-Casein	95	7
		Casein	96	8, 4
		Caseinate	95	7
		Rennet-Casein	94	7
	Cheese	Cheese, Cheddar	99	4
		Cottage, Cheese	99	2
	Lactalbumin	Lactalbumin	94	2
	Milk	Milk Retentate	97	7
		Milk, Skim	94	8
		Milk, Whole	94	2
		Milk, Whole, Powdered	95	2
	Whey	Whey Protein	95	4
Egg and Egg Products		Egg albumen	97	2
		Egg, Flakes	92	2
		Egg, Powdered, Dried	93	4
		Egg, Dried	98	2
		Egg, Powdered Defatted	100	2
		Egg, Scrambled	96	2
		Egg, Spray Dried	92	2
		Egg, Whole, Unprocessed	97	2, 9
Legumes and Oilseed Products	Beans (Mucunoa Spp.)	Beans, Velvet	68	4
	Beans (Phaseolus lunatus)	Beans, Butter	57	4
		Beans, Lima	78	4
	Beans (Phaseolus vulgaris)	Beans, Black	69	4, 10
		Beans, Brown, Cooked	79	11
		Beans, Common	82	4
		Beans, Haricot	71	4
		Beans, Kidney	81	8
		Beans, Natal round Yellow	80	4
		Beans, Pinto, Canned	73	8
		Beans, Red	78	4
		Beans, Seafarer	84	4
		Beans, Snap, Frozen	82	11
		Beans, Spotted Sugar	81	4

APPENDIX B.—TRUE PROTEIN DIGESTIBILITY VALUE OF COMMON FOODS—Continued

Major product group	Subgroup	Product	True digestibility	References
		Beans, Sugar	69	4
		Beans, Sugar, Speckled	78	4
		Beans, White Kidney	78	4
	Beans (Vicia Faba)	Beans, Broad	87	4
		Beans, Faba	86	10
	Cottonseed	Cottonseed	78	2
		Cottonseed Meal	80	4
		Cottonseed, Glandless flour	98	2
	Flaxseed	Flaxseed	85	4
	Lentils (Len culinaris)	Lentils	85	4, 8
	Lupins (Lupinus albus)	Lupine	76	4
	Peanut Products	Peanut Butter	95	2
		Peanut Flour	93	2
		Peanuts	87	4
		Peanut Meal	91	12
	Peas (Cajanus cajan)	Pigeon Peas	76	13
		Pigeon Peas, Raw	41	13
	Peas (Cicer Arietinum)	Chick peas, Canned	88	8
	Peas (Pisum sativum)	Pea Concentrate	94	3
		Peas	88	14
		Peas, Century, Autoclaved	83	10
		Peas, Green, Frozen	94	11
		Peas, Trapper, Autoclaved	84	10
		Peas, Yellow, Cooked	86	11
		Pea Flour	88	10
		Peas, Alaskan Field	88	2
	Peas (Vigna unguiculata)	Cowpeas	79	4
	Sesame	Sesame Seed, Dehulled	82	4
	Soy Products	Soybean	91	4
		Soy Concentrate	95	4
		Soy Flour	84	2
		Soy Flour, Defatted	87	2
		Soy Isolate	96	2
		Soy protein, spun	100	2
	Sunflower	Sunflower Seed	82	2
		Sunflower Seed-Flour	90	2
Meats and Meat Products	Beef	Beef	95	2
		Beef, Low Fat, Ground	91	2
		Beef, Powdered, Defatted	97	2
		Beef, Salami	98	8
		Beef, Stew	89	8
		Beefsteak	97	2
		Beef Tenderloin, Roasted	91	2
	Fish and Seafood	Haddock	100	4
		Sardine	95	4
		Shark	72	4
		Tuna, Canned	90	2
	Luncheon Meats	Canned Frankfurters	97	4
		Chicken, Frankfurters	97	8
		Sausage	94	8
	Pork	Pork Loin and Tenderloin	98	2
	Poultry	Chicken	100	4
		Chicken, Dark Meat	92	4
		Chicken, Light Meat	93	4
		Turkey Breast, Roasted	91	2
Miscellaneous Foods		Macaroni/Cheese, Canned	94	3
Nuts and Nut Products		Cashew	85	4
		Coconut, meal (defatted)	80	4
		Pecan	71	4
Starchy Roots, Tubes		Potato	89	4
Vegetables		Cabbage	88	4
		Kale	85	4
		Rape	85	4
		Mustard	82	4
		Turnip Leaves	86	4
		Mushrooms	90	4

Notes

True digestibility values obtained using adult subjects were considered first followed by data using the rat as the animal model. When more than one value was considered the values were averaged. Data sources:

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Appendix C:
Sweet potatoes, Canned

Nutrition Facts

Serving Size 1/2 cup (95g)
Servings Per Container 4

Amount Per Serving

Calories 90 Calories from Fat 0

	% Daily Value*
Total Fat 0g	**0%**
Saturated Fat 0g	**5%**
Cholesterol 0mg	**0%**
Sodium 55mg	**2%**
Total Carbohydrate 21g	**7%**
Dietary Fiber 2g	**8%**
Sugars 5g	
Protein 2g	

Vitamin A 160% (100% as Beta Carotene)

Vitamin C 40% • Calcium 2% • Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Appendix D

Nutrition Facts

Serving Size 1/2 cup (114g)
Servings Per Container 4

Amount Per Serving	
Calories 260 Calories from Fat 120	
	% Daily Value*
Total Fat 13g	**20%**
Saturated Fat 5g	**25%**
Cholesterol 30mg	**10%**
Sodium 660mg	**28%**
Total Carbohydrate 31g	**11%**
Dietary Fiber 0g	**0%**
Sugars 5g	
Protein 5g	

Vitamin A 4%	•	Vitamin C 2%
Calcium 15%	•	Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Appendix D:
Footnote to side

Nutrition Facts

Serving Size 1/2 cup (114g)
Servings Per Container 4

Amount Per Serving	
Calories 260 Calories from Fat 120	
	% Daily Value*
Total Fat 13g	**20%**
Saturated Fat 5g	**25%**
Cholesterol 30mg	**10%**
Sodium 660mg	**28%**
Total Carbohydrate 31g	**11%**
Dietary Fiber 0g	**0%**
Sugars 5g	
Protein 5g	

Vitamin A 4% • Vitamin C 2%
Calcium 15% • Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Appendix E:
Sample labels with dual declaration

Nutrition Facts

Serving Size 1/12 cup (45g)
Servings Per Container 12

Amount Per Serving	Mix	Baked
Calories	190	280
Calories from Fat	45	135
	% Daily Value**	
Total Fat 5g*	**13%**	**36%**
Saturated Fat 2g	**10%**	**13%**
Cholesterol 0mg	**0%**	**23%**
Sodium 300mg	**8%**	**9%**
Total Carbohydrate 34g	**9%**	**9%**
Dietary Fiber 0g	**0%**	**0%**
Sugars 18g		
Protein 2g		
Vitamin A	0%	0%
Vitamin C	0%	0%
Calcium	6%	8%
Iron	2%	4%

*Amount in Mix

**Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Appendix E:
Dual declaration with footnote of nutrients added by combination of foods

Nutrition Facts

Serving Size 1 cup (35g)
Servings Per Container 10

Amount Per Serving	Cereal	Cereal with 1/2 cup Skim Milk
Calories	130	170
Calories from Fat	0	0
	% Daily Value**	
Total Fat 0g*	**0%**	**0%**
Saturated Fat 0g	**0%**	**0%**
Cholesterol 0mg	**0%**	**0%**
Sodium 200mg	**8%**	**11%**
Total Carbohydrate 30g	**10%**	**12%**
Dietary Fiber 4g	**16%**	**16%**
Sugars 18g		
Protein 3g		
Vitamin A	25%	25%
Vitamin C	25%	25%
Calcium	0%	15%
Iron	10%	10%

*Amount in Cereal. One half cup skim milk contributes an additional 40 calories, 65 mg sodium, 6g total carbohydrate (6 g sugars), and 4g protein.

**Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Appendix F:
Simplified format (Vegetable oil)

Nutrition Facts

Serving Size 1 Tbsp (14g)
Servings Per Container 64

Amount Per Serving	
Calories 130 Calories from Fat 130	
	% Daily Value*
Total Fat 14g	**22%**
Saturated Fat 2g	**10%**
Polyunsaturated Fat 4g	
Monounsaturated Fat 8g	
Sodium 0mg	**0%**
Total Carbohydrate 0g	**0%**
Protein 0g	

Not a significant source of cholesterol, dietary fiber, sugars, vitamin A, vitamin C, calcium, and iron.

* Percent Daily Values are based on a 2,000 calorie diet.

Appendix F:
Simplified format (Soft Drink)

Nutrition Facts

Serving Size 1 can (240 ml)

Amount Per Serving	
Calories 145	
	% Daily Value*
Total Fat 0g	**0%**
Sodium 20mg	**1%**
Total Carbohydrate 36g	**12%**
Sugars 36 g	
Protein 0g	**0%**

* Percent Daily Values are based on a 2,000 calorie diet.

Appendix G:

Format for same food represented to be specifically for children less than 2 years of age (Fruit Dessert)

Nutrition Facts

Serving Size 1 jar (140g)
Servings Per Container 1

Amount Per Serving	
Calories 110	
	Amount
Total Fat	**0g**
Sodium	**10mg**
Total Carbohydrate	**27g**
Dietary Fiber	**4g**
Sugars	**18g**
Protein	**0g**

Vitamin A 6%	•	Vitamin C 45%
Calcium 2%	•	Iron 2%

Appendix G:
Format for foods for children less than 4 years of age (Fruit Dessert)

Nutrition Facts

Serving Size 1 jar (140g)
Servings Per Container 1

Amount Per Serving

Calories 110 Calories from Fat 0

	Amount
Total Fat	**0g**
Saturated Fat	**0g**
Cholesterol	**0mg**
Sodium	**10mg**
Total Carbohydrate	**27g**
Dietary Fiber	**4g**
Sugars	**18g**
Protein	**0g**

Vitamin A 6%	•	Vitamin C 45%
Calcium 2%	•	Iron 2%

Appendix H:
Tabular Display

Nutrition Facts

Serv. Size 1/3 cup (56g)
Servings about 3
Calories 80
Fat Cal. 10
*Percent Daily Values (DV) are based on a 2,000 calorie diet.

Amount/serving	% DV*	Amount/serving	% DV*
Total Fat 1g	2%	**Total Carb.** 0g	0%
Sat.Fat 0g	0%	Fiber 0g	0%
Cholest. 10mg	3%	Sugars 0g	
Sodium 200mg	8%	**Protein** 17g	

Vitamin A 0% • Vitamin C 0% • Calcium 0% • Iron 6%

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BILLING CODE 4160-01-C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 101 and 104

[Docket No. 90N-0134]

RIN 0905-AD08

Food Labeling; Reference Daily Intakes and Daily Reference Values

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to establish two sets of label reference values, Reference Daily Intakes (RDI's) and Daily Reference Values (DRV's), for use in declaring the nutrient content of a food on its label or labeling. FDA intends to use these two sets of values as a single set of label reference values known as the Daily Value, which will assist consumers in understanding the relative significance of the information about the amount of certain nutrients in a food in the context of a total daily diet. It will also assist consumers in comparing the nutritional values of food products.

EFFECTIVE DATE: May 8, 1994.

FOR FURTHER INFORMATION CONTACT: Christine Lewis, Center for Food Safety and Applied Nutrition (HFS-165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5588.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 19, 1990 (55 FR 29476), FDA published a proposed rule entitled "Food Labeling; Reference Daily Intakes and Daily Reference Values" (the July 1990 proposal) to amend its food labeling regulations by revising and expanding label reference values for nutrients in foods. In the **Federal Register** of November 27, 1991 (56 FR 60366, and corrected at 57 FR 8178, March 6, 1992), FDA issued a document entitled: "Food Labeling: Reference Daily Intakes and Daily Reference Values; Mandatory Status of Nutrition Labeling and Nutrient Content Revision" (hereinafter referred to as the "supplementary proposal") to supplement and to republish, in modified form, the July 1990 proposal. The agency proposed to: (1) Replace the current label reference values known as "U.S. Recommended Daily Allowances" (U.S. RDA's) with RDI's; (2) provide RDI's for five groups: adults and children 4 or more years of age, children less than 4 years of age, infants, pregnant women, and lactating women; (3) establish RDI's for protein and 26 vitamins and minerals for all five groups; and (4) establish DRV's for adults and children 4 or more years of age for eight nutrients and food components considered important to the maintenance of good health. FDA requested comments on the proposed regulation. Interested persons were given until February 25, 1992, to comment.

FDA received approximately 800 responses to the July 1990 proposal and approximately 700 responses to the supplementary proposal, each of which contained one or more comments, from trade and retail associations, government organizations, retailers, consumer groups, State groups, private organizations, professional societies, and universities. Many comments suggested modification and revision of various provisions of the proposal. A summary of the suggested changes and the agency's responses follows.

On October 6, 1992, Congress passed the Dietary Supplement Act of 1992 (hereinafter referred to as the "DS Act" that, in section 203, instructed FDA to not promulgate regulations that require the use of, or are based upon, recommended daily allowances of vitamins or minerals before November 8, 1993, (other than regulations establishing the United States recommended daily allowances specified in 21 CFR 101.9(c)(7)(iv) as in effect on October 6, 1992).

II. Authority for New Label Reference Values

A. RDI's: Revision of U.S. RDA's

1. Several comments suggested that the change from the current label reference values, the U.S. RDA's, to the proposed new label reference values, the RDI's, was not mandated by the Nutrition Labeling and Education Act of 1990 (Pub. L. 101-535) (the 1990 amendments), and that retaining the U.S. RDA's is not inconsistent with the amendments.

FDA agrees that the 1990 amendments do not require that the U.S. RDA's be changed. The agency points out, however, that section (2)(b)(1)(A) of the 1990 amendments (21 U.S.C. 343 note) does require that the required nutrition label information be conveyed in a manner that enables the public to readily observe and comprehend the information and to understand its relative significance in the context of a total daily diet. Such information should be consistent with current scientific knowledge about nutrients and health.

Over the last 20 years, there have been significant advances in scientific knowledge with respect to essential nutrient requirements. In 1989, the National Academy of Sciences (NAS) updated the Recommended Dietary Allowances (RDA's)—the basis for label reference values derived by the agency—to include for the first time RDA values for vitamin K and selenium and to make significant revisions in the allowances for several nutrients, including vitamin B_6, folate (folic acid), vitamin B_{12}, magnesium, iron, and zinc. In addition, scientific advances permitted NAS to substantively revise values for the listing known as "Estimated Safe and Adequate Daily Dietary Intakes" (ESADDI's). The ESADDI's published in 1989 include revised values for three nutrients (biotin, pantothenic acid, and copper) for which FDA established U.S. RDA's in 1973 as well as new values for manganese, fluoride, chromium, and molybdenum.

Based on these considerable changes in scientific knowledge, FDA tentatively determined that it was appropriate to revise the current U.S. RDA's to be more consistent with newer data on nutrient allowances. FDA attempted in this food labeling initiative to base its actions on the most current scientific and public health knowledge. Continuing to base label reference values on a 1968 standard would be inconsistent with such an approach and would not appropriately assist consumers in understanding the nutrition label information relative to a total daily diet. However, based on the provisions of the DS Act, the agency is, in this rulemaking, retaining the current label reference values, the U.S. RDA's as established in 21 CFR 101.9(c)(7)(iv). As discussed in section III below, the terminology used to designate label reference values for vitamins and minerals is being changed however.

The label reference values in current § 101.9(c)(7)(iv) will be referred to, in this document and in companion documents published elsewhere in this issue of the **Federal Register**, as "Reference Daily Intakes" (RDI's). As specified by the DS Act, the agency will promulgate final regulations on label reference values for vitamins and minerals after November 8, 1993. The agency will consider any further information submitted or obtained in the interim in reaching a decision on the form and substance of such final regulations.

B. DRV's: New Label Reference Values for Nutrients of Public Health Concern

2. A few comments suggested that establishing DRV's was beyond the authority granted by the 1990 amendments.

The majority of comments supported the concept of establishing a DRV. These comments were provided by consumers, health professionals, and trade representatives. Several comments specifically highlighted the DRV's as an invaluable addition to nutrition labeling, as a labeling component that is important to the idea of the relative contribution of a food to the total day's recommended amount of a nutrient, and as a way to decrease confusion among consumers.

FDA disagrees that the establishment of DRV's is inconsistent with the 1990 amendments. The agency proposed this new set of label reference values in 1990 in an attempt to address current concerns about information on food components that have an important bearing on diet and health. With the passage of the 1990 amendments, the agency also recognized that these values respond to the directive in the legislation that the information required in the nutrition label be conveyed to the public in a manner that enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet (section 2(b)(1)(A) of the 1990 amendments).

FDA does not believe that merely listing the quantitative amount of nutrients such as fat and fiber on the nutrition label will adequately allow consumers to understand the significance of the amount of the nutrient in the food in the context of the total daily diet or to understand the nutrition information pertaining to that food in relation to recommended daily intakes of the food component. FDA found in focus group discussions that it conducted as part of its research on label format that many persons could not specify the recommended intakes for nutrients such as sodium, even when they indicated that the nutrient was important to their health and were concerned about their intake of the nutrient (Ref. 29).

Moreover, contrary to the assertion in some of the comments, the use of DRV's was clearly contemplated by Congress. In discussing section 2(b)(1)(A) of the 1990 amendments, the House report states:

> In order to present nutrition information in a manner that facilitates the public's understanding, the Secretary may choose among a variety of options. For example, one way that this could be accomplished would be to include information about the recommended daily intake on the label.

(Ref. 19, p. 18)

Therefore, for the foregoing reasons and consistent with the majority of the comments, FDA concludes that DRV's provide an appropriate approach to accomplishing the statutory mandate and are fully consistent with the authority extended to the agency by the 1990 amendments. Significantly, consumers are becoming more aware of diet/health interrelationships and have expressed growing interest in the inclusion of information about food components on labels to help them determine how individual foods fit within general recommendations for a total daily diet. Additionally, "Healthy People 2000: National Health Promotion and Disease Prevention Objectives" (Ref. 30) proposes that there be an increase in nutrition labeling that provides information to facilitate choosing foods consistent with the Dietary Guidelines for Americans published jointly by the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (DHHS). The DRV's will be an important tool for this purpose.

III. RDI'S: Label Reference Values for Vitamins and Minerals

A. Terminology

3. Several comments expressed concerns about consumer confusion if the more familiar U.S. RDA term was replaced with a new term. These comments generally suggested that the term "U.S. RDA" be retained and used on the label in order to reduce consumer confusion. One comment argued that while the agency asserts that the term "U.S. RDA" is too confusing, FDA cited no evidence of this confusion.

A number of other comments supported eliminating the term "U.S. RDA." One health professional stated that even professionals fail to make the distinction between the RDA established by NAS and the U.S. RDA. A food company stated that it frequently encountered expressions of confusion from consumers and professionals alike over the difference between the U.S. RDA and the NAS RDA. An association of nutrition educators agreed that a change in terminology is needed in order to reduce consumer confusion surrounding the distinction between RDA's and U.S. RDA's. Several comments specifically supported the term "RDI." One comment stated that the use of terminology that differentiates between reference standards used for nutrition labeling and the RDA established by NAS should be beneficial to the consumer.

In 1973, FDA created label reference values known as "U.S. RDA's" and based them on the "Recommended Dietary Allowances," 7th ed., 1968 (the NAS RDA publication) (Ref. 27). As stated in the proposal for this final rule, FDA believes that the term "U.S. RDA" can easily be confused with "RDA," and that this confusion presents difficulties both in consumer education and professional communication (55 FR 29476 at 29478). The comments received have supported the need for a change in terminology, and FDA agrees that because of the potential for confusion a change in terminology is appropriate. FDA notes that in the comments submitted in response to this proposal, the agency found numerous examples of confusion and inappropriate interchange concerning the two terms.

Additionally, the agency advises that consumers will not be confused by the change from U.S. RDA to RDI because the term will not appear on the food label. The RDI's, which refer to label reference values for vitamins and minerals only, will not be used on the food label because a new more comprehensive term will be used, a term that includes label reference values for DRV's as well as RDI's. The provision for a single term ("Daily Value") is discussed in more detail in a companion document entitled "Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision" (hereinafter referred to as "Mandatory Nutrition Labeling final rule"), published elsewhere in this issue of the **Federal Register**.

As discussed in this companion document, the decision to use a single term is based on the fact that the nutrition label will contain label reference values for nutrients other than those with NAS RDA's (e.g., total fat). Clearly, the term "RDI" cannot be used to generally refer to all the new label reference values because it implies that all values are based on the NAS RDA. In fact, less than half of the mandatory components of the nutrition label will be nutrients with a NAS RDA. The agency also believes that it would be needlessly confusing to consumers if the two terms were used on the food label. Consumers are expected to perceive the label reference values as a single overall set of values. Therefore, to reduce consumer confusion, FDA has decided to choose a new term to denote the combined set of label reference values, a term that refers to both RDI's and DRV's.

The distinction between RDI and DRV nutrients remains necessary for regulatory purposes because the values were derived from separate sources and because these nutrients play different roles under the imitation and substitute food regulations. However, there is no need to make consumers aware of the regulatory distinction between RDI and DRV. Rather, educational efforts will focus on the overall set of label reference values.

4. Several comments suggested that FDA delay selecting terminology for the food label until consumer research can be completed.

While FDA supports and recognizes the value of consumer research, the time constraints placed on the agency by the 1990 amendments and the clear need to provide for the label terminology at the time of final rules, preclude the possibility of extensive consumer research. The terminology specified in these final rules derives from available information.

During the Fall of 1990, FDA conducted focus group research that included some discussions of terminology (Ref. 29). The sessions suggested that the term for the overall label reference value (proposed as "Daily Value") could be problematic, yet better terms for this or any other label reference values did not emerge during these sessions. The agency requested in the supplementary proposal (56 FR 60366) that persons submit available research, information, or suggestions concerning terminology. FDA has reviewed the relevant comments and they are discussed in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the **Federal Register**. Based on these comments, as explained in the Mandatory Nutrition Labeling document, FDA has decided to use the term "Daily Value" to refer to the combined set of label reference values.

5. Two comments suggested that the proposed term "RDI" created consumer confusion by continuing to use the letters R and D in some combination, and that "RDI" was too similar to "U.S. RDA" and "RDA." Another comment suggested that to avoid confusion with the previous U.S. RDA terminology, the term "recommended" be retained and used instead of the term "reference."

FDA acknowledges that the inclusion of the letters R and D in RDI may have the potential to cause consumer confusion relative to U.S. RDA. However, because the term will not be used either on the food label or in most consumer education programs, the agency rejects this argument as a basis to abandon a term that accurately reflects the fact that the value it denotes represents a point of reference rather than a specific recommended intake level for individuals. Therefore, FDA has retained the term "RDI" to denote those nutrients whose label reference values have been derived from the NAS RDA's and ESADDI's.

6. One comment requested that FDA work with the European Economic Community and Codex Alimentarius to establish compatible nomenclature whenever possible.

FDA agrees with this suggestion and will, in its ongoing labeling activities, attempt to harmonize with international terminology as much as possible. However, within the time constraints of the 1990 amendments, the agency finds that it must make a unilateral decision concerning terminology.

B. Use of the 1989 NAS RDA's as the Basis for Label Reference Values

In 1973, FDA created label reference values known as U.S. RDA's and based them on the 7th edition of the NAS RDA publication (Ref. 27). At that time, comments supported the use of a single set of values derived from the NAS RDA's. In the July 1990 proposal (55 FR 29476) and again in the supplementary proposal (56 FR 60366), FDA proposed to revise the U.S. RDA's using the 1989 NAS RDA's (Ref. 26). This section responds to the comments that addressed the continued use of the NAS RDA's as the basis for developing label reference values for vitamins and minerals, as well as the appropriateness of using the most current NAS RDA's (i.e., the 10th edition of the NAS RDA publication (1989)), for this purpose.

7. The majority of comments on this topic, primarily from health professionals and the food industry, supported the continued use of the NAS RDA's as the basis for developing label reference values for vitamins and minerals. These comments also supported the desirability of updating the current label reference values (U.S. RDA's) to be consistent with the most recent edition (i.e., 1989) of the NAS RDA's. Numerous comments stated that revisions to the values were long overdue given the fact that changes had not been made by FDA since it developed the label reference values in 1973 based on the 1968 NAS RDA's. Comments urged FDA to continue to review and update label reference values as advances in scientific data lead to significant changes in the NAS RDA's. One comment requested that FDA establish an official mechanism in the final rule to provide for regular updates of label reference values.

FDA tentatively agrees with the appropriateness of continuing to rely on the NAS RDA's as the basis for label reference values. Strong and uniform support was provided for the use of NAS RDA's during the initial development of label reference values in 1972. As evidenced by the comments to the current proposal, this support remains. The agency believes that these established nutrient allowances remain the most widely accepted and respected source of information on human nutrient requirements and recommended intakes. FDA also notes that the preface to the 1989 edition of the NAS RDA's (Ref. 26) states that the RDA's reflect a concurrence of scientific opinion and will be appropriate for use by governmental and private agencies as a basis for developing nutrition programs and policies pertaining to public health. In general, the comments submitted in this rulemaking agreed with this statement. FDA therefore, has tentatively concluded that the label reference values (formerly known as U.S. RDA's, now RDI's) should be based on the 1989 NAS RDA's. However, based on the provisions of the DS Act and as discussed above, the agency is, for the time being retaining the current label reference values as established in § 101.9(c)(7)(iv) and will reach a final decision on the issue of the appropriate reference values for vitamins and minerals following the provisions of the DS Act.

8. One comment suggested that the agency's reliance on the NAS RDA values raises questions under the Administrative Procedure Act. According to this comment, the NAS RDA report has been developed under closed processes and thus the use of such reports may not be appropriate for rulemaking. Another comment submitted by a health professional on behalf of 40 other health professionals suggested that any future replacement of the labeling standard should be developed by the nutrition and public health community, through an open and scientifically sound process conducted by FDA, USDA, and other relevant Federal agencies.

FDA does not agree with the comment that use of the NAS RDA's as the basis for the RDI's is inconsistent with the requirements of the Administrative Procedure Act. The NAS RDA's were developed under a National Institutes of Health (NIH) contract and are based on nutrient intake measurements, nutrient balance studies, experimental intake studies, biochemical measurements, epidemiological observations of nutrient status, and extrapolation of data from animal experiments. Furthermore, as

part of the contract, public meetings were held which afforded opportunity for public input into the development of the NAS RDA's. Additionally, the NAS subjected the draft of the RDA publication to outside review by qualified experts.

More importantly, while the NAS RDA's served as the starting point for the RDI's, FDA developed its proposal based on its review of the NAS RDA's, its views on the relevant science, and its tentative conclusions about how to turn the NAS RDA's into RDI's. Moreover, the agency subjected its proposed approach to public comment (55 FR 29476 and 56 FR 60366). In reviewing the comments that it received, FDA was open to any evidence that values other than those derived from the NAS RDA's would provide a more appropriate starting point in developing values that will place the information required to appear on the nutrition label into the context of a total daily diet. No such evidence was submitted. Thus, FDA tentatively finds that the NAS RDA's provide a scientifically valid starting point from which to develop the RDI's. As stated above, FDA will reach a final decision on the appropriate reference values for vitamins and minerals in accordance with the DS Act.

9. One comment suggested that the NAS RDA's are of questionable value for developing RDI's because NAS RDA's are reflective of diets that people actually eat without showing signs of deficiency, rather than being based on the recommended diets that people should eat according to government authorities. Several comments suggested that the NAS RDA's are designed to avoid deficiency diseases and are not the optimal levels to prevent chronic diseases. A few comments suggested that the NAS RDA's (and resulting label reference values) are inconsistent with current dietary guidance.

As stated in the "Summary" section of the 10th edition of the NAS RDA publication (Ref. 26), the NAS RDA's are based not only on data from nutrient intake measurements but also on information from nutrient balance studies, experimental intake studies, biochemical measurements, epidemiological observations of nutrient status, and extrapolation of data from animal experiments. The NAS RDA's reflect scientific judgment on nutrient allowances for the maintenance of good health. Their purpose is not just to prevent nutrient deficiency but also to meet nutrient needs for good health (Ref. 26).

Available government reports have stressed the importance of healthy dietary patterns and increased consumption of certain food categories and food components rather than quantitative recommendations for intake, especially for vitamins and minerals (Refs. 2, 3, and 5). FDA is not aware of any Federal government-issued quantitative recommendations for the general public for a vitamin or mineral that surpasses the levels specified by the NAS RDA's with the exception of 1,500 milligrams (mg) calcium for postmenopausal women suggested as a result of a 1984 consensus conference sponsored by NIH (Ref. 31) and, very recently, a PHS recommendation that women of childbearing age consume 400 µg/day of folate (Ref. 40). NIH republished the report of this conference in 1986 with the following caveat: "It has not yet been proven by convincing scientific evidence that a high calcium intake will prevent osteoporosis" (Ref. 81). This qualification reflected the results of studies that failed to show that calcium intakes above the NAS RDA slowed bone loss in postmenopausal women (Refs. 81 through 84).

Furthermore, the major consensus report Diet and Health (Ref. 3), which is an important summary of the current science on the relationship between diet and chronic disease, does not offer quantitative intakes for vitamins and minerals for the purpose of reducing the risk of chronic disease. Instead, it states that it is advisable to use the NAS RDA's in combination with the dietary recommendations in planning optimal diets to attain maximal benefit. This view is echoed in the 10th edition of the NAS RDA publication (Ref. 26), which states that the RDA's and the recommendations specified in Diet and Health should be considered together in planning appropriate diets.

Therefore, FDA concludes that the NAS RDA's are consistent with, as well as necessary for, implementation of current dietary recommendations. As such, NAS RDA's can be considered to be an appropriate basis for developing label reference values (i.e., RDI's) for nutrition labeling of foods.

10. Two comments stated that while it is reasonable for FDA to begin to develop new label reference values based on the most current NAS RDA's, FDA should not necessarily limit label reference values to only those values derived from the NAS RDA's because the most current NAS RDA's are derived from data available 3 or more years ago. Therefore, these comments suggested that rather than adopting the 1989 NAS RDA's as the sole basis for setting label reference values for vitamins and minerals, FDA should consider the totality of evidence for each nutrient. Another comment suggested that FDA, as a well-qualified, scientifically-based agency, should conduct its own reviews, if for no other reason than to be sure that the latest data are encompassed in its rulemaking.

FDA is aware that it is desirable to base label reference values on the most current scientific data. However, the existence of data from recently completed or ongoing studies does not necessarily mean that there is scientific agreement or consensus that these data require changes in the NAS RDA, or that these data render the NAS RDA invalid. FDA believes that, should scientific consensus shift or compelling evidence of a need for change in the RDI's be presented to the agency, its rulemaking procedures are sufficiently flexible to allow for timely and appropriate changes to label reference values.

In this rulemaking, FDA tentatively concludes that the NAS RDA's provide an appropriate starting point for the values that it is adopting. FDA will reach a final decision in this matter in accordance with the provisions of the DS Act.

11. One comment from a consumer organization suggested that 1989 NAS RDA values for certain nutrients (vitamin D, vitamin B_{12}, and vitamin B_6) are too low for older persons, and that this, in turn, results in label reference values that are too low. The comment urged FDA to consider basing the reference values for certain nutrients on the NAS RDA's in the 1980 edition which are higher than the 1989 NAS RDA's, and thus, according to the comment, provide greater protection to older citizens. Furthermore, two comments specifically expressed concern for the nutriture of the elderly relative to the 1989 NAS RDA's for vitamin B_{12} because these values are lower than the 1980 NAS RDA's. The comments suggested that FDA retain the current U.S. RDA value of 6 micrograms (µg) rather than adopting the 1989 NAS RDA's as the basis for the RDI's.

FDA does not agree that it is necessary to use the 1980 rather than the 1989 NAS RDA's for certain nutrients because of nutritional risk relative to older persons. The comment provided no specific evidence to support the statement that the 1989 values are too low for this segment of the population. FDA notes that the discussion provided in the 1989 NAS RDA publication clearly reveals that the development of the NAS RDA's took into consideration available evidence on nutrient levels needed by the elderly.

FDA further notes that the 1980 NAS RDA for vitamin D for persons 51 or more years of age is the same as the

1989 NAS RDA for vitamin D. While the 1989 NAS RDA's for vitamins B_1 and B_6 are lower, they are the result of a systematic lowering for all persons, not just those over 51 years of age. The 1989 NAS RDA publication cites decisions on the desirability of maintaining a substantial body pool of the vitamin as the reason for the change for vitamin B_{12} relative to 1980 levels, and the need to correct the figure for mg per gram (g) of protein as the basis for the change in vitamin B_6. Thus, FDA finds that this comment does not provide any basis for changing the agency's approach in calculating the RDI's.

Finally, FDA does not agree that concerns for vitamin B_{12} nutriture among the elderly require that the agency retain the U.S. RDA value for vitamin B_{12} (which is based on the 1968 NAS RDA's). FDA notes that the discussion in the 1989 NAS RDA publication (Ref. 26) clearly states that the NAS RDA's are based on consideration of the available evidence on the nutrient needs of older persons. In fact, an allowance is specified for persons 51 or more years of age.

Furthermore, the discussion on vitamin B_{12} in the NAS RDA publication (Ref. 26) specifically addresses the issue of vitamin B_{12} nutriture and the elderly. The text states that the results of various surveys have shown that although serum vitamin B_{12} levels decline in the elderly, they tend to remain in the normal range. The evidence suggests that the decline in the serum level is the result of the gradual appearance among the elderly of vitamin B_{12} malabsorption. As stated in the NAS RDA report (Ref. 26), such malabsorption would require injection of vitamin B_{12}, rather than an increase in the allowance or, by implication, the label reference value. Therefore, the agency's tentative view is that the need for an increased RDI relative to the issues of malabsorption cannot be supported.

However, based on the provisions of the DS Act, the agency is, for the time being, retaining the current label reference values as established in current § 101.9(c)(7)(iv) and will reach a final decision on this issue following the provisions of the DS Act.

C. Use of a Population-Adjusted Mean of the NAS RDA's to Derive RDI's for Vitamins and Minerals

The NAS RDA for a vitamin or mineral is established for each of approximately 18 age and sex categories. When FDA created the label reference values known as U.S. RDA's in 1973, it concluded that it was most practical to develop a single label reference value for each nutrient for the purposes of food labeling. Generally, the agency selected the highest NAS RDA value (for persons 4 or more years of age excluding pregnant and lactating women) to serve as the U.S. RDA. In July of 1990 and again in November of 1991, FDA proposed to replace the approach of generally selecting the highest NAS RDA value with an approach that averages the NAS RDA values for the various age/sex categories and adjusts the average for differences in population size of the age/sex groups. This section deals with the comments that addressed the proposed change in approach used to calculate label reference values for those vitamins and minerals based on NAS RDA's.

The use of a population-adjusted average (or mean) of NAS RDA's was the major issue addressed by many commenting on the proposal. Several health professional groups and food industry representatives supported the use of an averaged value as the label reference values for vitamins and minerals. However, the majority of comments urged FDA to abandon the averaging approach and to continue to use the approach of selecting the highest NAS RDA value as the label reference value. A wide range of persons submitted comments supporting this view, including health professionals, industry representatives, and consumers. Many of the comments from consumers were variations of a form letter that opposed the change but did not provide a substantive rationale for the position expressed.

12. A few comments opposing use of averaged values raised the concern that lower label reference values would downgrade the nutritional quality of fortified and substitute foods. Some comments asserted that a change in label reference values would affect FDA food fortification practices or the nutrient content of food assistance programs. Other comments expressed concern that the approach changed the label reference values by as much as 80 percent.

The agency notes that many comments concluded that the difference (i.e., lower values) between the current label reference values (U.S. RDA's) and the proposed label reference values (RDI's) could be attributed solely to the change in the approach used to calculate the values. The comments were incorrect. The proposed approach lowered the label reference values for vitamins and minerals by an average of about 14 percent compared to values that would have been derived if the agency had used the approach of selecting the highest 1989 NAS RDA value, i.e., the traditional approach with the most recent NAS RDA values. The remaining differences are the result of changes in the NAS RDA values from 1968 to 1989. In the 10th edition of the NAS RDA publication, NAS lowered several of its RDA values compared to the 1980 or earlier NAS RDA values to reflect new evidence in nutrition science and advances in analytical methodology. Thus, regardless of which approach had been used with the 1989 NAS RDA's—either the population adjusted mean approach or the approach of selecting the highest NAS RDA value—the resulting revised label reference values would be lower when compared to the existing U.S. RDA's.

FDA further advises that label reference values are not used in the agency's policies on nutrient fortification. Some foods must be fortified to meet standards of identity, nutrition quality guidelines, substitute food regulations, or infant formula regulations. Moreover, FDA's guidelines on food fortification (§ 104.20 (21 CFR 104.20)) recommend that nutrients be added on the basis of specific quantities for a given amount of food. The levels are based on the needs of those segments of the population that are at risk of deficiency of those nutrients and not on the U.S. RDA's.

FDA's fortification policy states that traditional foods will be fortified if there is a public health need, or if nutrients need to be restored to a particular food, for example, if they are depleted during processing. Fortification of foods not covered by this policy is at the discretion of the manufacturer. The agency acknowledges that it is common practice for some manufacturers to fortify to a specific percentage of the label reference value (e.g., 25 percent). To the extent that this practice is continued, nutrient levels in some foods could be affected by changes in label reference values. However, this practice does not derive in any way from FDA regulations.

FDA also advises that the current label reference values (U.S. RDA's) have never served as standards for food packages or meal patterns for government feeding programs such as the Food Stamp Program, the Special Supplemental Food Program for Women, Infants and Children (WIC), or the National School Lunch Program and other child-feeding programs. There is one reference to U.S. RDA's in the regulations governing the National School Lunch Program, but it is merely used to determine whether certain foods—such as some snack food items that do not contain meaningful levels of nutrients—can be sold near or in school

cafeterias in competition with the school lunch program (7 CFR 210.11). The food packages and meal patterns used by these programs are based on the specific NAS RDA for each program's targeted group or include foods that contain required amounts of nutrients per unit. Thus, much of the comment that opposed the use of the averaging approach was significantly misinformed in several important respects.

13. The most frequent concern expressed in the comments that opposed the averaging approach was that the approach resulted in a value that was too low for at least half of the population, and that these lower values will result in suboptimal nutrient intakes. Many commented that consumers should be assured that if they meet 100 percent of the label reference value, they are meeting or exceeding their own individual allowances. Some were concerned that for certain nutrients, such as calcium, for which health authorities are emphasizing maximum intakes within a target population group, a label reference value based on an average undermines these dietary guidance efforts. Several comments argued that health educators have invested years in teaching consumers about the use and interpretation of the current label reference value (U.S. RDA), and that the proposed change would consequently cause consumer confusion as well as erase educational inroads. One professional commented that the label reference value should not provide guidance about what amount a person should consume; rather, its purpose is to provide values that allow comparative shopping. However, according to the comment, if a single value is to be used as a guide for nutritional adequacy, the first principle of public health should be followed, which is to aim at the most vulnerable group. Several comments provided data or reviews of studies linking nutritional deficiencies or suboptimal intakes with a range of adverse effects from learning disabilities to cataracts.

FDA is persuaded by the comments that the proposed averaging approach should be modified. To understand the modified approach some background discussion is necessary.

The agency has always viewed the food label as an important tool for informing consumers about the nutritional content of the foods that they buy—one that shoppers can use to compare the vitamins, minerals, and protein in one food with another. This view is reinforced by the 1990 amendments. Additionally, the agency has been concerned that label reference values be set at levels consistent with levels of nutrients found naturally in foods so that regular, unfortified foods do not appear to be less than nutritious. If regular, unfortified foods were to appear less than nutritious, this could encourage needless fortification of foods.

Furthermore, FDA has also been concerned that the label reference values that appear on food labels not be interpreted as recommended intakes for individuals. Given the limited nutrition information that can be presented within the small space of most food labels, the agency sought in the proposal to establish values that represented a population-based average that consumers could use as a reference, adjusting it upward or downward based on how they compared to the average.

Most comments agreed that nutrition information on food labels must by necessity be limited and generalized, but suggested that public health concerns as well as consumer confidence and educational goals are best served by selecting label reference values that target "vulnerable groups" or at least that provide coverage for most of the population (i.e., the highest level recommended). Comments urged FDA to select protective levels of intake for vitamins and minerals that would be compatible with health promotion and disease prevention.

One comment suggested that consumers will not necessarily distinguish between a reference intake and a recommended intake, and that FDA should assume that consumers will see label reference values as recommended intakes. This comment offered a modification of the general approach of selecting the highest NAS RDA values. According to the comment, for each nutrient FDA should choose the most vulnerable segments of the population as the basis for the RDI. This segment should be established, the comment said, by identifying the group that has the highest NAS RDA and assessing its risk of a health problem caused by inadequate intakes of the nutrient. If the group with the highest NAS RDA is not at risk, FDA should move to the group with the second highest NAS RDA and assess its risk, and so on until the agency identifies a group that is at risk, or until it reaches a group that constitutes a major portion of the population.

FDA has considered all of these comments in determining the most appropriate alternative approach. FDA finds that there is considerable and uniform support for continuing to establish a label reference value for vitamins and minerals with NAS RDA's by selecting the highest NAS RDA value from among those persons 4 or more years of age (excluding pregnant and lactating females). The comments clearly demonstrated that vulnerable or at-risk groups would be sufficiently covered by selecting the highest value. While FDA understands the intent of the comment suggesting that the agency conduct an iterative process to determine at-risk groups or vulnerable segments of the population, the broad support in the comments for the view that the highest value is sufficient to protect vulnerable groups must be taken into account. Moreover, the iterative approach could complicate the selection of label reference values, especially in situations where data are limited or subject to varying interpretations. Thus, FDA has concluded that the iterative process offers no public health advantages as compared to the approach of selecting the highest NAS RDA.

Furthermore, it is likely that the overall concern of the comment that suggested the iterative process is reasonably met by selecting the highest NAS RDA, in that the comment suggested an approach that was intended to provide coverage for a larger proportion of the population than did the proposed averaging approach. Therefore, FDA has tentatively determined that label reference values (i.e., RDI's) should be based on an approach that selects the highest NAS RDA values from among those for adults and children 4 or more years of age but excludes values for pregnant females and lactating females. FDA refers to this approach as the "population coverage approach." The label reference values that result from application of this approach to the 1989 NAS RDA's are set out in the following table:

Nutrient	Unit of measurement	Adults and children 4 or more years of age	Children less than 4 years of age[1]	Infants[2]	Pregnant women	Lactating women
Vitamin A	retinol equivalents[3]	1,000	400	375	800	1,300
Vitamin C	mg	60	40	35	70	95
Calcium	do	1,200	800	600	1,200	1,200

Nutrient	Unit of measurement	Adults and children 4 or more years of age	Children less than 4 years of age[1]	Infants[2]	Pregnant women	Lactating women
Iron	do	15	10	10	30	15
Vitamin D	µg[4]	10	10	10	10	10
Vitamin E	alpha-tocopherol equivalents[5].	10	6.0	4	10	12
Vitamin K	µg	80	15	10	65	65
Thiamin	mg	1.5	0.7	0.4	1.5	1.6
Riboflavin	do	1.8	0.8	0.5	1.6	1.8
Niacin	niacin equivalents[3]	20	9.0	6	17	20
Vitamin B_6	mg	2.0	1.0	0.6	2.2	P2.1
Folate[5]	µg	400	50	35	400	400
Vitamin B_{12}	do	2	0.7	0.5	2.2	2.6
Phosphorus	mg	1,200	800	500	1,200	1,200
Magnesium	do	400	80	60	320	355
Zinc	do	15	10	5	15	19
Iodine	µg	150	70	50	175	200
Selenium	do	70	20	15	65	75
Chloride	mg	3,400	1,000	800	3,400	3,400[1]

[1] The term "children less than 4 years of age" means persons 13 through 47 months of age.
[2] The term "infants" means persons not more than 12 months of age.
[3] 1 retinol equivalent = 1 µg retinol or 6 µg beta-carotene; 1 alpha-tocopherol equivalent = 1 mg d-alpha-tocopherol (RRR-alpha-tocopherol); 1 niacin equivalent = 1 mg niacin or 60 mg of dietary tryptophan.
[4] As cholecalciferol.
[5] Discussion of folate RDI in section III. G. (comment 21) of this document.

However, based on the provisions of the DS Act, the agency is retaining the current label reference values established in § 101.9(c)(7)(iv) (recodified as § 101.9(c)(8)(iv) and redesignated as "Reference Daily Intakes"). It should be noted, however, that there are, in current § 101.9(c)(7)(iv), no label reference values for vitamin K, selenium, or chloride. Therefore, for the time being, the agency is not establishing label reference values for these three nutrients. FDA will reach a final decision on these issues, following the provisions of the DS Act.

D. Use of the NAS ESADDI as a Basis for Establishing an RDI

14. One comment was received that suggested that the RDI's based on ESADDI's may be a risk to health because in establishing the ESADDI's, NAS has stated that the upper limits of the ranges of intake should not be habitually exceeded. The comment asserted that some of the proposed RDI's based on ESADDI's exceed the upper limits of intake for children, specifically biotin, pantothenic acid, copper, manganese, and molybdenum.

FDA disagrees that the proposed label reference values based on the ESADDI's represent a risk to children. The agency is unaware of any evidence that would suggest that consumption at the proposed levels constitutes a health risk for children. The 10th edition of the NAS RDA publication (Ref. 26) states that:

(1) There have been no reports of toxicity associated with biotin intakes as high as 10 mg/day;

(2) Evidence suggests that pantothenic acid is relatively nontoxic;

(3) Usual intakes of copper in the U.S. are between 2 and 5 mg/day which is considered safe, and occasional intakes of up to 10 mg/day are probably safe for human adults;

(4) Manganese toxicity is rare, and nearly all cases are associated with environmental exposure. While there have been reports that learning disabilities in children might be associated with increased manganese levels in hair, more evidence is required before this association can be substantiated; and

(5) While the level of dietary intake of molybdenum that is known to be associated with increased loss of copper in the urine is approximately 2-fold that of the highest ESADDI, relatively large doses are necessary to overcome homeostatic mechanisms (Ref. 35).

Chloride tolerance is very high and likely many times the proposed RDI. The 9th edition of the NAS RDA publication (Ref. 36), which provides the basis for the RDI for chloride, does not even discuss the possibility of chloride toxicity.

As for chromium, although the agency is unaware of any safety issues at levels of current consumption, FDA recognizes that the safe range of intake of this mineral is fairly narrow. Thus, until sources of chromium have been affirmed, FDA advises that the RDI for chromium should not be interpreted as a recommendation for use for either direct supplementation or adding nutrients to foods.

Finally, a label reference value for fluoride does not present issues of risk for children because it is to be used only in conjunction with a declaration of the level of this nutrient that is naturally present in a food.

Thus, the agency concludes that children eating from the general food supply are extremely unlikely to be at risk for toxic intakes of these micronutrients. To be consistent with the population coverage approach being used for other vitamins and minerals with NAS RDA's, FDA has selected the highest ESADDI within the specified age group to serve as the label reference value. If an ESADDI value is presented as a range, FDA has used the midpoint of the range as the RDI. No comments were received that objected to this approach.

FDA's approach would provide RDI's for three age groups for nutrients with ESADDI's: adults and children 4 or more years of age, children less than 4 years of age, and infants. The NAS does not provide ESADDI's for pregnant or lactating females, but, as proposed, FDA used the midpoint of the ESADDI range for adults as the basis for the RDI for pregnant and lactating women in order to provide a reasonably appropriate reference value for this population. No comments objected to this approach. The RDI's determined by the agency based on the ESADDI's are set out in the following table:

Nutrient	Unit of measurement	Adults and children 4 or more years of age	Less than 4 years of age[1]	Infants[2]	Pregnant women	Lactating women
Biotin	µg	65	20	15	65	65

Nutrient	Unit of measurement	Adults and children 4 or more years of age	Less than 4 years of age[1]	Infants[2]	Pregnant women	Lactating women
Pantothenic acid	mg	5.5	3.0	3.0	5.5	5.5
Copper	do	2.5	0.9	0.7	2.5	2.5
Manganese	do	3.5	1.3	0.8	3.5	3.5
Fluoride	do	3.0	1.0	0.6	3.0	3.0
Chromium	µg	130	50	40	130	130
Molybdenum	do	160	38	30	160	160

[1] The term "children less than 4 years of age" means persons 13 through 47 months of age.
[2] The term "infants" means persons not more than 12 months of age.

However, based on the provisions of the DS Act, the agency is retaining the current label reference values as established in § 101.9(c)(7)(iv) (recodified as § 101.9(c)(8)(iv) and redesignated as "Reference Daily Intakes"). FDA notes that, in current § 101.9(c)(7)(iv), there are no label reference values for manganese, fluoride, chromium, and molybdenum. Therefore, for the interim, the agency is not establishing label reference values for these four nutrients. FDA will reach a final decision on these issues following the provisions of the DS Act.

E. Five Sets of RDI's for Different Developmental Groups

15. One comment supported the development of RDI's for different age groups and recognition of the special needs of pregnant or lactating women. However, the comment suggested that the grouping of adults and children more than 4 years of age into a single group is not appropriate and is contrary to well established evidence that nutritional requirements vary throughout the lifecycle. On the other hand, many comments supported the agency's proposed approach.

FDA faced considerable difficulties in developing the RDI's for use on foods given that nutritional needs vary considerably among persons who will consume the foods. This issue was also a consideration in the early 1970's when FDA was promulgating its first set of label reference values known as U.S. RDA's.

Because of space constraints on the food label—a problem that is becoming ever more compelling given the mandatory requirement for nutrition labeling on most foods—FDA does not believe that a viable option exists other than to develop a single set of label reference values for most consumers of the general food supply. Clearly, children over the age of 4 years consume the same foods that the rest of the population consumes.

Further, label reference values are intended to help persons to understand the nutrient levels in the context of a total daily diet, to compare foods, and to plan general diets. They are not intended to be used to decide whether a particular individual's consumption of nutrients is appropriate. Therefore, FDA believes that no harm can be done by using a single set of label reference values for nutrition labeling, especially if appropriate nutrition education is conducted.

The agency notes that, in following the provisions of the DS Act and retaining the label reference values in current § 101.9(c)(7)(iv), there will be no label reference values codified specifically for use on foods purported to be or represented for use by infants, children under 4 years of age, or pregnant or lactating women. FDA had proposed such label reference values and had intended to include RDI's for different development groups in these final regulations.

The agency further notes that label reference values for these groups had been established in 1976, based on the 1968 NAS RDA's (41 FR 46156, October 19, 1976). These values were codified in § 125.1(b) (21 CFR 125.1(b)), later redesignated as § 105.3(b) (21 CFR 105.3(b)). In 1979, FDA in response to a decision by the Court of Appeals of the Second Circuit, revised § 105.3 by, among other things, deleting paragraph (b) (44 FR 16005, March 16, 1979). Therefore, since 1979 there have been no codified label reference values for these specific groups. However, some manufacturers have continued to use the values that were contained in § 105.3(b) for labeling products, without objections from FDA.

Thus, following the spirit of the DS Act that implies that 1968 NAS RDA's should be used for labeling purposes and to provide guidance to manufacturers, the agency is republishing, in this document, the values formerly contained in § 105.3(b). The label reference values are as follows:

Vitamins and Minerals	Units of measurement	Infants	Children under 4 years of age	Pregnant or lactating women
Vitamin A	International Units	1,500	2,500	8,000
Vitamin D	do	400	400	400
Vitamin E	do	5	10	30
Vitamin C	Milligrams	35	40	60
Folic acid	do.	1	.2	.8
Thiamine	do	.5	.7	1.7
Riboflavin	do	.6	.8	2.0
Niacin	do	8	9	20
Vitamin B_6	do	.4	.7	2.5
Vitamin B_{12}	Micrograms	2	3	8
Biotin	Milligrams	.05	15	.30
Pantothenic acid	do	3	5	10
Calcium	Grams	.6	.8	1.3
Phosphorus	do	.5	.8	1.3
Iodine	Micrograms	45	70	150
Iron	Milligrams	15	10	18
Magnesium	do	70	200	450
Copper	do	.6	1.0	2.0
Zinc	do	5	8	15

These values are to be used as guidance in the interim for labeling products purported to be or represented for use by infants, children under 4 years of age, or pregnant or lactating women. FDA will make a final decision on these issues, following the provisions of the DS act.

F. Units of Measurement

16. A dietary supplement trade association requested that the agency continue to use the International Units nomenclature for vitamins A, D, and E. The comment stated that the new equivalents nomenclature (e.g., retinol equivalents) would be confusing and is not well understood by either professionals or consumers.

FDA advises that units of measurement based on units of equivalents have been in wide use for over 15 years, and, in fact, the NAS RDA has been listed in such units since the 1980 edition. The comment cites no evidence to support the contention that professionals are confused by the nomenclature, or that consumers will necessarily be mislead. FDA believes that it is more likely that consumers will use label information to compare products, and that the agency's provision for uniform units of measurement that are consistent with current measurement practices will be most beneficial. Additionally, for many foods, specific units of measurements will not be expressed. Rather, the levels of the nutrient present will appear as a percentage of the label reference value.

However, based on the provisions of the DS Act, the agency is, for the time being, retaining the current label reference values as established in § 101.9(c)(7)(iv) (recodified as § 101.9(c)(8)(iv)), including the units of measurement contained therein. Therefore, in the interim the agency will continue to use the International Units nomenclature for vitamins A, D, and E. FDA will reach a final decision on these issues, following the provisions of the dietary supplement act.

G. RDI's for Specific Nutrients

17. Several comments stated that the proposed RDI's for particular nutrients were too low. Several of the comments recommended higher levels for these nutrients. Specifically, the comments said that vitamin A should be 1,000 retinol equivalents; calcium, 1,200 mg; iron, 15 mg; vitamin D, 400 IU; vitamin E, 10 alpha-tocopherol equivalents; thiamin, 1.5 mg; riboflavin, 1.7 mg; niacin, 19 niacin equivalents; vitamin B_6, 2 mg; and zinc, 15 mg.

If FDA decided to use the population coverage approach in establishing the RDI for vitamins and minerals, the RDI values for the nutrients listed above would be consistent with the comments. However, based on the provisions of the DS Act, the agency is retaining the label reference values as established in current § 101.9(c)(7)(iv). Therefore, FDA notes that the RDI for vitamin A is 5000 International Units; for calcium, 1.0 g; iron, 18 mg; vitamin E, 30 International Units; and niacin 20 mg. FDA will reach a final decision on these issues, following the provisions of the DS Act.

18. Several comments asserted that there is a need to distinguish between retinol and beta-carotene as a source of vitamin A activity, and one requested that FDA establish a label reference value for beta-carotene. The general rationale provided was that beta-carotene is more strongly associated with reducing the risk of chronic disease than is retinol.

The issue of providing for separate beta-carotene declarations in the nutrition label is discussed in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the **Federal Register**. FDA does not agree that it is appropriate to establish a label reference value for beta-carotene separate from the value for overall vitamin A activity. As set forth in the preamble to the proposal for this final rule (55 FR 29476 at 29479), FDA intended to establish label reference values for those nutrients for which quantitative values were provided by the widely recognized and accepted consensus reports, specifically the 10th edition of the NAS RDA publication (Ref. 26), Diet and Health (Ref. 3), and the Surgeon General's Report on Nutrition and Health (Ref. 2). While these reports have discussed evidence to link lower beta-carotene consumption with increased risk for certain cancers, notably lung cancer, the reports noted the evolving nature of the issue and failed to make specific dietary recommendations concerning this food component. The reports, therefore, did not specify quantitative recommendations for intake, and the comments received relative to this proposal have not suggested or justified an appropriate intake level.

Without guidance from established scientific bodies and in the absence of scientific consensus both on the role of beta-carotene in the risk of onset of certain chronic diseases and on the quantitative level that could be appropriate for a population-based recommended intake of beta-carotene, FDA concludes that establishing such a label reference value cannot be supported. However, FDA will continue to monitor scientific advances as well as ongoing recommendations relative to beta-carotene nutriture. The agency will consider modifying or expanding label reference values as evidence warrants.

19. A few comments specifically expressed concern that the RDI for vitamin C was too low for persons in the U.S. population who smoke. This concern stems from evidence that persons who smoke cigarettes may require more vitamin C than persons who do not.

FDA is aware that the 10th edition of the NAS RDA publication includes a statement in the text that recommends that regular cigarette smokers ingest at least 100 mg of vitamin C daily. However, FDA advises that the NAS RDA for vitamin C for the general population is set no higher than 60 mg. FDA has established label reference values that, of necessity, must be targeted to the entire population, rather than special population subgroups. In the absence of information to suggest that the 1989 NAS RDA's are an inappropriate basis for label reference values, FDA does not agree that the RDI for vitamin C should be a value other than the highest value set for persons 4 or more years of age. FDA supports nutrition education efforts that will inform those individuals whose requirements may be altered by lifestyle choices about their special nutrient needs.

20. One comment from a research foundation expressed concern about the high levels of iron available in the diet and thus supported the proposed RDI for iron of 12 mg as compared to the current U.S. RDA of 18 mg. The comment was made within the context of a discussion of hemochromatosis, a genetic disorder resulting in iron overload. A number of comments from consumers also expressed concern about excess levels of iron in the diet and supported lower label reference values for iron.

FDA advises that with the advent of mandatory nutrition labeling, virtually all foods will bear information on iron content. Thus, those persons diagnosed with, or at risk for, hemochromatosis will be able to select or reject a food based on their special dietary needs. Additionally, the agency will continue to make use of the active nutrition monitoring system to evaluate clinical measures and dietary intakes concerning the incidence of hemochromatosis. The agency notes that data from the Third National Health and Nutrition Examination Survey conducted by the National Center for Health Statistics can be used as a basis for reconsidering of the values for iron if concerns regarding hemochromatosis are demonstrated.

21. A number of comments addressed the issue of the RDI for folate. The majority opposed the proposed RDI value of 180 µg, which is lower than the current U.S. RDA of 400 µg. Several of the comments suggested that the 1989 NAS RDA for folate was an

inappropriate basis for establishing a RDI for folate, and a number of comments requested that the agency retain the U.S. RDA level of 400 µg (800 µg for pregnant women). One comment, in referring to the conclusion in the 1989 NAS RDA publication (Ref. 26) that diets containing about half as much folate as the previous NAS RDA maintain adequate folate status, asserts that the folate content of foods in nutrient data bases is recognized as inaccurate and incomplete. According to the comment, basing recommended intakes on intake data derived from these data bases is unsound. Several comments stated that there is evidence that folic acid supplements play a role in reduction in neural tube defects.

To a certain extent, some of these comments would be addressed by use of the population coverage approach to deriving RDI's. As a result of this approach, the RDI for folate would be 200 µg, i.e., based on the highest RDA value for persons 4 or more years of age (excluding pregnant or lactating women). However, FDA is aware of concerns regarding the adequacy of the data base for folate content of foods, which in part served as the basis for establishing the RDA for folate. Recent analytical work (Ref. 37) has shown that folate content of some foods may be underestimated because of methodological problems in current food folate assay procedures. FDA therefore agrees that additional work is needed to evaluate the adequacy of current intakes of folate.

Moreover, several studies have become publicly available since the publication of the 1989 RDA's, and these studies have shown that periconceptional intake of folate may reduce the risk of some neural tube defects. A randomized clinical intervention trial conducted in Great Britain by the Medical Research Council (Ref. 38) showed significant protective effects against recurrence of neural tube defects when women at high risk of recurrence were treated periconceptionally with daily doses of 4,000 µg of folic acid. Additionally, data available from a recently terminated Hungarian trial showed reductions in occurrence of neural tube defects with periconceptional use of a multivitamin/multimineral supplements containing 800 µg/day of folic acid (Ref. 39).

The results of these trials have led to reassessment of several earlier observational studies. Protective effects of the vitamin at levels of 100 to 1,000 µg/day (obtained from foods and supplements) against occurrence of neural tube defects have been found in several but not all such observational studies.

FDA concludes that the available data demonstrate that there is a folate-related subset of neural tube defects in populations with high prevalence rates for these defects, and that folate intakes of about 400 µg/day may reduce the risk of some, but not all, neural tube defects in such populations. Furthermore, the agency notes that the United States Public Health Service (U.S. PHS) recently recommended that women of childbearing age in the United States who are capable of becoming pregnant should consume 400 µg of folate/day for the purpose of reducing their risk of having a pregnancy affected with spina bifida or other neural tube defects (Ref. 40).

FDA has seriously considered these findings relative to the appropriateness of retaining the approach of selecting the highest 1989 NAS RDA value (excluding pregnant or lactating women) when determining the RDI for folate. The agency has weighed the established and well-recognized scientific consensus inherent in the NAS RDA along with newer evidence of a possible at-risk population that constitutes a considerable segment of the U.S. population. Taken together, the agency concludes that these findings—specifically, the evidence of problematic data on folate intakes, the possibility that intakes of 400 µg/day may reduce the risk of some neural tube defects, and the recommendation of the U.S. PHS that women of childbearing age consume 400 µg/day of folate—are sufficiently compelling to justify at this time a RDI value of 400 µg for persons 4 or more years of age and, for consistency, a RDI of 400 µg for lactating women. Given that the current U.S. RDA is 400 µg, and that the DS Act compels retaining the U.S. RDA's at this time, no action is necessary. However, the issue of folate allowances for women is a significant one. Specifically, as discussed in a companion document entitled "Final Rule; Health Claims: Folic Acid and Neural Tube Defects" published elsewhere in this issue of the Federal Register, FDA is concerned about the uncertainties regarding the folate requirement of women of childbearing age and is planning to implement a peer review of several scientific issues relating to folate and its benefits for U.S. women. In this review, the agency will include an evaluation of the appropriate intake level for folate for women of childbearing age.

22. Two comments suggested that an intake based on a range of 6 to 10 mg/kilogram (kg) body weight would be appropriate for maintenance of healthy magnesium status. Another comment suggested that the RDI be increased to at least 350 mg as compared to the proposed value of 300 mg.

The 10th edition of the NAS RDA publication (Ref. 26) states that 4.5 mg/kg is the upper range of requirements determined in modern balance studies for adults of both sexes. Therefore, FDA cannot agree that a range of 6 to 10 mg/kg is supported. The level of 4.5 mg/kg provides the basis for the NAS RDA's for magnesium which range from 120 to 400 mg for persons 4 or more years of age. Given that dietary magnesium deficiency has not been reported in people consuming foods commonly available and has been induced experimentally only once (Ref. 26), the agency believes that this level is more than adequate to cover the needs of virtually all population groups.

Moreover, FDA use of the population coverage approach in establishing the RDI for vitamins and minerals, would result in an RDI for magnesium of 400 mg, and thus would respond to concerns that the proposed RDI of 300 mg was too low. However, in accordance with the DS Act, FDA is not acting on this issue at this time.

23. FDA received several comments expressing concern about the generally recognized as safe (GRAS) status of selenium, fluoride, and chromium. These comments centered primarily around issues of their use in supplements.

The use of selenium, fluoride, and chromium compounds in dietary supplements is discussed in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the Federal Register. In that final rule, the agency states that FDA is deferring resolution of the status of selenium and chromium. However, FDA would like to reiterate (as stated in the July 1990 proposal, 55 FR 29476) that until the GRAS status of sources of these nutrients is resolved, the RDI's for selenium, fluoride, and chromium, if established, would be intended to be used only in conjunction with a declaration of the levels of these nutrients that are naturally present in the food or, in the case of fluoride, that are present as a result of the use of a fluoridated water supply in the processing operation (in accordance with 21 CFR 250.203). Any direct addition of these trace minerals to a food is based solely on the manufacturer's judgment that the nutrient sources are GRAS and is not sanctioned by the agency.

However, because FDA is, for the time being, retaining the label reference values in current § 101.9(c)(7)(iv), there

are no label reference values for selenium, fluoride, or chromium. FDA will reach a final decision on these issues based on the provisions of the DS . ct.

IV. Label Reference Value for Protein

24. Two comments were received concerning the inconsistency between the label reference value for protein (RDI) and the label reference values for fat and carbohydrate (DRV's) in that the total caloric contribution of the three nutrients does not sum to 100 percent. One comment stated that the proposed value of 50 g for protein is too low because, based on a 2,350 calorie diet (i.e., the level proposed to serve as the basis for certain label reference values), the proposed 50-g level of protein would provide only 8.5 percent of the calories in a daily diet. The comment suggested that a level of protein that is consistent with 10 to 11 percent of calories from protein is appropriate, along with levels of 35 percent of calories from fat and 55 percent of calories from carbohydrate. The second comment suggested that FDA should resolve the discrepancy between the proposed protein RDI (50 g) and the value for protein that would be established if the value were based on the percentage of calories derived from protein. The comment stated that 10 percent of calories from protein is appropriate, and that the remaining 5 percent of calories that results after 30 percent of calories is attributed to fat, 10 percent to protein, and 55 percent to carbohydrate should be added to the carbohydrate caloric contribution (specifically, to the contribution from complex carbohydrates).

FDA has not traditionally specified label reference values for calorie-providing nutrients other than protein (i.e., no label reference values existed for fat or carbohydrate). Thus, the agency has not needed to consider issues related to the sum of caloric contributions from protein, carbohydrate, and fat, specifically that these values sum to 100 percent. Furthermore, recognized authorities on protein allowances provide for the allowance based on the amount of protein needed per kg of body weight rather than on the basis of percent of calories (Refs. 2, 3, and 26).

However, the agency agrees that with the advent of label reference values for fat and carbohydrate, it is appropriate to reconsider the approach used to derive the label reference value for protein. In addition to providing for a consistent and interrelated set of label reference values for calorie-providing nutrients, the change in approach will facilitate consumer education efforts.

Furthermore, the decision to use the population coverage approach (i.e., selecting the highest NAS RDA value for persons 4 or more years of age excluding pregnant or lactating females) for establishing label reference values for essential vitamins and minerals (i.e., nutrients with NAS RDA's) must also be evaluated relative to its appropriateness for protein, a nutrient for which an NAS RDA is also established. This is especially important given the caution expressed in Diet and Health (Ref. 3) concerning excessive protein intake, particularly from animal sources.

While FDA received many comments that suggested that FDA return to the approach of selecting the highest NAS RDA value to serve as the label reference value, no specific comments were received suggesting that the proposed label reference value for protein (50 g, based on an adjusted average of the RDA's for protein) was too low because of public health concerns, or that the label reference value placed certain population groups at-risk for low protein intakes. Therefore, the appropriateness of using the population coverage approach for protein was not specifically supported by the comments.

FDA therefore concludes that there is sufficient support to establish a DRV for protein rather than a RDI. This change to a DRV is necessary because the agency is no longer basing the label reference value for protein on the RDA's for protein. RDI's are based on RDA's. Rather, like the label reference values (i.e., DRV's) for fat and carbohydrate, the label reference value for protein is based on percent of calories.

Neither the NAS RDA publication (Ref. 26), the Surgeon General's Report (Ref. 2), nor Diet and Health (Ref. 3) suggests a specific level of total daily calories from protein. However, current intake of total dietary protein among Americans is estimated to be about 11 percent of calories (Ref. 3) and generally exceeds the NAS RDA for all age groups. Furthermore, some international guidelines for nutrient intake recommend that protein constitute 10 to 12 percent of calories (Ref. 3).

Based on the comments that suggested that approximately 10 percent of calories from protein should provide the basis for establishing a label reference value for this nutrient, FDA concludes that basing the DRV for protein on 10 percent of calories is reasonable. The level of 10 percent of calories is consistent with the NAS RDA in that the percent of calories from protein that results when the NAS RDA for each age/sex group is compared with the caloric allowance established for that group ranges from 5 to 11 percent and could be rounded to 10 percent.

Thus, FDA advises that the label reference value for protein for adults and children 4 or more years of age (excluding pregnant or lactating females) will be a DRV rather than a RDI (proposed as § 101.9(c)(12)(i) and redesignated below as § 101.9(c)(9)), and will be the value that constitutes 10 percent of the calorie level to be used as the caloric basis for the DRV's. As discussed below, this calorie level is 2,000 calories. Therefore, the label reference value (DRV) for protein will be 50 g (i.e., 10 percent of 2,000 calories = 200 calories from protein; because 1 g of protein furnishes 4 calories (Ref. 26), the result is 50 g of protein).

FDA did not propose DRV's for infants, children less than 4 years of age, pregnant women, and lactating women. Therefore, for these groups the protein label references remain as RDI's (proposed as § 101.9(c)(11)(iv) and redesignated below as § 101.9(c)(8)(iv)). To be consistent with the population coverage approach, FDA has selected the highest NAS RDA for protein for infants and the highest NAS RDA for protein for lactating females. Only one NAS RDA value is provided for pregnant women and for children less than 4 years of age, thus no selection need be made. However, despite the change in approach, the RDI's for protein are the same as those proposed for these four groups. Therefore, the label reference value for protein will be: (1) A DRV of 50 g for adults and children 4 or more years of age and (2) RDI's of 14 g for infants, 16 g for children less than 4 years of age, 60 g for pregnant women, and 65 g for lactating women.

The decision to establish a DRV for protein based on 10 percent of calorie intake (so that DRV's for calorie-providing nutrients sum to 100 percent of calories) requires an adjustment in the proposed label reference value for total carbohydrate, i.e., 55 percent calories from carbohydrate. The necessary adjustment is discussed below.

Also, consistent with these changes, additional changes are necessary in proposed conforming amendments. FDA is amending § 101.3(e)(4)(ii) (21 CFR 101.3(e)(4)(ii)) by not only removing the term "U.S. RDA" and adding in its place the term "RDI," but also by adding the term "DRV of protein." FDA is also amending § 104.20(c)(1) and (d)(3) to list the DRV for protein.

V. DRV'S: Label Reference Values for Eight Nutrients without NAS RDA'S

A. Terminology

25. Two comments were received that expressed concern about the use of the word "value" in the term DRV. These comments stated that the word "value" may imply a goal rather than a reference level, and that the word generally connotes desirability.

No data were submitted to support the suggestion that word "value" may mislead consumers. Furthermore, FDA research has indicated that the term is generally understood by consumers as a point of reference. No other comments objected to the term on these grounds. FDA finds there is no compelling reason to abandon the proposed DRV terminology.

B. Scientific Basis for DRV's

26. Several comments expressed concern that the DRV's were based on insufficient or conflicting data, or that they lack sufficient scientific justification.

FDA acknowledges that the role of nutrients and food components in reducing the risk of disease is in an evolving state. However, numerous dietary reports and reviews relating to diet and health—particularly on the effect of diet on the risk of developing certain chronic diseases—have been published within the last decade. These reports, including Diet and Health (Ref. 3), the Surgeon General's Report on Nutrition and Health (Ref. 2), and Dietary Guidelines for Americans (Ref. 5), represent a sufficient scientific consensus that justifies the agency's proceeding with the establishment of DRV's. This conclusion is supported by the Institute of Medicine report entitled "Nutrition Labeling: Issues and Directions for the 1990s" (Ref. 1), which states that health professionals have achieved a consensus on the characteristics of foods Americans should choose to have both a healthier diet and to reduce the risk factors for chronic diseases and conditions.

Concerns pertaining to the possibility that scientific consensus may change are not unique to the DRV's. The NAS RDA's, and thus the RDI's, are also subject to change and can be affected by shifts in scientific consensus. While it can be argued that the NAS RDA's are less likely to change because they have evolved over a longer period of time than the DRV's, any force from this argument is not sufficient to preclude using widely recognized and accepted recommendations to establish DRV's. This action is important given current public health goals and the clear role that the food label can play in achieving these goals. FDA acknowledges that the scientific knowledge that underlies the DRV's may change over time, and so the agency intends to monitor and evaluate scientific consensus relative to existing DRV's as well as other nutrients known to bear on to the diet/health relationship. Furthermore, the petition process provided by agency regulations enhances and encourages this review. Accordingly, FDA is adopting the DRV's as proposed, with some modifications.

C. Caloric Basis for DRV's

27. While several comments supported FDA's proposal to use 2,350 calories as the basis for establishing certain DRV's that are based on daily caloric intake, most comments were opposed to the proposed value because they believed that it is too high. Many expressed concern that the resulting DRV's for total fat and saturated fat would overstate acceptable intakes for population groups that habitually consume less than 2,350 calories. Others were concerned that the calorie level would appear too high and, thus, would be irrelevant to many consumers. A few comments suggested that the level of 2,350 may encourage overconsumption of calories, especially among women.

Many comments suggested that FDA use 2,000 calories as the basis for the DRV's. The rationale for selecting 2,000 calories as opposed to other lower values varied, but reasons given included the fact that it is consistent with widely used food plans, it approximates the caloric requirements for postmenopausal women who are at-risk for excessive intake of calories and fat, and it is a "rounded down" value for 2,350 calories. These comments also pointed out that 2,000 calories is easier to use in quick, mental calculations compared to other calorie levels such as 1,900 or 2,350. Therefore, it is an easier tool for education purposes and is "consumer friendly." A few comments suggested 1,900 calories be used as the basis because it reflects the caloric allowance set by the NAS for women 51 or more years of age, a group believed to be at-risk for excessive calorie and fat intake.

FDA agrees with the comments that there is a need to select a lower calorie level for the DRV's. First, FDA agrees that a rounded value will be easier for consumers to use and is less likely to suggest such a level of precision that consumers lose sight of the concept of tailoring recommendations and reference values to their own diets. Secondly, the use of a lower caloric value is consistent with the population coverage approach to be used for vitamins and minerals. The group "at risk," in this case the group most often targeted for weight control (i.e., older women), is covered by selecting a lower caloric basis for the DRV's, one that approximates the caloric requirements of such women. Given the support expressed for the 2,000 calorie level and how well it fits the reasons that support making this change, FDA will use 2,000 calories as the basis for DRV's (proposed as § 101.9(c)(12)(i), redesignated below as § 101.9(c)(9)).

Based on a 2,000 calorie level, the resulting DRV's being incorporated into § 101.9(c)(9) are listed in the following table:

Food component	Unit of measurement	DRV
Total fat	g	65
Saturated fat	do	20
Cholesterol	mg	300
Total carbohydrate.	g	300
Dietary fiber	do	25
Sodium	mg	2,400
Potassium	do	3,500
Protein	g	50

As stated in the July 1990 proposal (55 FR 29476 at 29484), revisions of the nutrition labeling regulations in § 101.9 to update the U.S. RDA values necessitate that, for consistency, FDA revise several other regulations. FDA proposed to revise § 104.20(d)(3) to include the statement "The food contains all of the following nutrients per 100 calories based on 2,350-calorie total intake as a daily standard" and by providing a proposed table that listed the amounts of nutrients (per 100 calories) based on a 2,350 calorie diet and based on the proposed RDI levels. FDA has recalculated the nutrient levels in § 104.20(d)(3) to reflect the RDI values presented in this final rule based on a 2,000 calorie diet and included a statement indicating that the amounts of nutrients per 100 calories are based on a 2,000 calorie total intake.

28. Several comments stated that DRV's should be established in a fashion that provides for a different set of DRV's for different caloric intakes or, alternatively, that provides for a range of values such as a minimum/maximum range. These comments argued that the proposed DRV's are too simplistic and would encourage overconsumption of calories and fat, especially among women. One of these comments provided an extensive rationale for developing three sets of DRV's based on three levels ("benchmarks") of calorie intake.

FDA is aware of the problems associated with providing a single label reference value when in fact

recommended intakes or nutrient allowances for individuals vary considerably. The concern expressed is somewhat analogous to the difficulties in deriving a single set of RDI's based on the NAS RDA's, which are established for different sex/age groups.

In the case of DRV's, FDA believes that the purposes of nutrition labeling are better served by implementing a single value to serve as the DRV for each nutrient because the percent DRV (expressed as Daily Value) will be a component of mandatory nutrition labeling. This labeling will be required on virtually all foods and, therefore, space considerations are significant. At the same time, if consumers are to use the important and necessary information provided by DRV's (expressed as Daily Value), the information must be presented in a readable format and in a manner that does not overburden or overwhelm consumers. The agency finds that a single value DRV will best accommodate these considerations of space and readability. In the companion document that specifies the final rule for Mandatory Nutrition Labeling, FDA is providing for a statement that is to be added to the label advising that the particular amount of certain nutrients a person may consume will vary depending upon calorie requirements. This information, coupled with education, should adequately address the concerns raised by the comments by ensuring that consumers will understand that diets of individuals will not necessarily match label reference values.

The concerns that the proposed DRV's will encourage overconsumption among women is addressed by FDA's decision to base the DRV's on a caloric consumption of 2,000 calories rather than 2,350 calories. The 2,000 calorie level is very close to the 1,900 calories recommended for women 51 or more years of age.

However, the requirement that a single DRV be used in the nutrition label does not preclude the option of manufacturers voluntarily adding a listing of DRV's for other calorie intakes if label space allows. The comments have persuaded FDA that this voluntary declaration could be useful to consumers. Therefore, while the DRV's based on a 2,000 calorie diet constitute the mandatory component of the listing (space permitting), producers and retailers may voluntarily add a listing of DRV's for a different specified calorie level or levels than those provided by § 101.9(c)(9). Manufacturers who wish to take advantage of this option should calculate, with appropriate rounding, (1) fat based on 30 percent of calories, (2) saturated fat based on 10 percent of calories, (3) carbohydrate based on 60 percent of calories, (4) protein based on 10 percent of calories, and (5) fiber based on 11.5 g of fiber per 1,000 calories. These calculations reflect those used to derive the DRV's based on a 2,000 calorie diet. As an example, a manufacturer could voluntarily list DRV's for a 1,500 calorie diet as follows: 50 g fat, 15 g saturated fat, 225 g carbohydrate, 40 g protein and 20 g fiber; or for a 2,500 calorie diet: 80 g fat, 25 g saturated fat, 375 g carbohydrate, 60 g protein, and 30 g fiber.

D. Units of Measurement and Rounding Procedures for DRV's

29. One comment disagreed with FDA's rounding procedure for the DRV's for fat, unsaturated fat, polyunsaturated fat, and carbohydrate. The comment suggested that the whole numbers derived before rounding should be used as the DRV. For instance, 30 percent of calories from fat (based on a 2,350 calorie diet) results in 78.3 g of fat. The comment argued that the DRV should be a value rounded to 78 g instead of the proposed 75 g.

FDA's rounding procedures for DRV's were intended to provide values that are "consumer friendly" numbers easily incorporated into educational programs as well as values that are generally consistent with the dietary recommendations. The possibility that DRV's could be listed on food labels as quantitative amounts instead of as percentage values led the agency to conclude that rounding to numbers such as 25 or 325 facilitated consumer education and did not imply more scientific precision than is justified given the evolving state of dietary recommendations. Furthermore, several comments urged FDA to select values that are easy for consumers to use and that do not suggest precision in determining the values. Therefore, the agency believes that there is support for the rounding approach that it used and agrees that consumers will find numbers such as 75 and 25 as more "friendly" and easily remembered than numbers such as 78 and 26. No other comments were received concerning this issue, and therefore FDA finds no compelling reason to provide alternative rounding procedures.

E. DRV for Total Fat

30. Several comments suggested that the use of 30 percent of calories from fat is inappropriate as the basis for developing a DRV for total fat. Some comments suggested that the level used should be 25 percent of calories from fat; one stated that 20 percent of calories from fat should be used. These comments argued that the established recommendation is a maximum level because it is stated as 30 percent or less of calories from fat. Therefore, some level below this maximum should be used. On the other hand, one comment recommended that FDA use 35 percent of calories from fat. The concern expressed in this comment was that levels below 35 percent of calories from fat will bias diets toward vegetarianism.

FDA rejects the arguments that the DRV should be based on a criterion other than 30 percent of calories from fat. As described in the preamble to the proposal, the major available consensus documents, which were used by FDA in developing the DRV, consistently recommend 30 percent of calories or less from fat as an appropriate intake, given that current intake approaches 40 percent of calories from fat. Thus, a level higher than 30 percent of calories cannot be supported because the widely supported recommended intake is no more than 30 percent of calories from fat. The comment stating that intake levels below 35 percent of calories from fat will bias diets toward vegetarianism did not provide evidence to support this statement. FDA is not aware of any data that suggests that diets at or below 30 percent of calories from fat preclude the inclusion of animal products.

On the other hand, while current consensus reports suggest that less than 30 percent of calories from fat is achievable and may be desirable, they fail to provide specific quantitative recommendations as to how far below 30 percent is advisable. In fact, no consensus exists on the appropriateness of specific intakes of less than 30 percent of calories from fat.

However, the agency is aware of the desirability of alerting consumers to the direction of the DRV for total fat in that it is helpful for consumers to know that intakes of 30 percent of calories or less is the goal. Thus, FDA is providing that the listing of the DRV for total fat on the nutrition label include the words "less than," as described in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the Federal Register.

31. Many comments suggested that the DRV for total fat should be lower than the proposed value of 75 g.

FDA agrees with these comments. With the change to a 2,000 calorie basis for DRV's, the DRV for total fat will be 65 g. The level was derived by calculating 30 percent of 2,000 calories and dividing by 9 which is the number of calories per g of fat. The calculated value is 66.7 g of fat. FDA rounded this

amount down to 65 g because, given that the current recommendation for total fat intake is 30 percent of calories or less, it is more appropriate to round down than to round up. Furthermore, as explained above, many comments have encouraged the agency to select label reference values that are easier for consumers to work with and recall, for instance 65 g of fat rather than 66 g.

F. DRV for Saturated Fat

32. Several comments suggested that because the proposed calorie basis (2,350 calories) is greater than the allowance for many persons, the proposed DRV for saturated fat (25 g) is too high.

FDA agrees with these comments. With the change in the basis for DRV's to 2,000 calories, and using the recommended intake of less than 10 percent of calories from saturated fat, the DRV for saturated fat is 20 g. The actual amount calculated using 10 percent of 2,000 calories is 22.2 g. However, because the current dietary recommendation specifies less than 10 percent of calories from saturated fat and for other reasons discussed above, FDA rounded this value down to 20 g.

33. One comment referenced Diet and Health (Ref. 3) which states that a saturated fat intake that is 7 to 8 percent of calories or lower would confer greater health benefits than the recommendation for less than 10 percent of calories. The comment suggested that FDA use 7 percent of calories from saturated fat as the basis for the DRV.

While the report cited does include an advisory statement as to the possibility of increased benefits with lower intakes, the committee responsible for Diet and Health specifically recommended less than 10 percent of calories from saturated fat. This recommendation was based not only on issues of health benefits but also on considerations of realistic diet modifications among American consumers. FDA believes that this approach is both prudent and practical. No other comment suggested the level of 7 percent of calories from saturated fat as the basis for the DRV. The agency, therefore, used 10 percent of calories from saturated fat with a rounding down procedure as described above in deriving the DRV for saturated fat.

G. DRV for Unsaturated Fat

FDA's intent in developing a DRV for unsaturated fat was to complete the set of label reference values for fat. The DRV's for fat and saturated fat reflect current recommendations to limit total fat intake to 30 percent of calories and saturated fat intake to less than 10 percent of calories. To account for the component of total fat that remains, FDA derived the DRV for unsaturated fat by calculating 20 percent of calories and dividing by 9. The agency arrived at the factor of 20 percent by subtracting the 10 percent of calories from saturated fats from the 30 percent of calories for total fat.

However, as discussed in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the **Federal Register**, comments have convinced the agency that the listing of unsaturated fat on the food label is potentially confusing to consumers and could result in consumer deception. As discussed in that companion document, comments stated that the listing was not useful, that it offered no additional information that could not be obtained by subtracting the saturated fat content from total fat, and that it obscures the presence of essential fatty acids.

Moreover, other comments persuasively argued that the term "unsaturated fat" is misleading because it suggests that all unsaturated fats are synonymous by including both cis and trans isomers and poly- and monounsaturated fats together. Based on these comments, FDA decided not to include a listing of unsaturated fat in nutrition labeling. Therefore, FDA finds that there is no need for a label reference value for unsaturated fat and, accordingly, has deleted the proposed DRV for it in this final rule.

34. One comment requested that FDA eliminate the proposed DRV for unsaturated fat and replace it with a DRV for polyunsaturated fat with a value of 25 g. The comment argued that this approach was supported by evidence that: (1) Polyunsaturated fats lower serum cholesterol, (2) current dietary recommendations are to maintain or modestly increase polyunsaturated fat intake, (3) low polyunsaturated fat intake is linked to increased risk of coronary heart disease, (4) consumers are familiar with polyunsaturated fat declarations on labels, and (5) declarations of unsaturated fat will clutter a nutrition label and do not provide useful information.

While FDA has been persuaded to eliminate the DRV for unsaturated fat, FDA does not agree that the establishment of a DRV for polyunsaturated fat of 25 g is appropriate. As stated in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the **Federal Register**, FDA is not persuaded that there is a need to require the inclusion of polyunsaturated fats on the nutrition label. As discussed, these fatty acids do not meet the agency's criteria set forth in the proposal to the final rule (55 FR 29487 at 29493) that the nutrient be of particular public health significance and that quantitative intake recommendations be given in major scientific consensus reports.

Nonetheless, given consumer interest in polyunsaturated fats, FDA is allowing manufacturers to voluntarily list the amounts of polyunsaturated fats on the nutrition label. This provision is discussed in detail in the Mandatory Nutrition Labeling final rule, published elsewhere in this issue of the **Federal Register**. Also, the agency acknowledges that Diet and Health (Ref. 3) has recommended that total polyunsaturated fat intake be maintained at 7 percent of calories and not exceed 10 percent of calories. This guideline translates into a recommended level of intake of approximately 16 g of total polyunsaturated fat, which should not exceed 22 g, based on the criterion of a 2,000 calorie diet.

However, FDA's definition for polyunsaturated fat includes only the cis isomers of the polyunsaturated fatty acids, as described in the Mandatory Nutrition Labeling final rule. Thus, voluntary label declarations for polyunsaturated fat exclude trans isomers. As discussed in the Mandatory Nutrition Labeling proposed rule (55 FR 29487 at 29496), FDA believes that the limited definition is appropriate because declarations concerning polyunsaturated fats are at a level of specificity associated with targeted diet and health relationships.

Therefore, while label declarations include only the cis isomers, the available recommendation for polyunsaturated fat intake is based on total polyunsaturated fat intake. There are no quantitative recommendations for polyunsaturated fat intake that distinguish between the recommended intake of cis isomers and trans isomers of polyunsaturated fat. FDA concludes that a DRV based on recommendations pertaining to total polyunsaturated fat would be inappropriate when label declarations are to be based on only a component of the total polyunsaturated fat. Declarations when compared to the DRV would be misleading. Thus, the agency has not established a DRV for polyunsaturated fat.

35. One comment stated that the proposed DRV for unsaturated fat (50 g) was too high because current guidelines suggest that saturated and polyunsaturated fat should be up to 10 percent of calories, and that the rest of

the caloric contribution should come from monounsaturated fats.

The comment does not reference the source for the guideline that it discusses, and FDA is unaware of such a guideline. FDA does not agree that the current consensus reports suggest that 20 percent of calories should come from monounsaturated fats, and that the remaining caloric contribution of 10 percent of calories should be attributed to all other fats. Rather, as discussed in Diet and Health (Ref. 3), the current general recommendations are that polyunsaturated fat not exceed 10 percent of total calories, and that saturated fat be less than 10 percent of total calories. No specific recommendations for monounsaturated fat are provided in the major consensus reports currently available to the agency.

36. One comment stated that it is not appropriate to recommend 20 percent of calories from unsaturated fat without also stating that linoleate is an essential fatty acid and as such should comprise at least 3 percent, and perhaps as much as 7 percent, of calories in line with the current average intake in the United States.

The agency's decision to eliminate the DRV for unsaturated fat responds to the essential concern of this comment, that declarations concerning levels of unsaturated fat could be misleading without further information. As stated earlier, no DRV for unsaturated fat will be established, and thus the issue concerning the linoleate component of the DRV need not be addressed.

H. DRV for Cholesterol

37. One comment suggested that many experts agree that a single number for recommended cholesterol intake cannot be supported and requested that FDA eliminate this DRV. The comment also suggested that if the DRV is to be retained, the DRV for cholesterol should be expressed as a range. However, the comment did not specify an appropriate range. One comment stated that the DRV for cholesterol was inappropriate because Canadian nutrition recommendations do not provide quantitative advice on cholesterol intake.

FDA cannot agree that a DRV for cholesterol is unnecessary, or that many experts do not support a single overall recommended intake for cholesterol. Major public health initiatives in the United States have cited the need to limit cholesterol intake, and quantitative recommendations for cholesterol intake have evolved over a long period of time. Recently, the report of the Expert Panel on Population Strategies for Blood Cholesterol Reduction, National Cholesterol Education Program (Ref. 41) stated that it is important for Americans to change their eating patterns to reduce the average intakes of dietary cholesterol.

As documented in Diet and Health (Ref. 3), there are a number of sources of recommendations concerning cholesterol intake, and the most widely used recommendation is to limit intake to 300 mg or less/day. The American Heart Association has recently re-reviewed this issue and recommended that cholesterol intake should be less than 300 mg/day (Ref. 42). Furthermore, a review of a summary table in Diet and Health (Ref. 3) reveals only one U.S. recommendation that provides a range for cholesterol. The range is 250 to 300 mg/day prescribed for a high-risk population rather than for the general public. Therefore, FDA does not agree that the DRV for cholesterol is unnecessary or inappropriate, nor that it should be expressed as a range. The agency is retaining the DRV for cholesterol at 300 mg (proposed as § 101.9(c)(12)(i) and redesignated below as § 101.9(c)(9)).

38. One comment recommended that the DRV for cholesterol be eliminated because the 300 mg level may encourage women and children, whose mean intakes as indicated by national surveys are below 300 mg, to increase their intakes.

FDA cannot agree that the DRV of 300 mg for cholesterol will encourage women and children to increase consumption of cholesterol. The major consensus reports, upon which the DRV is based, have considered the intake of cholesterol relative to women and children and have found no evidence that establishing a recommendation at approximately 300 mg/day will cause risk for these groups, which constitute a large percentage of the target population (Refs. 2 and 3).

More importantly, the lower calorie intakes among these population groups will likely result in lower intakes of cholesterol by these persons. Given current widespread and highly visible education programs, it is very unlikely that individuals will attempt to increase cholesterol intake to match a label reference value for a nutrient that is so generally known as one to be limited in the diet. Furthermore, as discussed in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the **Federal Register**, the DRV for cholesterol will be stated as less than 300 mg, thus providing nutrition information in a way that will further discourage any increase intake.

39. One comment referenced a statement in Diet and Health (Ref. 3) that reductions beyond 300 mg/day of cholesterol intake, for example to levels of 250 or 200 mg/day, may also confer health benefits. The comment suggested that the 300 mg level was based not only on issues of public health but on the feasibility of achieving lower intakes given current consumption patterns, which, in turn, was based largely on anecdotal evidence and personal opinion.

While the report cited does include a statement as to the possibility of increased benefits with lower intakes of cholesterol, the committee responsible for the report specifically recommended a level of 300 mg/day. This recommendation was based not only on issues of health benefits but also on considerations of realistic diet modifications among American consumers. The comment does not cite specifically in what way this recommendation is based on anecdotal evidence or personal opinion, and the agency is unaware of any evidence to support this claim. FDA believes that the DRV of 300 mg for cholesterol is both prudent and practical, and is consistent with current dietary recommendations. No other comment suggested a lower level of cholesterol for the DRV. The agency will therefore retain the DRV of 300 mg. However, as with other nutrients, FDA will continue to monitor consensus reports and scientific evidence concerning the appropriateness of this DRV.

I. DRV's for Total Carbohydrate, Complex Carbohydrates, and Sugars

In the July 1990 proposal (55 FR 29476) and again in the supplementary proposal (56 FR 60366), FDA proposed a level of 325 g to serve as the DRV for total carbohydrate. This quantity was based on recommendations provided by major consensus reports, and specifically on the quantitative recommendation from Diet and Health (Ref. 3) that carbohydrate intake be 55 percent or more of calories. The amount, 325 g, reflects 55 percent of 2,350 calories, the caloric level proposed to serve as the basis for the DRV's.

40. One comment expressed concern that the proposed DRV for carbohydrate exceeds levels that should be consumed by many in the population and is not based on a scientific consensus. The comment suggested that the DRV for carbohydrate be eliminated.

FDA disagrees with this comment. The vast majority of comments that FDA received support the appropriateness of establishing DRV's as well as the validity of the scientific documents

upon which they (including the DRV for carbohydrate) are based. A DRV for total carbohydrate is necessary to assist consumers in understanding the significance of the level of that nutrient in a food within the context of an overall total daily diet. Thus, establishing a DRV for total carbohydrate is consistent with section 2(b)(1)(A) of the 1990 amendments. Additionally, several comments stated that it would be desirable to account for 100 percent of caloric intake in the DRV's for fat, protein, and carbohydrate (i.e., the energy-providing nutrients). Therefore, FDA concludes that a DRV for carbohydrate is appropriate.

41. A few comments requested that FDA establish a DRV for complex carbohydrate. One comment suggested that FDA establish such a DRV because it could be used in nutrition education efforts to help consumers put the dietary recommendations regarding increased carbohydrate intake into perspective. This comment provided a rationale based on the assumption that the current dietary recommendation to increase consumption of complex carbohydrates is meant to provide a caloric source to replace the decrease in caloric intake that will result from following the recommendation to decrease fat in the diet. On this basis, a DRV for complex carbohydrate derived from 35 percent of calories was suggested. Another comment suggested that a DRV based on 40 percent of calories is appropriate (assuming that 10 percent of calories is attributed to naturally-occurring sugars and 10 percent to added sugars, for a total carbohydrate DRV of 60 percent of calories). The third comment suggested that a DRV for total carbohydrate in the absence of DRV's for complex carbohydrates and simple sugars is inappropriate. One comment suggested eliminating the DRV for total carbohydrate and replacing it with a DRV for complex carbohydrate.

FDA agrees that recent dietary recommendations have included suggestions that persons increase their intake of complex carbohydrates. However, FDA does not agree that there is scientific agreement on a specific recommended intake of complex carbohydrates, particularly a level of agreement that will support establishing a DRV. To date, major consensus reports and dietary recommendations have provided only qualitative recommendations for intake of complex carbohydrates. No quantitative recommendations exist. While the calculations that accompany the suggestion of 35 percent of calories from complex carbohydrate are well thought out, they are not at this time supported by other sources. The alternative suggestion of 40 percent of calories from complex carbohydrate is based on a calculation by difference that assumes that 20 percent of calories from naturally occurring and added sugars is justified. Again, FDA finds no basis in the consensus reports upon which to agree.

Moreover, as discussed in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the **Federal Register**, the chemical definition for complex carbohydrate remains problematic. A DRV for complex carbohydrate would be inappropriate in the absence of an acceptable chemical definition for complex carbohydrate because the agency does know which chemical entities should be reflected in the complex carbohydrate DRV, and because the agency would be unable to measure complex carbohydrate to determine whether a level listed as present in a food is correct. FDA acknowledges that recommendations concerning complex carbohydrate intake as well as the analytical methodologies for this food component are in an evolving state. Therefore, the agency will continue to monitor scientific evidence relative to the appropriateness of establishing a DRV for this food component.

42. One comment from a consumer advocacy group suggested that a DRV for added sugars and a DRV for naturally-occurring sugars be developed. The comment stated that DRV's in general do not describe ideal diets and do not reflect absolute scientific knowledge but are instead estimates based on the best knowledge available. The comment suggested that because sugars intake is a major public health concern, it is appropriate for FDA to establish a DRV for sugars despite the fact that neither the Surgeon General's Report (Ref. 2) nor Diet and Health (Ref. 3) present quantitative recommendations on sugars intake. The comment suggested that a DRV of approximately 50 g be established for added sugars. The comment said that this level was derived from a FDA report (Ref. 43) that estimated that, on average, 53 g of added sugars are consumed per person per day. The comment asserted that FDA underestimated added sugars intake by one half (although it did not provide evidence to support this claim) and thus said that 50 g would be an appropriate level. The comment also suggested that the DRV for naturally-occurring sugars should be 50 g, also based on the FDA report concerning average consumption/day. The comment again suggested that this estimate is too low by half.

Another comment concerning complex carbohydrates stated that a DRV for complex carbohydrate should be based on 35 percent of calories from carbohydrate, and implied that 20 percent of calories should be attributed to sugars.

In reviewing these comments, FDA considered the report from the World Health Organization (WHO) entitled "Diet, Nutrition and the Prevention of Chronic Diseases" (Ref. 44). The agency recognizes that the recommendation in the WHO report that consumption of refined sugars be limited to 10 percent of calories is not inconsistent with the comment that recommended that a DRV for added sugars be established at 50 g, because, with the agency's use of 2,000 calories as the basis for the DRV's, 50 g of sugars would constitute 10 percent of calories. Furthermore, the agency stated in its proposals (47 FR 53917, November 30, 1982 and 47 FR 53923, November 30, 1982) to affirm that sucrose, corn sugar, corn syrup, and invert sugar are GRAS, that it would monitor average dietary consumption of these ingredients and would reevaluate the safety of their use if total dietary consumption were to increase significantly. The agency concluded in those documents that there could be safety concerns if intake of these ingredients increased significantly over the current levels (approximately 50 g).

FDA acknowledges that there is some support for limiting the intake of added sugars to current intakes of about 50 g or 10 percent of calories. However, the agency has concluded that this support does not furnish a sufficient basis for establishing a DRV for added sugars. First, DRV's are established for nutrients of public health concern. As such, a rational basis for a DRV must in some way link particular, if not specific, levels of intake with adverse or positive health outcomes. Other than dental caries—the incidence of which has been declining considerably among the American population (Ref. 43)—no public health concerns are articulated by the comment or in the relevant reports. Further, in a special review conducted by the agency in the mid-1980's, FDA concluded that other than the contribution to dental caries, there is no conclusive evidence that demonstrates that sugars intake from any source is associated with chronic disease conditions (Ref. 43). The report also states that the development of dental caries occurs whether a sugar is added or naturally occurring, and that caries development is associated with the nature and texture of the food

consumed, not just the total amount of sugars present in the food. Therefore, a specific level of intake that causes risk cannot be identified.

Secondly, as discussed in more detail in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the **Federal Register**, there is currently no analytical methodology that would allow the agency to distinguish between sugars that are added to a food and those that are naturally occurring. Therefore, FDA would be unable to evaluate the accuracy of claims about the levels of added sugars in foods. FDA discussed this consideration earlier in its final rule on the GRAS status of certain sugars (53 FR 44863, November 7, 1988). The agency concluded that it would be impractical to enforce limitations on the use of these ingredients in foods.

Moreover, in the absence of analytical capabilities to distinguish between added sugars and naturally-occurring sugars, FDA does not believe that it would be appropriate to establish a DRV for total sugars. There is no consensus concerning the specific proportions of total carbohydrate that should be attributed to total sugars and to complex carbohydrate. Moreover, a DRV for total sugars could be inconsistent with dietary guidelines that encourage the consumption of certain foods, such as fruits and dairy products, that contain naturally-occurring sugars, sometimes at high levels. FDA, therefore, concludes that DRV's for added sugars, naturally-occurring sugars, and total sugars cannot be supported.

This conclusion, however, does not mean that FDA supports unlimited intake of sugars or sugar-rich foods that contain few nutrients except calories. Rather, FDA analyses of food consumption data (Ref. 45) suggest that certain groups in the population would benefit from educational efforts to help them assess the amount of sugars present in foods in relation to the amounts of other nutrients contained in the food. Given this need, as well as consumer interest in levels of sugars in food, FDA has made provision in the Mandatory Nutrition Labeling final rule, published elsewhere in this issue of the **Federal Register**, for declarations in the nutrition label concerning the amount of total sugars present in the food. With educational efforts, consumers will be able to use the nutrition label to differentiate between sugars-containing foods with high versus low nutrient values.

J. Adjustment in DRV for Carbohydrate Resulting from Change in Label Reference Value for Protein

As discussed earlier, the agency has decided to use a caloric basis for the DRV's of 2,000 calories instead of 2,350 calories and to establish a DRV for protein based on 10 percent of calories. These changes from the proposed approach have necessitated an adjustment in the DRV for total carbohydrate.

Based on comments, particularly as discussed above in comment 24, FDA is establishing a DRV for protein rather than an RDI. The DRV value reflects 10 percent of calories from protein, based on a 2,000 calorie diet. FDA proposed to base the DRV's for fat and carbohydrate on their percent contribution to total calories, 30 percent and 55 percent, respectively. If protein is to contribute 10 percent of calories, then it is necessary to account for the remaining 5 percent of calories using the contribution from fat or from carbohydrate. Given the current established recommendation that persons consume 30 percent or less of calories from fat (Refs. 2 and 3), FDA does not believe it would be appropriate to add the remaining 5 percent of calories to the contribution from fat.

Guided by a comment submitted to this docket, discussed above in comment 41, as well as by the fact that Diet and Health recommends that 55 percent or more of calories be derived from carbohydrate (Ref. 3), FDA believes that it is appropriate to increase the DRV for carbohydrate. While the comment suggested the change from 55 to 60 percent of calories from total carbohydrate within the context of providing a DRV for complex carbohydrates (which was not proposed by the agency), the approach can still be applied to total carbohydrate in the absence of a DRV for complex carbohydrate.

This change from 55 percent to 60 percent of calories from carbohydrate is consistent with the recommendation that persons consume 55 percent or more of their calories from carbohydrate, and it allows the energy-yielding nutrients to sum to 100 percent of calories as suggested by the comments to this docket. Therefore, FDA is adopting a DRV for carbohydrate of 300 g, which is 60 percent of 2,000 calories (i.e., 60 percent of 2,000 calories = 1,200 calories; carbohydrate provides 4 calories per g (Ref. 26), thus 1,200 calories divided by 4 calories per g results in 300 g). This change is incorporated into § 101.9(c)(9)).

K. DRV for Dietary Fiber

43. Two comments suggested that the DRV for dietary fiber should not be associated with a specific caloric intake, and that, as in the case of cholesterol, this DRV should be independent of the number of calories consumed. One comment stated that nutritionists recommend similar levels of fiber intake at different levels of caloric intake. However, the comment did not specify a level that would be appropriate for all persons.

As acknowledged in the proposal for this regulation, there is a relative lack of consensus concerning recommended quantitative values for fiber intake. However, several scientific bodies have recommended increased intake of fiber, and comments from consumers and health professionals have strongly suggested the desirability of providing quantitative fiber content labeling on foods. Available recommendations tend to be expressed as a range or as a level that should not be exceeded, rather than as a single number applicable to all persons.

FDA considers the current most authoritative source on recommended fiber intake to be the report issued by the Life Sciences Research Organization (LSRO) of the Federation of American Societies for Experimental Biology (Ref. 46). This report based recommended fiber intakes on an amount (10 to 13 g) per 1,000 calories which, when based on the 2,000 calorie level used for the DRV's, results in a level of intake (20 to 26 g) that is in general agreement with the recommendation of the National Cancer Institute, i.e., 20 to 30 g per day (Ref. 47).

FDA finds no reason to change the basis for deriving the DRV for dietary fiber that it used in the proposal which involved calculating 11.5 g, the midpoint of the 10 to 13 g range, of fiber per 1,000 calories. The change to a 2,000 calorie basis from a 2,350 calorie basis will not change the DRV for fiber (proposed as § 101.9(c)(12)(i) and redesignated below as 101.9(c)(9)), which FDA proposed as 25 g based on a 2,350 caloric intake. The 2,000 calorie calculation (i.e., 11.5 g times 2) results in a value of 23 g, which rounds up to 25 g to provide a number that is easily incorporated into educational programs and is generally consistent with the dietary recommendations.

44. One comment recommended that the DRV for fiber be established as 20 g rather than 25 g. The comment noted that the National Cancer Institute (Ref. 47) and the report from LSRO (Ref. 46) both specify a range of about 20 to 35 g per day. The comment suggested that

the low end of the range is a more realistic goal for the U.S. population considering that current intakes are half of that amount.

FDA does not find the argument for dietary feasibility sufficiently compelling to abandon a level that is clearly within the range recommended by major scientific bodies. FDA is unaware of any evidence to suggest that 25 g per day cannot be met by consumers who select foods from the available food supply, or that it is not achievable through realistic diet modifications. FDA believes that the recommended intake is readily achievable with enhanced educational efforts. FDA is planning for and supporting such efforts.

45. One comment expressed concern that the proposed DRV for fiber exceeds levels consumed by many in the population and is not based on sufficient scientific data. The comment did not further specify the nature of the insufficient data.

As stated in the proposal to this document (55 FR 29476 at 29483), comments received by FDA show that many consumers and health professionals desire quantitative fiber content labeling. Yet, as the agency acknowledged, there is a lack of consensus concerning quantitative values for recommended fiber intake. However, several scientific bodies (Refs. 2, 3, 47, and 48) have recommended increased intake levels for fiber on the basis that fiber may have important health benefits, particularly relative to intestinal function. Furthermore, LSRO has issued a report that provides a quantitative recommended intake for dietary fiber (Ref. 46). Its recommendation of 10 to 13 g fiber per 1,000 calories in the diet is consistent with that of the National Cancer Institute (Ref. 47). The report developed for LSRO by a panel of qualified scientists contains numerous references to scientific research articles and reports in professional journals and publications. FDA is not aware of any concerns about the soundness of the LSRO review. Therefore, FDA is not persuaded that the scientific rationale for the fiber DRV is based on insufficient data.

Secondly, the fact that the DRV exceeds levels currently consumed by many in population is not significant in setting this DRV. As discussed in the preceding comment, FDA is unaware of any evidence to suggest that 25 g per day cannot be met by consumers who select foods from the available food supply. Therefore, FDA concludes that the 25 g level for the DRV for fiber is appropriate.

L. DRV for Sodium

46. A few comments specifically supported creating a DRV for sodium by pointing out that the scientific evidence demonstrates that sodium reduction is beneficial for hypertensive and normotensives alike, and that high salt intake coupled with low potassium and calcium intake is a major cause of high blood pressure and risk of stroke. A few were opposed and argued that the data are scientifically insufficient or questionable.

FDA disagrees that the data are insufficient or questionable. The basis for the agency's position is discussed in detail in the proposal pertaining to a sodium/hypertension health claim (56 FR 60825, November 27, 1991) and in the final rule for this health claim published elsewhere in this issue of the **Federal Register**. As discussed in these documents, it is the agency's opinion that based on the totality of publicly available scientific evidence, there is significant scientific agreement that there is a relationship between sodium and hypertension. There is also agreement that reductions in dietary sodium intake will provide a substantial public health benefit. Given the need to reduce sodium intake and the directive in the legislation that the information required in the nutrition label be conveyed to the public in a manner that enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet (section 2(b)(1)(A) of the 1990 amendments), FDA believes that a DRV for sodium is supported.

47. Some comments argued that there is no consensus regarding sodium recommendations, and that a DRV is therefore inappropriate. One comment stated that Canada provides no quantitative advice regarding sodium, and another noted that public health agencies do not agree among themselves about an appropriate recommendation. It was pointed out that the Joint National Committee (Ref. 49) described "moderate sodium intake" as 1,500 to 2,500 mg, while the Surgeon General's Report (Ref. 2) discussed a desirable range of 1,100 to 3,300 mg in noting that dietary intakes exceed this range, which was established as "safe and adequate" in the 9th edition of the NAS RDA publication (Ref. 36). The Dietary Guidelines for Americans (Ref. 5) recommend "moderation" but provide no quantitative values, while the 10th edition of the NAS RDA publication (Ref. 26) specifies a minimum intake of 500 mg but no maximum bound. The comment pointed out that the participants at the National Heart, Lung, and Blood Institute (NHLBI) Workshop held in 1989 (Ref. 50) expressed disparate views.

FDA is aware of these differences but believes that they are attributable to differences in the intended purposes of the recommendations and not necessarily to a lack of underlying agreement. In fact, these recommendations are usually expressed as a range that includes the 2,400 mg level proposed as the DRV.

The Surgeon General's Report (Ref. 2) cited the 9th edition of the NAS RDA publication (Ref. 36) that has been superseded by the more recent 10th edition (Ref. 26). The 10th edition of the NAS RDA publication identifies a minimum safe adult intake of 500 mg but also supports the level of 2,400 mg recommended in Diet and Health (Ref. 3). Diet and Health served as the basis for establishing the DRV for sodium.

The Joint National Committee (Ref. 49), in the context of hypertension detection and treatment, reported no serious adverse effects with moderate sodium restriction of 1,500 to 2,500 mg, which includes the 2,400 mg level used for the DRV. Finally, the NHLBI workshop (Ref. 50) was designed to explore current research topics and was not convened as a Federal government consensus panel, nor did it have the objective to identify a recommended intake.

Therefore, FDA believes that the level of 2,400 mg that is proposed as the DRV for sodium, and that is recommended in the major consensus report Diet and Health, is consistent with other recommendations and government reports and, thus, provides an appropriate basis for a DRV. The level of 2,400 mg is also well above the recommended minimum safe intake levels of 500 mg.

48. A few comments supported a DRV for sodium that is lower than the proposed 2,400 mg. One comment from a consumer stated that 2,400 mg seems too high. Two comments that preferred 1,800 mg argued that Diet and Health (Ref. 3) had recommended 2,400 mg as an "initial goal" and had stated that a level of 1,800 mg would probably confer greater health benefit. One of these comments supported the lower value as a way to better protect millions of Americans, especially older citizens, with hypertension.

FDA proposed a DRV for sodium of 2,400 mg based on the recommendation in Diet and Health. While this report does note that a lower value of 1,800 mg may confer greater benefit, the committee specifically recommended 2,400 mg sodium. This recommendation

was based not only on issues of health benefits but also took into consideration realistic diet modifications among American consumers. FDA, therefore, concludes that a DRV of 2,400 mg is consistent with the recommendation provided by Diet and Health. However, to guide consumers to the benefits of even lower levels, the agency is providing for the use of the phrase "less than" in the presentation of the DRV standard on the label. This label format provision is discussed in more detail in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the **Federal Register**.

49. Several comments favored a higher DRV for sodium. One comment supported 2,900 to 3,000 mg, suggesting that a reasonable interpretation of the guideline provided in the 10th edition of the NAS RDA publication (Ref. 26) was to add the recommended intake to the 500 mg minimum naturally occurring (2,400 mg + 500 mg). This approach would produce a DRV of 2,900 mg (rounded to 3,000 mg). The comment stated that this level would be more realistic than 2,400 mg. Two other comments favored the 3,000 mg level. One expressed support for the American Heart Association position which is that sodium intake should not exceed 3 g per day (Ref. 42), and another stated that 3,000 mg has been recommended by most reputable health and nutrition organizations. One comment supported 3,300 mg, and another suggested a DRV of no less than 3,500 mg for a 2,350 calorie diet. According to the comment, the latter value represented a one-quarter decrease in what the comment identified as the usual American dietary intake of 4 to 6 g of salt. The one-quarter reduction was identified as the moderate intake recommended by Dietary Guidelines (Ref. 5). Another comment supported 4,000 mg, noting that the DRV is considered by dietitians to be in the range of "low sodium" diets (less than 2,000 mg), and that the general public should not use a "low sodium" diet as a reference because consumers would wrongly believe that sodium intakes in excess of safe and adequate levels would be harmful. One comment suggested that a range from 500 to 4,600 mg would be preferable to a single value.

First, FDA does not agree that the committee responsible for the 1989 NAS RDA's intended that 2,400 mg sodium should be consumed in addition to the 500 mg identified as safe and adequate in the 10th edition of the NAS RDA publication (Ref. 26). The publication specifically states that "there is no known advantage in consuming large amounts of sodium" and references the recent NAS Diet and Health report (Ref. 3) which recommends that daily intakes of sodium chloride be limited to 2,400 mg of sodium or less. Further, FDA believes that a sodium DRV of 2,400 mg is not inconsistent with the current American Heart Association position that sodium intake should not exceed 3 g per day (Ref. 38). The agency notes that the written comments to this docket submitted by the American Heart Association did not object to the DRV of 2,400 mg for sodium (Ref. 51).

FDA remains unconvinced that there is any reason to establish a value that is higher than the 2,400 mg specified in Diet and Health. The suggested higher values are not consistently supported, whereas 2,400 mg is consistent with other Federal agency recommendations and with current public health agency policies to moderate or reduce sodium intake. Furthermore, the 2,400 mg level is a feasible goal because sodium in food is primarily present as added salt, and current dietary recommendations specify a moderate reduction that is large enough to produce significant decreases in intake while remaining well in excess of the minimum safe intake level of 500 mg specified in the 10th edition of the NAS RDA publication (Ref. 26).

50. The feasibility of achieving an intake approximating the proposed DRV of 2,400 mg of sodium was questioned by a few comments. These comments stated that the proposed DRV is not reasonable or practical, will be difficult to achieve, and will cause unnecessary frustration to consumers trying to meet the goal. One comment suggested that the proposed DRV is too restrictive for restaurant nutrition programs, which must be concerned with taste, affordability, and availability. To emphasize the difficulty of achieving daily sodium intakes of 2,400 mg, the comment referred to a recent review article on sodium intervention trials (Ref. 52) that found that daily intakes of 3,000 mg were only achievable with intensive, multifaceted interventions and highly motivated individuals. The article concluded that general population goals must be modest, or the food supply must change significantly.

FDA recognizes that the current sodium intake of many people exceeds the DRV level of 2,400 mg (56 FR 60825 at 60825), and that sodium is very prevalent in the food supply. However, the agency disagrees that intakes of 2,400 mg sodium are not feasible. Sodium is largely a discretionary addition to foods, usually as sodium chloride or table salt. In fact, estimates suggest that 90 percent of the sodium in foods is from added salt (Refs. 53 and 54) and thus can more easily be controlled by food processors and consumers than can substances in food that are naturally-occurring. Additionally, because reduced sodium intake is a recognized public health priority (Refs. 2, 3, and 5), the agency believes that it is appropriate to set the DRV at a level that is consistent with that goal and that will stimulate changes in the marketplace that are technologically feasible. Therefore, FDA is retaining the DRV of 2,400 mg for sodium (proposed as § 101.9(c)(12)(i) and redesignated below as § 101.9(c)(9)).

51. One comment suggested that the statement in FDA's proposal that the "majority of the current dietary intake of sodium results from ingestion of sodium chloride" contradicts a previous FDA statement that a substantial amount of sodium comes from nonsalt sources. The comment did not identify the FDA statements to which it was referring.

This comment infers that "substantial" and "majority" are synonymous. FDA disagrees with this comment. A dictionary definition (Ref. 55) for the word "substantial" characterizes the word as meaning of ample or considerable amount, quantity, size, etc., or of real worth, value, or effect. It does not define "substantial" as "majority." In its proposal on RDI's and DRV's, the agency referenced a statement from Diet and Health (Ref. 3) that the majority of sodium intake is from sodium chloride. This statement is not inconsistent with the agency's 1982 findings (47 FR 26590) that nonsalt sources can also provide meaningful, important, or "substantial" contributions to the diet.

M. DRV for Potassium

52. One comment suggested that the DRV's should be limited to those dietary components that are the subject of dietary guidelines. It highlighted the establishment of a DRV for potassium as scientifically unjustifiable.

As described in the proposal to this final rule, FDA has used major consensus reports in developing the DRV's. Among these is the well recognized and accepted Diet and Health (Ref. 3), published by NAS. This report specifically recommends a quantitative intake of potassium to assist in reducing the risk of stroke. FDA does not find compelling the comment's argument that, because potassium is not specifically listed in Dietary Guidelines for Americans (Ref. 5), a DRV is not justified. The Dietary Guidelines are intended to provide general food guidance and do not necessarily specify recommended intakes for individual nutrients. The agency notes that no

other comments were received expressing concern about this DRV. The agency is, therefore, retaining the DRV for potassium (3,500 mg).

Additionally, for completeness, FDA is including the listing of potassium based on its DRV value in §§ 101.3(e)(4)(ii) and 104.20(c)(1) and (d)(3).

VI. Conforming Amendments

53. One comment expressed concern that the proposed RDI's will have implications for all alternative products (e.g., reduced fat) formulated to achieve nutritional equivalency to their traditional counterparts. According to the comment, a traditional product containing nutrient levels at less than the 2 percent U.S. RDA criterion, and thus not requiring fortification of the analog, could now meet a 2 percent RDI criterion and thus fortification of the analog would be required. For example, a typical dressing contains 1.88 percent of the U.S. RDA for vitamin E. Because this amount is less than the 2 percent U.S. RDA criterion, fortification of an analog product is not required. However, under the proposed RDI's, the traditional product would contain 4.58 percent of the RDI for vitamin E, requiring fortification in an analog product if the analog did not contain this level of the nutrient. The comment questioned whether the agency intended expanded fortification of analog products with introduction of new RDI's, because the agency had failed to address identity labeling of food in packaged form (§ 101.3(e)), particularly where the definition of "nutritional inferiority" is concerned.

The agency acknowledges that the levels of nutrients chosen as the RDI's will have an effect on achieving nutritional equivalency for all alternative products formulated to be substitutes for traditional products. However, FDA believes that the levels of the RDI should not be established or influenced by the effect that they will have on how nutritional equivalency is achieved in the formulation of alternative products. Rather, they should be based on sound public health principles. FDA established the 2 percent threshold for achieving nutritional equivalency (§ 101.3(e)) because that level is a measurable amount of most nutrients in a food. The adjustment of the RDI's upward, consistent with the population coverage approach, would however limit the number of situations in which nutrient levels in traditional products were below the threshold for some U.S. RDA's but are above that threshold with respect to the RDI's.

54. One comment suggested that vitamin K, molybdenum, and chloride be removed from the list of nutrients required to meet nutritional equivalency (proposed § 101.9(c)(11)(iv) and redesignated as § 101.9(c)(8)(iv)), and that FDA should include a clear statement in § 101.3(e) that selenium, fluoride, and chromium are not to be considered for nutritional equivalency purposes. According to the comment, these nutrients are of little health significance for the general healthy population.

The agency acknowledges that an increase in the number of nutrients for which label reference values (RDI's) are established would mean that efforts to obtain nutritional equivalency may require the addition of additional nutrients to substitute foods. Furthermore, the agency agrees that some of these nutrients are not considered to be of public health interest. However, any change in what constitutes nutritional equivalency would require a reevaluation of § 101.3(e), which is beyond the scope of the 1990 amendments.

However, the agency recognizes that at this time there are no listed sources (i.e., GRAS or approved food additive) for selenium, molybdenum, fluoride, and chromium. In its proposal to this final rule, the agency failed to identify molybdenum as a nutrient without a listed source. However, despite no known issues of safety, the agency believes that it would be inappropriate to include molybdenum on a list of nutrients to be added to a food for nutritional equivalency when there are no listed sources for molybdenum. Therefore, FDA would have amended § 101.3(e)(4)(ii) to state that these elements are not required for nutritional equivalency.

However, based on the provisions of the DS Act, FDA is retaining, for the time being, the label reference values as established in current § 101.9(c)(7)(iv). Because there are no label reference values for the nutrients mentioned in the comments (i.e., vitamin K, molybdenum, chloride, selenium, fluoride, and chromium), there is no need to revise § 101.3(e)(4)(ii) to specifically exclude these nutrients. Therefore, § 101.3(e)(4)(ii) is amended to be consistent with these final regulations by referring to the Daily Reference Values (DRV's) of protein in § 101.9(c)(7)(iii) and of potassium in § 101.9(c)(9) and to the Reference Daily Intakes (RDI's) of vitamins and minerals in § 101.9(c)(8)(iv). FDA will reach a final decision on the other issues discussed in this comment following the provisions of the DS Act.

VII. Environmental Impact

The agency previously considered the environmental effects of the action being taken in this final rule. As announced in the proposed rule on reference daily intakes and daily reference values and mandatory nutrition labeling (56 FR 60366, November 27, 1991), the agency determined that under 21 CFR 25.24(a)(8) and (a)(11), these actions are of a type that do not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

Several comments on the proposed rule suggested that there would be significant adverse environmental effects from the final rules unless the agency allowed more time between the publication of the final rules and their effective dates. The concern in these comments was that, if the agency did not allow firms more time between the publication of the final rules and their effective dates to use up existing label inventories, large stocks of labels and labeled packaging would have to be discarded. These comments questioned whether the agency had sufficiently examined the impact of disposing of obsolete labels and labeled packaging on this country's solid waste disposal capabilities. Two comments estimated the amounts of labeling from their respective industries, i.e., dairy and confectionery, that would need to be discarded following publication of FDA's final rules on several food labeling actions, including this action. However, these comments did not: (1) Provide details on how these estimates were derived, (2) identify what portion of the estimated amounts are attributable to these two actions, or (3) describe what impact the discarded labels and packaging would have on the disposal of solid waste. In its November 27, 1991, nutrition labeling proposed rule, the agency proposed that the final rules for these actions would become effective 6 months following their publication in the **Federal Register**.

However, the agency has decided not to make the final rule effective until May 8, 1994. FDA believes there will thus be ample time for food companies to use up most of the existing labeling and packaging stocks and to incorporate labeling language that complies with FDA's regulations into their food labels. Consequently, the comments on the potential for adverse environmental effects do not affect the agency's previous determination that no significant impact on the human

environment is expected and that an environmental impact statement is not required.

VIII. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), and along with the food labeling proposals the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

IX. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects

21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

21 CFR Part 104

Food grades and standards, Frozen foods, Nutrition.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 101 and 104 are amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.3 is amended by revising paragraph (e)(4)(ii) to read as follows:

§ 101.3 Identity labeling of food in packaged form.

* * * * *

(e) * * *

(4) * * *

(ii) For the purpose of this section, a measurable amount of an essential nutrient in a food shall be considered to be 2 percent or more of the Daily Reference Value (DRV) of protein listed under § 101.9(c)(7)(iii) and of potassium listed under § 101.9(c)(9) and the Reference Daily Intake (RDI) of any vitamin or mineral listed under § 101.9(c)(8)(iv).

* * * * *

3. Section 101.9 is amended by adding paragraphs (c)(7)(iii), (c)(8)(iv), and (c)(9) to read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(c) * * *

(7) * * *

(iii) For the purpose of labeling with a percent of the Daily Reference Value (DRV) or RDI, a value of 50 grams of protein shall be the DRV for adults and children 4 or more years of age, and the RDI for protein for children less than 4 years of age, infants, pregnant women, and lactating women shall be 16 grams, 14 grams, 60 grams, and 65 grams, respectively.

* * * * *

(8) * * *

(iv) The following RDI's and nomenclature are established for the following vitamins and minerals which are essential in human nutrition:

Vitamin A, 5,000 International Units.
Vitamin C, 60 milligrams.
Thiamin, 1.5 milligrams.
Riboflavin, 1.7 milligrams.
Niacin, 20 milligrams.
Calcium, 1.0 gram.
Iron, 18 milligrams.
Vitamin D, 400 International Units.
Vitamin E, 30 International Units.
Vitamin B_6, 2.0 milligrams.
Folic acid, 0.4 milligrams.
Vitamin B_{12}, 6 micrograms.
Phosphorus, 1.0 gram.
Iodine, 150 micrograms.
Magnesium, 400 milligrams.
Zinc, 15 milligrams.
Copper, 2 milligrams.
Biotin, 0.3 milligram.
Pantothenic acid, 10 milligrams.

(9) For the purpose of labeling with a percent of the DRV, the following DRV's are established for the following food components based on the reference caloric intake of 2,000 calories:

Food component	Unit of measurement	DRV
Fat	gram (g)	65
Saturated fatty acids	do	20
Cholesterol	milligrams (mg)	300
Total carbohydrate	grams (g)	300
Fiber	do	25
Sodium	milligrams (mg)	2,400
Potassium	do	3,500
Protein	grams (g)	50

* * * * *

PART 104—NUTRITIONAL QUALITY GUIDELINES FOR FOODS

4. The authority citation for 21 CFR part 104 continues to read as follows:

Authority: Secs. 201, 403, 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 343, 371(a)).

5. Section 104.20 is amended in paragraph (a) by removing "U.S. RDA's" the two times it appears and replacing it with "Reference Daily Intakes (RDI's)" and "RDI's", respectively, and by revising paragraphs (c)(1) and (d)(3) to read as follows:

§ 104.20 Statement of purpose.

* * * * *

(c) * * *

(1) The nutrient is shown by adequate scientific documentation to have been lost in storage, handling, or processing in a measurable amount equal to at least 2 percent of the Daily Reference Value (DRV) of protein and of potassium and 2 percent of the Reference Daily Intake (RDI) in a normal serving of the food.

* * * * *

(d) * * *

(3) The food contains all of the following nutrients per 100 calories based on 2,000 calorie total intake as a daily standard:

Nutrient	Unit of measurement	DRV or RDI[1]	Amount per 100 calories
Protein	grams (g)	50	2.5
Vitamin A	International Unit (IU)	5,000	250
Vitamin C	milligrams (mg)	60	3
Calcium	g	1	0.05
Iron	mg	18	0.9
Vitamin D	IU	400	20
Vitamin E	do	30	1.5
Thiamin	mg	1.5	0.08
Riboflavin	do	1.7	0.09
Niacin	do	20	1
Vitamin B_6	do	2.0	0.1
Folate	micrograms (µg)	400	20
Vitamin B_{12}	do	6.0	0.3
Biotin	mg	0.3	0.015
Pantothenic acid	do	10	0.5
Phosphorus	g	1.0	0.05
Magnesium	mg	400	20
Zinc	do	15	0.8
Iodine	µg	150	7.5
Copper	mg	2.0	0.1
Potassium	do	3,500	175

[1] RDI's for adults and children 4 or more years of age.

Dated: October 29, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 92-31502 Filed 12-28-92; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 90N-0165]

RIN 0905-AD08

Food Labeling; Serving Sizes

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its nutrition labeling regulations to: (1) Define serving size on the basis of the amount of food customarily consumed per eating occasion; (2) establish reference amounts customarily consumed per eating occasion (reference amounts) for 139 food product categories; (3) provide criteria for determining label serving sizes from the reference amounts; (4) require the use of both common household and metric measures to declare serving sizes; (5) define a "single-serving container;" (6) require that the use of claims such as "low sodium" be based on the reference amount; (7) permit the declaration of serving size in U.S. measures (ounces (oz), fluid ounces (fl oz)); and (8) permit the optional declaration of nutrient content per 100 grams (g) or 100 milliliters (mL). This action is in response to the requirements of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments).

EFFECTIVE DATE: May 8, 1994.

FOR FURTHER INFORMATION CONTACT: Youngmee K. Park, Center for Food Safety and Applied Nutrition (HFS-465), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5489.

SUPPLEMENTARY INFORMATION:

I. Background

A. Proposed Regulation, Nutrition Labeling and Education Act of 1990, and Institute of Medicine's Report on Nutrition Labeling

In the **Federal Register** of July 19, 1990 (55 FR 29487), FDA published a proposed rule entitled "Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision" to amend its food labeling regulations to require nutrition labeling on most food products that are meaningful sources of nutrients. In the same issue of the **Federal Register** (55 FR 29517), FDA published a technical supporting proposal entitled "Food Labeling; Serving Sizes" (hereinafter referred to as the 1990 proposal).

The 1990 proposal on serving sizes stated that in view of the many comments that the agency had received stating the need for more realistic and consistent serving sizes, FDA had concluded that reasonable and standardized serving sizes should be established. The agency proposed to amend the nutrition labeling regulations to: (1) Define serving and portion size on the basis of the amount of food commonly consumed per eating occasion by persons 4 years of age or older, by infants, or by children under 4 years of age (toddlers); (2) require the use of both U.S. and metric measures to declare serving size; (3) permit the declaration of serving (portion) size in familiar household measures; (4) permit the optional declaration of nutrient content per 100 g or 100 mL; (5) define "single-serving containers" as those that contain 150 percent or less of the standard serving size for the food product; and (6) establish standard serving sizes for 159 food product categories to ensure reasonable and uniform serving sizes upon which consumers can make nutrition comparisons among food products. Interested persons were given until November 16, 1990, to submit comments to the agency on the 1990 proposal.

On September 26, 1990, the National Academy of Sciences' Institute of Medicine (IOM) issued a report entitled "Nutrition Labeling, Issues and Directions for the 1990s" (hereinafter referred to as the IOM Report) (Ref. 1). The IOM report was written under contract to the Public Health Service, U.S. Department of Health and Human Services (DHHS) and the Food Safety and Inspection Service, U.S. Department of Agriculture (USDA). On October 5, 1990, FDA published a notice in the **Federal Register** (55 FR 40944) announcing the availability of the IOM report and requesting that interested persons comment on the implications of the report for the agency's July 19, 1990, proposals on food labeling. The report made several recommendations related to serving sizes.

On November 8, 1990, the President signed into law the 1990 amendments (Pub. L. 101-535). The 1990 amendments added section 403(q) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(q)). Section 403(q) of the act specifies, in part, that:

> * * * the serving size * * * is an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food, or * * * if the use of the food is not typically expressed in a serving size, the common household unit of measure that expresses the serving size of the food.

The 1990 amendments also require, in section 2(b)(1)(B), that FDA adopt regulations that: "* * * establish standards * * * to define serving size or other unit of measure for food, * * *."

While the requirements of the 1990 amendments that pertain to serving size are similar in many respects to FDA's 1990 proposal, differences exist, and questions about the exact meaning and the implementation of those provisions have been raised.

On February 26, 1991 (56 FR 8084), FDA announced a public meeting to discuss several issues arising from the comments on the serving size proposal, the 1990 amendments, and the IOM report. The meeting was held on April 4, 1991 (hereinafter referred to as the 1991 public meeting), and provided an opportunity for the public to submit oral and written comments on the issues identified in the notice.

B. The 1991 Serving Size Regulation

FDA carefully considered the serving size provisions of the 1990 amendments, the comments that it received in response to the **Federal Register** documents on serving size and at the 1991 public meeting, and the recommendations related to serving size contained in the IOM report. As a result, the agency decided to repropose the serving size regulation for two major reasons. First, FDA wished to take advantage of the explicit legal authority provided by the 1990 amendments to regulate the serving sizes used on the nutrition label. Secondly, the agency decided to make a number of changes in response to the comments received on the **Federal Register** documents and at the public meeting on serving sizes and to explain its reasons for agreeing or not agreeing with the comments.

To implement the 1990 amendments, FDA issued a proposed rule in the **Federal Register** of November 27, 1991 (56 FR 60394; corrected at 57 FR 8179, March 6, 1992) (hereinafter referred to as the 1991 serving size proposal). In that document, FDA proposed to: (1) Modify the definition of serving size in the 1990 proposal to be consistent with that in the 1990 amendments; (2) adopt regulations that provide standards for defining serving sizes; and (3) require the use of both common household and metric measures to declare serving sizes. The proposed standards had two basic elements: (1) Reference amounts of food that are customarily consumed per eating occasion for 131 product categories; and (2) procedures for determining serving sizes for use on

product labels from the reference amounts. The second element was necessary because while the reference amounts are defined primarily in metric units, under the act the serving sizes must be expressed in common household measures that are appropriate to the particular food.

In addition, in response to the many requests for changes in other aspects of the 1990 proposal and on its own initiative, the agency proposed to: (1) Revise the definition for single-serving containers to increase the upper limit from "150 percent or less" to "less than 200 percent;" (2) revise the basis for evaluating label claims such as "low sodium" to include both the declared serving size and the reference amount; (3) permit the optional declaration of serving size in U.S. measures; and (4) permit the optional declaration of nutrient content per 100 g, 100 mL, 1 oz, or 1 fl oz. Interested persons were given until February 25, 1992, to submit comments to the agency on the 1991 serving size proposal.

On January 3, 1992 (57 FR 239), FDA announced a public hearing to discuss all of the agency's proposed food labeling regulations that implement the 1990 amendments. The hearing was held on January 30 and 31, 1992 (hereinafter referred to as the 1992 public hearing). Some of the presentations and written comments submitted in response to this hearing discussed issues related to serving sizes.

This final rule responds to the written comments received on the 1991 serving size proposal and the written comments and presentations given at the 1992 public hearing on issues related to serving sizes.

II. Review of Comments

FDA received about 700 comments on the 1991 serving size proposal. Approximately 50 percent were from domestic food industries and trade organizations; about 35 percent were from consumers and consumer organizations; about 10 percent were from health professionals, health and other professional organizations, and academia; about 5 percent were from Federal, State, and local government; and less than 1 percent was from foreign industries and governments.

About 20 oral presentations at the 1992 public hearing discussed issues related to serving sizes. A written transcript of the meeting is on file with Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. FDA also received written comments that discussed issues related to serving sizes in response to the notice of the public hearing. Issues discussed at the hearing mostly reiterated the issues discussed in written comments on the 1991 serving size proposal. Therefore, a separate evaluation has not been done for the comments received in response to the 1992 public hearing. FDA will respond to these comments together with all comments received in response to the 1991 serving size proposal.

Consumers overwhelmingly supported the provisions in the 1991 serving size proposal and again emphasized the need for realistic and standardized serving sizes. Health professionals and nutritional or health professional organizations generally supported the provisions in the 1991 serving size proposal. Many industry and trade associations supported the general approach that FDA took in the 1991 serving size proposal. However, they often disagreed with specific aspects of the procedures used to determine reference amounts, specific reference amounts, or some other specific aspects of the 1991 serving size proposal. International comments again emphasized the need for international harmonization of food labeling (e.g., these comments usually recommended the use of 100 g (or mL) as the basis for the nutrition information).

The agency will describe the comments on serving sizes in more detail and respond to them by topic in the discussion of the final regulation that follows.

III. The Final Regulation

A. Legal Authority

1. A manufacturer contended that the 1990 amendments did not mandate that FDA establish, by regulation, specific serving sizes for each food. The comment objected to FDA taking away its right to set serving sizes within the broad parameters of being reasonable, fair, and consistent. The comment stated that the 1990 amendments authorized FDA to establish standards or guides that the manufacturer must follow when the manufacturer sets the specific serving size. A trade association stated that FDA's proposed "device" of reference amounts does not qualify as standards because when reference amounts are applied using the proposed procedures, they amount to specific serving sizes. Another industry comment stated that some reference amounts were expressed in common household measures (e.g., cups, tablespoon (tbsp.)), and therefore, label serving sizes in common household measures will be the same as the reference amount. This, the comment argued, disqualifies these reference amounts from being standards.

FDA disagrees with the comments. First, FDA did not establish "specific serving sizes" for each food. The agency established a system that consists of the two basic elements described above. A manufacturer uses these elements to determine the serving size most appropriate for specific products. The fact that a manufacturer has relatively limited discretion within that system does not represent an infirmity in the system. Section 403(q)(1)(A)(i) of the act establishes the fundamental principle for determining serving size. This principle is much more specific than, as one comment suggested, that the amount be reasonable, fair, and consistent. The act requires that the serving size be an amount of the food that is customarily consumed.

The legislative history in section 2(b)(1)(B) of the 1990 amendments is silent as to what type of standards that Congress contemplated in that section. It merely directs the agency to establish them (H. Rept. 101-538, 101st Congress, 2d sess. 18 (1990)). (See also the House report at page 7: "In order to make this information meaningful, the bill requires the FDA to issue standards providing that uniform serving size information and information concerning the number of servings be furnished on the food label.") Thus, the question as to whether the standards that FDA proposed are adequate and consistent with the act really becomes a question of whether the serving size that results from applying that standard represents an amount customarily consumed. Significantly, none of these comments claimed that it does not. Consequently FDA concludes that the two element system that it proposed in the 1991 serving size proposal constitutes a standard for determining serving sizes that is consistent with the act.

2. An industry comment stated that the 1990 amendments give FDA the legal authority to use any unit of measure (not necessarily a serving based on customarily consumed amounts) that it deems most appropriate for expressing the nutrient content of foods. The comment stated that food consumption surveys, such as the Nationwide Food Consumption Survey (NFCS) conducted by USDA, do not provide "real" consumption values, because there are too many varieties of different foods, different uses of the same foods, different foods for the same use, and other variables, and because there is too much diversity in individual consumption to establish any sort of meaningful or representative consumption standard. The comment

asserted that as long as competitive products are given the same serving size value, it is not that important whether there is valid supporting data. The comment recommended the use of "reference nutrition units" that would eliminate the idea that the serving size represents what people really eat. Under the system suggested by this comment, all foods would be given a reference point that represents a reasonable quantity of food for a given category, and all competitive foods would be given the same reference point.

FDA disagrees with the comment that the 1990 amendments allow the agency to use any unit of measure that it deems most appropriate for expressing the nutrient content of foods. Section 403(q)(1)(A)(i) of the act clearly defines serving size as an amount of food customarily consumed. As discussed in the 1991 serving size proposal (56 FR 60394 at 60400), FDA is well aware of the high variability in the amounts customarily consumed by individuals, as well as other factors such as many different uses of the same food and many different foods for the same use. These issues complicate the process for determining reference amounts. However, FDA continues to believe that by using data from national food consumption surveys, such as the NFCS, and by following the principles and procedures that it described in the 1991 serving size proposal, a reasonable reference amount that represents the amount of food customarily consumed within each product category can be determined for the major usage of the food.

FDA also disagrees with the comment that stated that as long as competitive products are given the same serving size value, valid supporting data are not important. FDA does not believe that the only intent of the 1990 amendments is to establish the same serving size for competitive products. FDA believes that the intent is also to ensure that nutrition information will be based on a meaningful quantity of food, the amount customarily consumed. Competitive foods often differ in characteristics (e.g., density) that affect the amount customarily consumed. For example, ready-to-eat breakfast cereals compete with one another, but their densities (g per cup) differ widely, from less than 20 g per cup to over 120 g per cup. Food consumption data show that the amount customarily consumed depends on the density of the cereal. Therefore, the same serving size should not be used for all ready-to-eat breakfast cereals. In this case using the same serving sizes for competitive products could be misleading to consumers.

B. Definition of Serving Size

In accordance with the 1990 amendments, FDA proposed in § 101.9(b)(1) to define "serving" or "serving size" to mean:

> an amount of food customarily consumed per eating occasion by persons 4 years of age or older which is expressed in a common household measure that is appropriate to the food. When the food is specially formulated or processed for use by infants or by toddlers, a serving or serving size means an amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively.

In the same section, FDA proposed to define "portion" to mean "an amount of a food that is not typically expressed in a serving size, i.e., a food customarily used only as an ingredient in the preparation of other foods, (e.g., 1/4 cup flour or 1/4 cup tomato sauce)."

Over 75 percent of the approximately 80 comments that addressed the definition of serving size agreed with FDA's proposal for the definition of serving size. These comments pointed out that the act explicitly states that the serving size shall be an amount customarily consumed in terms of a common household measure appropriate to the food, and that thus FDA's proposed definition is consistent with the requirements of the act. Approximately 25 percent of the comments received on this issue disagreed with FDA's proposal. The reasons for the disagreement, and the definitions suggested in these comments, are discussed below.

3. Several comments stated that FDA should use the serving sizes in the diabetic exchange list as the serving sizes for nutrition labeling of food because they are already in use, and because people are familiar with the serving size contained in the exchange list.

FDA disagrees with these comments. Section 403(q)(1)(A)(i) of the act defines serving size as "an amount customarily consumed." Thus, the act links serving size to the amount consumed. Serving sizes contained in the diabetic exchange list are not based on amounts customarily consumed by the American public. They are tailored to meet a special dietary need of a subpopulation that has a unique health problem. They are inappropriate to use as serving sizes for the nutrition labeling of products for the general population because the serving sizes for a population with a medical problem do not necessarily reflect the consumption practices of the general healthy population. For example, to facilitate achievement of medical goals of this subpopulation, the serving sizes in the exchange lists are based on the calorie content and the energy-producing macronutrient content of specific foods and may not, as required by the act, reflect amounts of food customarily consumed by average consumers. The 1991 serving size proposal discussed in detail the reasons why FDA cannot use the serving sizes contained in the diabetic exchange list for the nutrition labeling of food (56 FR 60394 at 60399). None of the comments provided any basis for finding that that discussion was wrong. Therefore, FDA has not modified the definition of "serving size" in response to these comments.

4. International comments and several U.S. manufacturers opposed nutrition information based on serving sizes. Some pointed out that the European Community directive requires that all nutrition information be on a 100 g or 100 mL basis. The comments argued that requiring nutrition information on a per serving basis offers little consistency with nutrition labeling in other countries and creates a significant trade barrier.

FDA recognizes that many foreign countries use 100 g or 100 mL as the basis for nutrition labeling. However, the act requires that the nutrition information be provided on a per serving basis. The act also defines serving size as an amount customarily consumed which is expressed in a common household measure that is appropriate to the food. The 100 g or 100 mL does not represent an amount customarily consumed for many foods. In addition, g and mL are not common household measures in the United States. Therefore, FDA cannot use 100 g or 100 mL as the basis for the primary serving size. However, partly to facilitate the utility of the serving size in the international community, FDA is requiring in new § 101.9(b)(7) that the equivalent metric quantity be declared on the label in addition to the serving size in a common household measure and is permitting, in new § 101.9(b)(10)(i), a voluntary listing of a second column of values on a per 100 g or 100 mL basis.

5. Several industry and consumer comments suggested using 1 oz for the serving size rather than customarily consumed amounts. The comments contended that: (1) A uniform 1-oz serving size allows nutrition comparisons of all foods; (2) nutrition information per oz allows calculation of the nutrient content of food per serving of an individual's choice; and (3) the word "serving" is confusing and should be eliminated. Another consumer comment argued that few people

measure out a serving of a product as noted on packages. Most people just pour an amount that they feel is reasonable or desirable. Therefore, it is not necessary to have standard serving sizes. Rather, FDA should use 1 oz as the basis for nutrition information.

As discussed above, section 403(q)(1)(A)(i) of the act requires that serving sizes be in amounts customarily consumed. Because 1 oz is not an amount customarily consumed for many products, FDA cannot use 1 oz as the basis for nutrition information for all products.

6. Some consumer comments suggested defining serving size as the amount consumed by adult females. The comments stated that females need smaller amounts of food to maintain good nutrition and health. The comments were concerned that if serving sizes are based on the amount consumed by adult males, the quantity will be too large for females. Another consumer comment suggested that FDA define serving size as the amount consumed by a "middle consumption group between youth and men." The comment contended that if the serving size is set at a middle consumption level, it would be "easier to decrease for youth and increase for men."

FDA believes that these comments misunderstand the purpose of a serving size on product labels. The serving size declared on the product label is not an amount recommended for consumption. It is, by statute, the amount customarily consumed. FDA believes that promoting recommended servings can best be addressed through public education. The agency's promulgation of nutrition labeling regulations will be followed by a consumer education program to assist consumers in using the nutrition information on the label, including how nutrition information based on labeled serving size should be adjusted on the basis of an individual's actual or recommended serving size. FDA is currently planning for these activities.

The general food supply is consumed by the general population which is defined, for regulatory purposes, as all persons 4 years of age or older. Therefore, serving sizes should reflect the amounts customarily consumed by the general population and not by any selected age or sex group (e.g., adult male or female) within the general population.

7. An industry comment stated that the phrase "per eating occasion" should be deleted from the definition of serving size because small amounts of food consumed, such as for tasting during food preparation, could be counted as an eating occasion.

FDA does not believe that the issue raised by this comment presents a problem. The term "eating occasion" in food consumption surveys usually refers to meals and snacks. Even if the small amounts of food consumed during tasting are included in determining the amount of food customarily consumed per eating occasion, the general principles and factors (e.g., use of the mean, median, and modal consumed amount per eating occasion) considered by FDA in arriving at the reference amounts ensure that such infrequently reported small amounts would not affect the determination of the amount customarily consumed per eating occasion. Furthermore, deletion of the term "per eating occasion" would leave the definition of serving size open-ended, which would likely result in more inconsistencies among serving sizes. Therefore, FDA is retaining the term "per eating occasion" as part of the definition for serving size.

8. A consumer comment stated that because different units are used for serving size (e.g., oz, tbsp.) and nutrition information (e.g., g), the current nutrition information is not useful to estimate the percent of a nutrient (e.g., fat) in the product. The comment stated that expressing both serving size and nutrition information in g would facilitate computation of the percentage of a nutrient in the product. The comment, therefore, suggested that FDA mandate that the nutrition information of all products be provided on a per 100-g basis, instead of common household measures.

FDA understands the consumers' desire for information on the percentage of fat in the product. However, the act mandates that the primary unit for the serving size should be a common household measure that is most appropriate to the specific product. Therefore, serving sizes will continue to be expressed in common household measures (e.g., cups, tbsp., oz). However, FDA notes that it is also requiring metric equivalents of the household measures (e.g., 1 cup (55 g)). Therefore, nutrition information on a per 100-g basis is not necessary to facilitate such computation. Consumers who desire information on the percentage of a nutrient in the product should be able to calculate this number from the metric equivalent of the serving size and the amount of the nutrient, expressed in g.

9. A trade association stated that industry makes no distinction between the terms "serving" and "portion." The comment contended that FDA's definition is not consistent with the industry's usage of "portion." Limiting the term "portion" for use with products that are used primarily as ingredients (e.g., flour, tomato sauce) creates more confusion in terminology and contributes nothing to nutrition labeling.

FDA agrees with this comment. Because foods such as flour and tomato sauce are not served by themselves but as part of other foods, conceptually the term "serving" may not be as appropriate as the term "portion" as defined in the 1991 serving size proposal. However, FDA acknowledges that many manufacturers use "serving" and "portion" interchangeably. These terms are also used interchangeably in the literature (Ref. 37). FDA also recognizes that consumers are not likely to distinguish between the two terms, and that the use of two different terms on the label could be confusing. For these reasons, FDA is deleting the definition of "portion" from new § 101.9(b)(1).

C. Definition of Single-Serving Container

FDA proposed in § 101.9(b)(6) to define a single-serving container as a product that is packaged and sold individually containing less than 200 percent of the applicable reference amount. (Section 101.9(b)(6) of the 1991 serving size proposal had a typographical error and stated "packaged or sold individually" instead of "packaged and sold individually.") The agency proposed to require that the entire content of such products be labeled as one serving. In addition, the agency proposed that packages sold individually that contain 200 percent or more of the applicable reference amount may be labeled as a single-serving if the entire content of the package can reasonably be consumed at a single eating occasion.

FDA received many comments on issues related to the definition of a single-serving container. About half of the comments agreed with the proposed definition. The other half, mostly industry comments, opposed or had reservations on some aspects of the proposed definition.

10. The majority of the comments disagreeing with the proposal objected to the proposed upper limit of "less than 200 percent." These comments argued that FDA provided insufficient reasons for increasing the upper limit from 150 percent to 200 percent of the reference amount, placing considerable importance on a few new single-serving products, such as buffet cans of canned fruit with pop-tops and king-sized candy bars. The comments stated that FDA ignored many other products on

the market for which the 200 percent cutoff level would be unreasonably high. Examples given included 6 oz cans of tuna, 10 oz cans of canned fruits, 9 oz cans of canned vegetables, and 15 to 16 oz cans of ready-to-serve soup or entrees (e.g., chili with beans, spaghetti). These comments recommended that the upper limit be lowered to 150 percent of the reference amount. Several other comments recommended that FDA allow manufacturers to decide whether a package containing 150 to 200 percent of the reference amount is a single serving.

FDA originally proposed 150 percent of the standard serving size (equivalent to the reference amount in the 1991 serving size proposal) for the upper limit (55 FR 29487, July 19, 1990). Several comments and presentations at the 1991 public meeting on serving sizes argued that single-serving packages that are larger than 150 percent of the "standard serving sizes" are not uncommon in the market and may be increasing in number. The agency had also learned, from its own observations in the marketplace, of a trend towards larger "single-serving" packages (e.g., snacks). Therefore, in the 1991 serving size proposal, FDA proposed to change the upper limit for the single-serving container from "less than or equal to 150 percent" to "less than 200 percent."

After careful examination of all comments for and against the 200 percent upper limit, the agency concludes that 200 percent of the reference amount is a more reasonable cutoff level for most products than 150 percent. If FDA lowered the upper limit for single-serving containers to 150 percent of the reference amount as the comments suggested, many foods that are clearly intended for one serving (e.g., 1.8 oz snacks, 1.7 oz candy bars) could be labeled as 2 servings. The agency does not believe that such a result would represent the amount that people customarily consume; therefore, representing such foods as two servings would be confusing and misleading to consumers.

However, FDA agrees with the comments that the 200 percent cutoff level may be too high for some products (e.g., canned fruits and vegetables, soups, and entrees). The reference amounts of these products are very large compared to many other products, and examination of food consumption data showed that the average variability (defined as the standard deviation as a percent of the mean) in the amount customarily consumed for foods having a reference amount of 100 g (or mL) or larger is about two-thirds of the variability for foods having a reference amount less than 100 g (Ref. 38). In other words, it is much less likely that a person will consume approximately twice the reference amount of a food with a reference amount of 100 g or more than it is that he or she would consume twice the reference amount of a food with a smaller reference amount. The agency has therefore concluded that for those products that have reference amounts of 100 g (or mL) or larger, 150 percent is a more reasonable cutoff for a single-serving container. Therefore, FDA is revising § 101.9(b)(6) to allow manufacturers to determine whether there are 1 or 2 servings in packages that contain more than 150 percent but less than 200 percent of the reference amount if the food in the package has a reference amount of 100 g (or mL) or larger.

The agency, however, also concludes that regardless of the package size, a product that is obviously intended to be consumed in one serving (e.g., one unit products in discrete units such as muffins, ice cream bars, and sandwiches; products bearing label descriptions that suggest a single serving such as "singles" or "the perfect size for one") must be labeled as one serving. Otherwise, the labeling will be misleading under section 403(a) of the act.

11. An organization of nutrition professionals recommended changing the upper limit for single-serving containers to include 200 percent of the reference amount, so that 16 fl oz soft drinks would be required to be labeled as one serving. An organization of health professionals urged FDA to require that snack foods provide nutrition information for the entire contents of the package, regardless of the declared serving size. The organization stated that such a requirement would reflect "more accurately consumption patterns for these products."

FDA does not believe that it is appropriate to change the definition of a single-serving container so that certain sizes of a selected class of products can be labeled as a single serving or to set a different requirement for a selected class of products without food consumption data or a scientifically sound basis that supports such a different requirement. The comments did not present any food consumption data or other scientific basis that would justify the suggested changes in the definition of single-serving containers. Therefore, FDA has not adopted these recommendations.

12. Several industry comments requested that the definition of a single-serving container be eliminated, and that nutrition information on all containers be based on the reference amount. The comments requested that the agency, if it chooses to retain the single-serving container definition, allow dual labeling of nutritional values for single-serving containers (i.e., per reference amount and per entire contents of the container). The comments expressed concern that the single-serving container definition would result in different nutrition information on the labels of the same food product found in different sized containers. The comments argued that: (1) Consumers would be confused by such information, and (2) consumers would not be able to compare nutritional values of different brands of the same food because they come in different single-serving sizes. Therefore, these comments contended that FDA should allow manufacturers to voluntarily provide a second column of values based on the reference amount. A few of the comments that supported dual labeling also preferred that the required nutrition information be based on the reference amount, not on the entire contents of the container. However, a large number of consumers requested that FDA require that nutrition information on single-serving products be provided for the entire contents of the container.

FDA recognizes that the proposed rule could result in different nutritional values appearing on the labels of the same food product contained in different container sizes. Whether this would be confusing to consumers was discussed at the 1991 public meeting. In the notice of public meeting, the agency specifically requested views and data on whether differences in the listing of the nutritional content of the same food in different container sizes would be confusing to consumers. No data on this issue were presented at the meeting or in written comments. Comments on the 1991 serving size proposal again claimed that different nutrition information on the same food found in different-sized containers would be confusing to consumers. However, the comments did not submit any data to support their claim. Considering the strong consumer support for the nutrition information based on the entire contents of the container, and in the absence of any data showing that the nutrition information based on the entire contents of the container would be confusing to consumers, the agency has concluded that the definition of single-serving container should be retained, and that nutrition information

of the single-serving containers should be based on the entire contents of the container.

With regard to the requests for dual labeling of single-serving containers, the agency does not believe that it is appropriate under the act. Because, by definition, a single-serving container has a number of servings of 1, nutrition information based on the reference amount would have a fractional number of servings (e.g., 1.4 servings). Consumers repeatedly complained about fractional number of servings on a single-serving container and asked that FDA require manufacturers to provide nutrition information based on the entire contents of the single-serving containers. Thus, there is strong evidence in the record to conclude that presenting a second column of nutrition information based on the reference amount on the single-serving containers will be confusing to consumers. The agency also notes that such information will clutter the label on the already limited space devoted to nutrition labeling. In considering whether to grant this request, FDA considered permitting dual labeling with the number of servings left blank. However, such labeling would fail to include a material fact—how many servings are being provided. Thus, such an approach is not acceptable under the act. Therefore, for these reasons, FDA is rejecting this request.

13. A manufacturer expressed confusion about the definition of single-serving containers. While the preamble of the 1991 serving size proposal specifically stated that no lower limit for the definition of a single-serving container is being established, proposed § 101.9(b)(2)(i) stated, "If a unit weighs 67 percent or more, but less than 200 percent of the reference amount, serving size shall be one unit." The comment interpreted this provision to mean that the lower limit for single-serving containers is 67 percent of the reference amount. The comment also requested clarification on how to label single-serving containers that contain less than 100 percent of the reference amount.

The comment confused a single-serving unit of products in discrete units (e.g., muffin, sliced bread, apple) in a multiunit, and thus multiserving, container with a single-serving container. For products in discrete units that come in multiserving containers, new § 101.9(b)(2)(i) describes the procedure to convert the reference amounts in new § 101.12(b) to label serving sizes in common household measures. Products in discrete units come in many different sizes. To promote uniformity in the serving sizes of similar products, FDA proposed in the 1991 serving size proposal that a unit that weighs at least 67 percent or more, but less than 200 percent, of the reference amount be called a single-serving unit. (The lower limit of the single-serving unit in the final regulation has been changed from 67 percent or more to more than 50 percent (see section III.E.1. of this document).) This provision (new § 101.9(b)(2)(i)) applies to products in discrete units that come in multiserving packages (e.g., sliced products, small candy bars), but it does not apply to single-serving containers.

A single-serving container is a product that is packaged and sold individually and that contains less than 200 percent of the reference amount. As discussed in the 1991 serving size proposal (56 FR 60394 at 60398), FDA did not consider that a lower limit for the single-serving containers was necessary because the agency proposed to base the qualification for claims on the reference amount and the label serving size. The use of the reference amount for the claim evaluation would prevent a single-serving container from qualifying for a descriptor based on the package size alone. Therefore, concern about the potential manipulation of single-serving container sizes to qualify for a "low" claim (e.g., a 1/2 oz. bag of potato chips making a "low sodium" claim) was eliminated. Because there is no lower limit for a single-serving container, a product that is packaged and sold individually and that contains less than the upper limit of the single-serving container must be labeled with the entire contents of the package being one serving. For example, if a muffin that weighs 45 percent of the reference amount is packaged and sold individually, it is a single-serving container product, and the nutrition information is to be provided per the entire content of the container, i.e., one muffin. The agency notes, however, that if a number of these muffins are packaged in a multiserving container, the label serving size for this multiserving container would be the number of muffins that most closely approximates the reference amount, i.e., in this case two muffins.

To avoid any potential confusion, FDA has modified new § 101.9(b)(2) to clearly state that single-serving containers are exempted from the general rule set forth in that section. The modified provision reads: "Except as provided in paragraphs (b)(3), (b)(4), and (b)(6) of this section, * * * serving size declared on a product label shall be determined from the 'Reference Amounts Customarily Consumed Per Eating Occasion' * * *." Single-serving containers are discussed in § 101.9(b)(6).

14. An industry comment did not object to a manufacturer voluntarily listing a product as a single serving if it is slightly greater than 200 percent of the reference amount, provided that this claim was preapproved by FDA. A nutrition professional organization also recommended preapproval of the single-serving status of a package that contains 200 percent or more of the reference amount.

FDA finds no basis to conclude that preapproval is necessary. Because the regulation requires that the serving size for single-serving containers or units (single-serving products) be the entire contents of the container or unit, FDA expects that the manufacturer's decision to declare products that contain 200 percent or more of the reference amount as a single serving will be self-limiting. As the size of the single-serving product increases, the nutrition information will show proportionately larger amounts of nutrients. Although a larger size of single-serving product will show larger amounts of nutrients having positive connotations (e.g., calcium, fiber), most foods also contain nutrients having negative connotations (e.g., calories, fat, sodium). Therefore, single-serving products that are good sources of nutrients with positive connotations will also show larger amounts of nutrients with negative connotations. FDA thus does not anticipate that there will be abuse of this option. In addition, the agency can control obvious abuses of this option under section 403(a) of the act.

15. A consumer organization expressed concern that the proposed upper limit restriction may lead to the declaration of two servings for obviously single-serving products (e.g., a large candy bar, ice cream bar, frozen dinner) that contain slightly more than 200 percent of the reference amount. The comment contended that consumers would be misled by a label that gives nutrition information for half of the obviously single-serving products. The comment requested that FDA require manufacturers to disclose how many servings the package contains on the front panel of packages that contain between 200 and 300 percent of the reference amount.

FDA does not believe that it should require the number of servings on the front panel of products that contain more than the upper limit for the single-serving container. The agency is concerned that such a requirement would result in an information overload, contribute to the space problem for single-serving containers,

and clutter the label. Moreover, to have a clear, readily understandable, and usable definition for "single-serving container," FDA finds that it is appropriate to adopt less than 200 percent of the applicable reference amount as the defining level. However, the agency recognizes the comment's concern. FDA's position, as stated earlier in this section, is that regardless of the package size, a product that is obviously intended to be consumed in one serving (e.g., one unit products in discrete units such as muffins, ice cream bars, and sandwiches; products bearing label descriptions that suggest a single serving such as "singles" and "the perfect size for one") must be labeled as one serving. If it is not, the labeling of the product will be misleading under section 403(a) of the act. Therefore, FDA concludes that no action in response to the comment is necessary.

16. An industry comment stated that, in determining whether a product meets the definition of a single-serving container, it is not clear whether the exact weight of an oz (i.e., 28.35 g) or a rounded value of 30 g or 28 g should be used to calculate the percent of the reference amount from the net oz weight of the package.

The Compliance Policy Guides (7150.17) define 1 oz as 28.34952 g for metric declarations of quantity of contents on product labels (Ref. 39). Therefore, manufacturers should use 28.35 g to convert the oz weight of the package to the g weight.

To calculate the percentage of the reference amount from the net weight of the package, because it is a determination made on a weight/weight basis, manufacturers should divide the net weight of the package in g by the reference amount of the product and multiply by 100. For example, the percent of a reference amount of a product having a net weight of 1.3 oz and a reference amount of 30 g would be [(1.3 x 28.35)/30] x 100, i.e., 123 percent.

For the purpose of expressing the serving size for nutrition labeling, new § 101.9(b)(5)(iv) defines 1 oz as 28 g. Therefore, to express the serving size, manufacturers should use 28 g to convert the serving size in oz to the g-weight equivalent.

D. Reference Amounts for Serving Sizes

To comply with the act with respect to serving sizes, FDA proposed, in § 101.12(b), reference amounts customarily consumed for 131 product categories, covering almost all food products that are regulated by FDA. FDA proposed that these reference amounts be used as the basis for determining serving sizes for specific products. FDA set forth the methodology (general principles and procedures) by which it arrived at the 131 reference amounts. FDA also proposed general rules for determining reference amounts for several product classes, including: (1) Products that require further preparation before consumption; (2) imitation or substitute foods, altered foods, and foods for special dietary use; and (3) products consisting of 2 or more foods having individual reference amounts. This section discusses the comments received on the methodology that FDA used to determine the reference amounts, the number and names of product categories, the reference amounts for specific product categories, the reference amounts for special product classes mentioned above, and how to express or present the reference amounts.

1. Methodology for determining reference amounts

This section discusses comments that addressed the general principles and procedures for determining the reference amounts. Comments that discussed the methodologies for determining the reference amounts for specific product categories are included in section III.D.5. of this document, which discusses issues related to the reference amounts for specific categories.

17. Some comments objected to using food consumption data as the primary source in determining the reference amounts. The reasons for this objection varied. Some comments reasoned that food consumption data have many limitations, and therefore it is not possible to derive accurate estimates of the customarily consumed amounts from such data. Other objections included that: (1) Food consumption data, such as the NFCS used by FDA, contain only a limited number of days of information (e.g., 3 days) and are not appropriate to use to determine "long-term" intake, and (2) reference amounts should be based on what people should eat rather than what they usually eat. The comments recommended using other sources of information such as industry's "longstanding" serving sizes, the serving sizes currently used by industry, or the serving sizes in dietary guidance documents. Some industry comments also stated that changing the currently used serving sizes would be confusing to consumers. Other comments, however, opposed the use of industry's "longstanding serving sizes or opposed the use of any data other than food consumption data, arguing that they do not fulfill the act's requirement that the serving sizes reflect amounts customarily consumed.

Section 403(q)(1)(A)(i) of the act, which states that a serving size is the amount customarily consumed, effectively requires the use of food consumption data as the primary basis for determining serving sizes. Without such data, it is impossible to determine the amount of food that is customarily consumed. FDA is well aware of the limitations of the available food consumption data bases. However, these data bases are still the best sources of food consumption data collected under actual conditions of use available to the agency. Thus, FDA concludes that its use of food consumption data as the primary source for the customarily consumed amounts of food for nutrition labeling purposes is appropriate.

FDA agrees with the comments that stated that sources other than food consumption data are sometimes appropriate. Thus, when food consumption data were inadequate, the agency used the other sources of information listed in § 101.12(a)(5) to determine the reference amounts.

As for the use of the "longstanding" serving sizes, in the notice for the 1991 public meeting (56 FR 8084), FDA requested comments and supporting data on the definition of a "longstanding" serving size. In response to this notice, the agency received only one comment that stated that "longstanding" serving size should include serving sizes used before 1973, as a minimum, and presented three examples of serving size used before that date. Since it had no established definition or sufficient data to define "longstanding" serving sizes, the agency took into consideration all serving sizes suggested in comments regardless of their history of use in determining the reference amounts proposed in the 1991 serving size proposal. In comments to the 1991 serving size proposal, the agency has not received any additional information or data on how to define a "longstanding" serving size. Therefore, it is unable to define "longstanding" serving sizes.

FDA does not agree with the industry comment that changing the currently used serving sizes would be confusing to consumers, and the agency has not received any data to support these arguments. On the contrary, consumer comments overwhelmingly attest to the fact that the current system that allows a proliferation of serving sizes has been very confusing. Congress also recognized this fact. The House Report specifically states: "The Committee believes that the current information

about serving size on many foods is extremely misleading" (H. Rept. 101–538, supra, 18). Establishing standard serving sizes will reduce this confusion and provide a consistent basis for serving sizes and for claims based on them. Moreover, some of the serving sizes currently in use (e.g., 2 servings on a 12-fl oz can of soft drink) are not consistent with the act because they do not reflect the amount customarily consumed.

With regard to the use of other dietary guidance materials and the claim that reference amounts should be based on what people should eat rather than what they usually eat, FDA acknowledges that it would be desirable to have serving sizes on product labels that are consistent with the serving sizes in the dietary guidance documents published by Federal agencies. However, FDA advises that the act defines serving size as an "amount customarily consumed," not an amount people should eat. The agency has made some modifications in reference amounts where the changes are consistent with the customarily consumed amounts of the products under consideration, such as those described for bread in section III.D.5. of this document. Although these changes have not deviated from the definition of serving size, they have resulted in serving sizes more in agreement with dietary guidance documents.

However, because dietary guidance documents were developed for purposes other than regulatory uses, these documents have several problems that prevent their use as the primary source in determining reference amounts. Of greatest significance is the fact that many serving sizes in the dietary guidance documents are not based on the amounts customarily consumed and, therefore, are not consistent with the definition of serving size in the act. Dietary guidance documents published by Government agencies usually list approximate amounts of food for the purpose of providing "general" guidance as to what quantity of each food group a person should consume to maintain good health. Therefore, the amount that represents a serving is often not well defined (e.g., 1 slice for bread when the weight of a slice of bread varies among different brands).

The documents also provide a measure that is not applicable for all products within a product category. For example, these documents recommend the serving size for vegetables, other than raw leafy vegetables, as 1/2 cup. Vegetables in small pieces (e.g., green peas, cut corn) can be measured with a cup. However, many other vegetables come in a form that cannot be measured with a cup (e.g., broccoli spears; although broccoli can be measured if it is cut in small pieces, the weight per cup would vary widely depending on the shape and size of the cut piece).

In addition, dietary guidance documents give one serving size for a broad food group. Customarily consumed amounts, however, vary for different types of food within the food group. Therefore, for nutrition labeling purposes, FDA cannot use one reference amount for the broad groups defined in these documents.

In summary, dietary guidance documents are written for purposes other than implementing the serving size requirements of the act, and thus the serving sizes in these documents do not provide the accuracy and specificity that are needed for the reference amounts that are used for nutrition labeling under section 403(q) of the act.

With regard to the comment that a food consumption data base such as the NFCS is inappropriate to determine long-term intake because the survey covered only a limited number of days, FDA notes that the comment has confused the procedures used to estimate the reference amounts with the procedures used to estimate the average daily intake of food. FDA advises that the number of days of data collection is not critical for the estimation of reference amounts, particularly if the survey included a large number of people as was done in the NFCS.

The number of days of data collection is an important issue when an estimate of the long-term intake (chronic intake) is needed, e.g., for the safety evaluation of a food or a component of food. A survey that contains a limited number of days of data may overestimate the chronic intake, by eaters, of a food that is consumed infrequently (e.g., a specific fish) but that was consumed during the survey. For example, estimates of the average daily intakes of swordfish derived from the NFCS are likely to overestimate the chronic intake of swordfish because this fish is not consumed frequently in the United States. If an uncommon food is consumed during the survey and the amount consumed is divided by the number of survey days, 3 in this example, the average daily intake estimate for long-term intake will be greatly exaggerated because even people who like swordfish are not likely to consume it once every 3 days.

However, in determining reference amounts, FDA used the amount consumed per eating occasion, which is a short-term not a long-term intake. Thus, it was not necessary to average the amount of food consumed by the number of survey days. For the determination of reference amounts, the amount of food consumed for each eating occasion reported was counted as a separate entry. Consequently, surveys that contain 3-day data for a large number of people, like the NFCS, are appropriate for use in determining the amount of food customarily consumed per eating occasion.

18. Several comments discussed the selection of the food consumption data base used in determining the reference amounts. Most of the comments objected to using the 1987–1988 NFCS either by itself or with the 1977–1978 NFCS. The comments were concerned that, because of the low response rate, the data from this survey may not represent the amount customarily consumed as directed by the act. Some comments stated that FDA should use only the 1977–1978 NFCS. Some comments opposed using the 1985 and 1986 Continuing Surveys of Food Intakes by Individuals (CSFII) because these data bases included only selected age/sex groups (women 19 through 50 and children 1 through 5 years of age). These comments asserted that the use of the CSFII data bases resulted in an underestimation of the amount customarily consumed because men and older children, who as a group usually consume larger quantities of food than women and younger children, were not included.

A comment from a consumer organization strongly objected to FDA's use of the 1987–1988 NFCS with validation by the CSFII if data from the 1987–1988 NFCS suggested a change in consumption practices since 1977–1978 NFCS. The comment asserted that the CSFII is an inappropriate data base for validating serving sizes because the CSFII included only women ages 19 through 50 and their young children ages 1 through 5. Therefore, the comment asserted, the data base did not reflect the food consumption practices of the entire population, and the validation cannot be used for the entire population. The comment also contended that in validating the trend change in consumption, FDA did not compare the data from the CSFII to what women and young children were eating in the 1977–1978 NFCS.

A manufacturer stated that FDA should solicit consumption data from manufacturers because "the industry may well be the most efficient, accessible and accurate source of information" because "an ongoing knowledge of current consumption data * * * is vital and basic to [the] production and marketing of a product."

Because the final results of the 1987–1988 NFCS were not available in time for the 1990 proposal, FDA relied primarily on the 1977–1978 NFCS to determine the "standard serving sizes." Numerous comments on the 1990 proposal opposed FDA's use of a data base that is more than 10 years old. The comments argued that the food consumption practices have changed since the 1977–1978 NFCS, and that, therefore, estimates derived from the 1977–1978 NFCS may not reflect current food consumption practices.

Since the publication of the 1990 proposal, USDA released the final data tape for the 1987–1988 NFCS. However, FDA could not use the 1987–1988 NFCS alone because this survey had an unusually low response rate. Therefore, FDA used both the 1977–1978 and the 1987–1988 survey data in developing the reference amounts in the 1991 serving size proposal. If the 1987–1988 NFCS had a higher response rate, the new survey data would have been preferable to the 1977–1978 NFCS data for determining the reference amounts of food because of its recency. The use solely of the 1977–1978 NFCS is also not desirable because the data are almost 15 years old, and many new products have been introduced into the marketplace for which the 1977–1978 NFCS had no data. Also, changes in the customarily consumed amounts that might have occurred since the 1977–1978 NFCS could not be determined from the use of that survey alone. Therefore, FDA tentatively concluded that using both survey data bases is the most desirable approach because such an approach compensates for limitations in each of the two surveys; increases the number of available data points; provides two sets of mean, median, and modal amount consumed rather than one; and therefore strengthens the reliability of the reference amounts determined. Comments that objected to the use of the 1987–1988 NFCS did not provide any solution on how to determine the current customarily consumed amount of food that reflect changes in the food consumption practices of the U.S. population since the 1977–1978 NFCS. In addition, the comments did not provide any suggestions on how to estimate the consumption of new products introduced into the marketplace since the 1977–1978 NFCS. Thus, in order to determine the customarily consumed amount of food that is representative of U.S. food consumption, that reflects current consumption practices, and that includes new products introduced into the marketplace since the 1977–1978 NFCS, the agency concludes that the use of both the 1977–1978 NFCS and the 1987–1988 NFCS is necessary to compensate for limitations in each of the two surveys.

The comments that objected to the use of the CSFII data bases because these data may have lowered the reference amounts, misunderstood the way FDA used these data bases in determining reference amounts. When the results of the 1987–1988 NFCS suggested a change in food consumption practices since the 1977–1978 NFCS (e.g., customarily consumed amounts increased or decreased substantially), FDA used the CSFII data bases, which had a high response rate, only to confirm the validity of the trends observed, i.e., to show that the apparent trends were not an artifact of the low response rate in the 1987–1988 NFCS. As mentioned in the 1991 serving size proposal (56 FR 60394 at 60403), such a validity check to confirm the trend observed in the 1987–1988 NFCS was recommended by an expert ad hoc committee that evaluated the impact of nonresponse in the 1987–1988 NFCS (Ref. 26). Only when the same trends were observed in the CSFII did FDA rely solely on the 1987–1988 NFCS, so that the reference amount would reflect the current consumption practices more accurately. The estimates of intakes derived from the CSFII were not used in arriving at the reference amounts proposed in the 1991 serving size proposal. Therefore, potentially lower estimates derived from the CSFII data bases had no effect on lowering reference amounts.

With regard to the objection to FDA's use of the 1987–1988 NFCS if it suggested a change in consumption since the 1977–1978 NFCS and the use of CSFII to validate that change, the agency recognizes that the CSFII included only limited age and sex groups. Although the CSFII data bases used to confirm the trends included only women 19 through 50 and children 1 through 5 years of age, these data bases were the only other recent data bases that: (1) Were produced in a study conducted about the same time period as the 1987–1988 NFCS using the same survey methodology, (2) reflected food consumption practices representative of the U.S. population groups that were studied under the actual conditions of use, and (3) had a high response rate. Therefore, the CSFII data bases were the only data bases available to the agency for the purpose of confirming the apparent trend observed in the 1987–1988 NFCS, and, as mentioned above, their use in this manner was recommended by an expert ad hoc committee that evaluated the impact of nonresponse in the 1987–1988 NFCS (Ref. 26).

As for the assertion that FDA should have compared the data from the CSFII to what women and young children were eating in the 1977–1978 NFCS, the agency has done data analysis for women and young children in the 1977–1978 NFCS for those product categories that relied on the 1987–1988 NFCS because of consumption changes since the 1977–1978 NFCS. The results showed that the same consumption changes were observed for women and young children as for the total population since the 1977–1978 NFCS (Ref. 40). Thus, FDA concludes that it used the 1987–1988 NFCS and the CSFII data appropriately, and that it made the best use of the available food consumption data bases.

With regard to the request that FDA solicit consumption data from manufacturers, in the preamble to the 1991 serving size proposal (56 FR 60394 at 60401), FDA requested such data by stating that "[T]he agency is willing to consider any data that may give a better estimate of an amount customarily consumed of a specific product category." Many comments submitted food consumption and other data in support of the requests for changes of the reference amounts. FDA has considered all data that were submitted. It will discuss and respond to these data in section III.D.5. of this document, which discusses requests for changes in reference amounts for specific product categories. However, while some of these data have led the agency to modify the specific reference amounts in Table 2 in new § 101.12(b), the fact that they have caused the agency to make only a relatively small number of changes supports the basic validity of FDA's reliance on the 1977–1978 and 1987–1988 NFCS data.

19. A few comments stated that reference amounts should be based solely on the modal amount consumed, which represents the most frequently consumed amount, not the mean or median amount consumed.

FDA received the same suggestions in the comments on the 1990 proposal. As explained in the 1991 serving size proposal (56 FR 60394 at 60400), the mode was not useful as the sole criterion for determining the reference amount because most food groups had two or more modes, and there usually was no obvious or rational basis to choose one over the other. Therefore, FDA used all three (or more, if there was more than one mode) values that could represent an amount customarily (commonly) consumed, i.e., the mean, the median, and the mode. Following

the procedures detailed in the 1991 serving size proposal (56 FR 60394 at 60404), FDA determined the reference amount that was most likely to represent the amount customarily consumed for each product category. The new comments offered no additional data or arguments to support that using only the modal value is better than using all three values suggestive of the amount customarily consumed and no suggestions for how to select one modal value over another when there were multiple modes that were similar in frequency. Thus, FDA concludes that it is appropriate to consider all three values that provide data on which to derive the customarily consumed amount (i.e., mean, median, and mode).

2. Expression of reference amounts

In the 1991 serving size proposal (56 FR 60394 at 60406), FDA described the general principles that it followed in expressing the reference amounts in proposed § 101.12(b). FDA expressed reference amounts for fluids in mL. It expressed reference amounts for other foods, to the extent possible, in g. For a limited number of product categories, FDA expressed the reference amounts in common household measures. For example, when foods within a product category varied considerably in density, and the customarily consumed amounts for different products were more uniform when expressed in volume than in weight, FDA expressed the reference amounts in cups, tbsp., and teaspoons (tsp.). In these limited cases, FDA selected volumes that could easily be expressed in fractions or multiples of common household measures as described in proposed § 101.9(b)(5). Several comments requested changes in some of these principles.

20. One manufacturer stated that all reference amounts should be expressed in g, and another suggested that reference amounts for specific product categories (e.g., soups, sauces, gravies, beans, and mixed dishes) should be in g instead of cups.

FDA agrees that when possible, reference amounts should be expressed in g. As discussed more fully in section III.D.5. of this document, some of the specific product categories originally expressed in volume-based reference amounts have been changed to weight-based reference amounts. However, the agency does not agree that it is appropriate or desirable to do so for all product categories, including some of those specifically mentioned in comments. As explained above, when products within a product category differ widely in density, the use of a fixed g reference amount would result in a serving size that is too large for some products in the category and too small for others, even though the volume amounts consumed are similar for all products within the category. For example, although the reference amount for "mixed dishes measurable with cup" is 1 cup, the g-weights of different types of products within the category differ widely, e.g., about 160 g for seafood with vegetables without sauce and about 250 g for seafood stew. Also, fluids (e.g., beverages) have been customarily expressed in volume (mL or fl oz) not in weight, and they can easily and accurately be measured in volumetric units. Thus, FDA has used weight-based reference amounts in most cases but has retained volume-based reference amounts for fluids and for a limited number of categories with products that vary greatly in density (e.g., mixed dishes measurable with a cup, product category having aerated products) or for which information on the g-weight of the household measure is scarce, and comments have provided no appropriate weight-based reference amounts that are accurate and nonmisleading for all products within the category (e.g., condiments).

21. A manufacturer stated that reference amounts should not be adjusted to reflect "nonmetric" household measures. The comment suggested that such adjustments would be confusing and of no assistance to the consumer. A consumer recommended expressing reference amounts in rounded metric units, e.g., 250 mL for juice (8.45 fl oz), not 240 mL (8 fl oz).

FDA disagrees with the comment. The act requires that serving sizes be declared in common household measures, and therefore, those measures must drive the reference amounts. The common household measures are the declaration that appears first on the nutrition label, followed in parentheses by the equivalent metric measure which may or may not be the same as the reference amount. Many consumers complained about odd fractions (e.g., 1.4, 2.3). Therefore, a fractional serving size such as 8.45 fl oz, which was suggested in the comment, is not desirable. Thus, it is important to adjust the reference amounts to be in metric amounts that convert to useful, whole number household measures rather than rounded metric units.

22. A manufacturer requested that FDA express the reference amounts in either U.S. measures or in metric equivalents that reflect the more precise factors of 28.35 g per oz instead of 28 g per oz and 29.57 mL per fl oz instead of 30 mL per fl oz.

FDA notes that the reference amounts are amounts customarily consumed that will guide manufacturers to determine the label serving sizes of their specific products in common household measures. The serving sizes in common household measures will be in units such as pieces, cups, tbsp., and tsp. These household measures are primarily for consumer use, and it is unlikely that they will measure a cup with the 4-digit accuracy suggested in the comment. Accordingly, the reference amount that will be used as a guide for determining the serving size in household measure does not need the 4-digit accuracy of the g and mL equivalency suggested in the comment. Also, both 28.35 g and 28 g will be translated to 1 oz for the label serving size when oz is used as the serving size. Both 29.57 mL and 30 mL will be translated to 1 fl oz for the label serving size. In addition, in the case of fl oz, the 30 mL equivalency of 1 fl oz allows for the exact conversion of 1 cup to 8 fl oz. Therefore, the agency has concluded that for nutrition labeling purposes, 28 g for 1 oz and 30 mL for 1 fl oz are sufficiently accurate and appropriate because they provide the accuracy needed for nutrition labeling purposes without implying unrealistic accuracy, and because whole numbers are easier to use than decimal fractions.

3. Presentation of reference amounts

23. In footnote 2 under Tables 1 and 2 in proposed § 101.12(b) in the 1991 serving size proposal (56 FR 60394 at 60418 and 60419), FDA stated that, unless otherwise noted in the reference amount column, the reference amounts in the tables are for the ready-to-serve or almost ready-to-serve form of the product (i.e., heat and serve, brown and serve), and that if the reference amount is not listed separately, the reference amount for the unprepared form (e.g., dry mix, concentrate) of the product is the amount required to make one reference amount of the prepared form.

A trade association requested that FDA delete footnote 2 from Tables 1 and 2 because it "implies that most of the major reference amounts used to determine number of servings will be based on a cooked (consumed) basis." The comment further requested that if FDA did not mean that the number of servings should be based on the cooked basis, the agency should provide a complete explanation in the preamble of this document or in another official, readily accessible reference. The comment contended that it would be difficult to determine the number of servings for the unprepared form of the product.

FDA believes that the comment has misinterpreted the footnote. Many foods are available in the marketplace in several different forms: Ready-to-serve, almost ready-to-serve, dry mixes, batters, or concentrates. For example, pancakes come in three different forms: Dry mix, batter, and the frozen almost ready-to-serve form, which requires only heating before consumption. If FDA were to list reference amounts for all of the different forms of these foods, the tables would be needlessly lengthy. In addition, the list would not include forms of the food requiring further preparation that may be introduced in the future. Because the amounts of food consumed are similar for the ready-to-serve and the unprepared forms on an as consumed basis, as explained in the preamble of the 1991 serving size proposal (56 FR 60394 at 60407), FDA listed all forms of the same food together and provided one reference amount listed on an as consumed basis. Footnote 2 merely explains that the reference amounts in the table are expressed in the quantity of the food that is in the ready-to-eat or the almost ready-to-eat form of the food. Since nutrition labeling is required to be on an "as packaged" basis, the footnote further informs the manufacturer that, for the unprepared form of a product that requires further preparation before consumption (e.g., dry mix, batter, uncooked food), the manufacturer must determine the quantity of the unprepared product that is required to make one reference amount of the prepared product as specified in new § 101.12(b). Using the reference amount for the unprepared product, the manufacturer must then determine what the serving size of the unprepared product "as packaged" should be in common household measure.

For the pancake example, this requires that the manufacturer determine the weight of dry mix or batter required to make one reference amount (110 g) of the prepared pancake according to the label directions for the preparation. If 40 g of a pancake mix is needed to make 110 g of pancakes, 40 g of dry mix is the reference amount of this pancake mix. The serving size for this pancake mix will be about 1/3 cup (40 g). The number of servings per container will then be estimated from the net quantity of contents of the container and the reference amount for the unprepared form of the product. For the pancake example above, if the net quantity of the package is 12 oz, the number of servings per container can be determined by dividing the net quantity in g by the reference amount for the dry mix (40 g), e.g., (12 oz) x (28.35 g/oz)/ 40 g = 8.5, i.e., about 9 servings according to the provision for declaring the number of servings per container in new § 101.9(b)(8).

As requested in the comment, FDA has provided a complete explanation of the footnote and how to determine the number of servings per container for unprepared products that require further preparation. Therefore, the agency is retaining Footnote 2 for Tables 1 and 2 in the final regulation to inform manufacturers that the reference amounts in Tables 1 and 2 are the amount of the final product on a ready-to-serve or almost ready-to-serve basis. In addition, for clarity, the agency has added, at the end of footnote 2 to Tables 1 and 2, the following statement: "Prepared means prepared for consumption (e.g., cooked)."

24. A trade association suggested that FDA express the reference amounts in Tables 1 and 2 in proposed § 101.12(b), where possible, in common household measures with the equivalent metric quantity in parenthesis. The comment stated that consumers, FDA, and the food industry will be best served if the reference amounts in the regulation tables are stated as they should appear on the label.

FDA understands the concern expressed by the comment. However, different characteristics (e.g., shape, size, density) of different products preclude the presentation of most reference amounts as they would appear on the product label. For example, the reference amount for bread is 50 g. The serving sizes for most sliced bread will be 1 slice. However, the parenthetical metric measure will differ depending on the thickness of the slice. In addition, if a slice weighs 50 percent or less of the reference amount, the serving size will be the number of slices that most closely approximates the reference amount. Thus, both the household measure and the metric measure may vary for brands that come in different thicknesses as shown in the examples below.

BRAND A: 1 slice (35 g)
BRAND B: 1 slice (28 g)
BRAND C: 2 slices (45 g)

Therefore, for most products, FDA cannot express the reference amounts as they should appear on the label. However, in response to the comment, FDA is adding a label statement column to Tables 1 and 2 in new § 101.12(b). This column provides guidance on how the serving sizes of specific products in each product category will appear on the product labels and should help reduce confusion and promote uniformity in label serving size units. For example, the label statement for bread and rolls states "——— piece(s) (———g) for sliced bread and distinct pieces (e.g., rolls); 2 oz (56 g) for unsliced bread." For sliced bread or rolls, manufacturers will then fill in the number of slices or rolls that most closely approximates the 50 g reference amount and the g-weight equivalent of that number of slices or rolls. For unsliced bread, oz is the household measure most appropriate for the food and 2 oz most closely approximates the 50 g reference amount for bread. The metric measure equivalent to 2 oz is 56 g because 1 oz in weight is defined as 28 g for nutrition labeling purposes in § 101.9(b)(5)(iv). Therefore, the label statement for unsliced bread states "2 oz (56 g 1-inch slice)."

Where possible, FDA has also provided the exact household measure and the equivalent metric measure for serving sizes in volumetric measures other than oz (e.g., cups, tbsp.), using the g weight of the household measure reported by the USDA. For example, for the product category of "Confectioner's sugar," the reference amount is 30 g which is equivalent to 1/4 cup. Therefore, the label statement column states "1/4 cup (30 g)," which is how the information will appear on the product label.

25. An industry comment urged FDA not to include the reference amount table (proposed § 101.12(b)) in the regulation itself. Instead, the comment asked that FDA generally establish its intention to use such a table, then reference and formalize the table through policy memoranda. The comment stated that if the reference amount table is in the regulation, the petition process for modifying the reference amounts would require a notice and comment rulemaking which would necessitate publication in the Federal Register before a change could be made.

The reference amount table appropriately is included in the regulation because these amounts have the force and effect of law. While it is true that any changes in the reference amounts will require a notice and comment rulemaking, FDA concludes that giving the reference amounts legal effect is required to implement section 403(q)(1)(A)(i) of the act. The legislative history of section 2(b)(1)(B) of the 1990 amendments directs FDA to establish meaningful serving size *requirements* (H. Rept. 101–538, supra, 18). Such requirements are necessary to ensure that the serving size that appears on the label reflects the amount customarily consumed.

4. Product categories

a. Number of product categories

FDA proposed 131 product categories: 9 for foods specially formulated or processed for consumption by infants or toddlers and 122 for the general food supply. The agency asked for comments on whether these categories adequately cover the food supply (56 FR 60394, 60407).

Many comments addressed whether the 131 product categories are adequate. Some comments expressed their support for the 131 product categories proposed in the 1991 serving size proposal. These comments stated that the proposed product categories are reasonable and recognizable. Several comments suggested that some of the product categories should be combined. The vast majority of the comments, however, stated that the 131 categories were too restrictive and recommended expanding some of the categories.

Because the comments about the number of product categories are closely related to the comments on the reference amount, those comments that requested merging or expanding specific categories will be discussed in the next section of this document on requests for changes in reference amounts for specific product categories. This section includes only those comments that requested recategorization of entire product categories or addition of a product category.

26. A State government comment recommended that FDA regroup all products into six categories and establish one standard measure for each category that is easily understood and multipliable. For example, the comment suggested grouping dry cereal, rice, beans, raisins, nuts, bread, tortilla, crackers, cooked fish, and hard cheese into one category with a standard serving size of 1 oz.

Section 403(q)(1)(A)(i) of the act defines serving size as an amount of food customarily consumed. Therefore, FDA has not grouped products together unless their customarily consumed amounts are similar. Grouping of foods into such broad categories as those suggested by the comment is not possible because the amounts customarily consumed vary widely. For example, 1 oz may be an appropriate reference amount for some foods in the grouping suggested by the comment (e.g., cheese, some ready-to-eat cereals), but it is too small for other foods in that grouping (e.g., bread, fish). Food consumption data show that the amount customarily consumed for fish without sauce is 3 oz cooked, and that for fish with sauce (e.g., fish with cream sauce), it is 5 oz cooked.

27. A manufacturer requested that FDA add a product category for snack sandwiches, which have recently been introduced into the market, with a reference amount of 70 g.

The 1991 serving size proposal has a product category that includes products such as snack sandwiches. These sandwiches belong to the category of "mixed dishes not measurable with cup." The proposed reference amount for this category, that is retained in the final regulation, is 140 g. Because snack sandwiches are discrete unit products, the label serving size will be one sandwich if it weighs more than 70 g. If the sandwich weighs 70 g or less each, the serving size will be the number of sandwiches that most closely approximates the 140 g reference amount. However, the agency notes that, as discussed in section III.F.1. of this document, new § 101.9(b)(10)(ii) allows manufacturers to voluntarily provide a second column of values per unit on multiserving containers.

Regardless of the size of the individual unit, the 140 g reference amount will be used to evaluate the product's qualification for claims unless the sandwich meets the definition of a meal product or main dish product in new § 101.13(l) and (m). If the sandwich meets the definition of meal product or main dish product, the product's qualification for a claim will be evaluated by the rules described in the nutrient content claim regulation published elsewhere in this issue of the **Federal Register**.

28. A comment from a Federal agency stated that there should be a product category for gelatin salad.

In the 1991 serving size proposal, all gelatin products were included in the "Custards, gelatin, or pudding" category under Desserts. Because some gelatin products are served as salads rather than desserts, FDA agrees with the comment that it would be desirable to have a separate category for gelatin salads. Accordingly, a new category "Gelatin Salad" has been added to Table 2 in new § 101.12(b). Following the general principles and the procedures described in the 1991 serving size proposal (56 FR 60394 at 60402), FDA has determined the reference amount for the category to be 120 g, which is equivalent to 1/2 cup (Ref. 41).

29. A manufacturer of "herring salad" and smoked salmon spread stated that their products were not included in the 131 product categories proposed in the 1991 serving size proposal. The manufacturer stated that "herring salad" is a "fanciful name" and is not a fish salad. "Herring salad" and smoked salmon spread are ground pastes of herring or salmon and other ingredients such as celery, pickle relish, mayonnaise, and spices. They are neither used nor marketed for use as sandwich spreads like tuna salad. They are promoted for use as an appetizer to be spread on crackers, in the same manner consumers would use pickled herring. The manufacturer stated that "herring salad" and smoked salmon spread should be added to the 'Smoked or pickled fish or shellfish" category.

FDA agrees that the characteristics and the usage of "herring salad" and smoked salmon spread suggested in the comment most closely resemble those products used as appetizers in the "Smoked or pickled fish or shellfish" category. In addition, "herring salad" and smoked salmon are canned fish products. Both of these categories have a reference amount of 55 g. Therefore, it is a matter of choice in which category these products are placed. FDA has concluded that "herring salad" and smoked salmon are types of fish products used in the same manner of those products in the "Smoked or pickled fish or shellfish" category and thus, fit better in the "Smoked or pickled fish or shellfish" category than in the canned fish category. Therefore, FDA has modified the name for the "Smoked or pickled fish or shellfish" category in Table 2 in § 101.12(b) to include fish or shellfish spread.

30. A consumer comment stated that a category is needed for products such as tempeh. The comment suggested 1 oz as the reference amount for these products.

FDA acknowledges that tempeh should be included in § 101.12(b). However, the agency disagrees with the comment that it should have a separate category with a reference amount of 1 oz. The comment did not provide any data on the amount customarily consumed to support the recommendation of a 1 oz reference amount. Because tempeh is a type of soy product that is used interchangeably with tofu (Ref. 42), the agency concludes that tempeh belongs in the "Bean cake (tofu)" category with a reference amount of 85 g. Accordingly, FDA has revised the "Bean cake (tofu)" category to include tempeh.

In addition, the agency is aware that there are an increasing number of ethnic foods entering the general food supply. However, available food consumption data do not usually provide information on these ethnic foods. Therefore, FDA requests that manufacturers or other interested persons submit a petition as described in § 101.12(h), if any

additions or amendments to § 101.12(b) are necessary to encompass the ethnic foods sold to the general public.

31. The spice industry requested exemption from nutrition labeling on the basis that spices in general contain insignificant amounts of nutrients on a 1/4 tsp. basis. The comments requested that FDA establish 1/4 tsp. as the reference amount and "acknowledge that when used at that level, the industry is not covered by the mandatory nutrition labeling requirements of the proposals."

Exemptions from mandatory nutrition labeling are discussed in the final regulation entitled "Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision" published elsewhere in this issue of the Federal Register. The agency agrees with the comment that there is a need for a reference amount for spices and herbs and, accordingly, has added a category for these products. Spices and herbs are used to flavor foods. Cookbooks (Refs. 43 and 44) usually recommend using 1 to 2 tsps. of these products in recipes that make several servings. Therefore, one serving of food contains only a fraction of a tsp. of spices or herbs (e.g., 1/4 tsp. or less). One-fourth tsp. is also the smallest household measure allowed to be declared as a serving size for nutrition labeling purposes. Therefore, FDA has concluded that 1/4 tsp. is the most reasonable reference amount for this product category. For spices and herbs that cannot be measured with a tsp. (e.g., whole clove, whole bayleaf), the agency has determined the reference amount of 0.5 g which represents the average g weight of 1/4 tsp. of spices and herbs. Consequently, FDA has added a new product category under the miscellaneous category for spices and herbs with a reference amount of 1/4 tsp. or 0.5 g if not measurable by a tsp.

32. An industry comment stated that it is confused about which products go into the breads category. Another industry comment requested clarification as to which category canned hot dog chili sauce belongs.

First, the agency notes that as discussed in section III.D.5. of this document, FDA has divided the "Bakery Products: Breads (excluding sweet quick type), biscuits, rolls, * * *" category (the original bread category) into two categories: One for breads and rolls, and the other for the remaining products included in this category in the 1991 serving size proposal. This was done in response to many requests for dividing the original bread category into several subcategories. The breads and rolls category in the final regulation includes all breads (e.g., white, wheat, rye, multigrain, raisin, and soda bread) and all rolls (e.g., dinner rolls, hamburger rolls, hot dog rolls).

With regard to the hot dog chili sauce, FDA advises that it belongs to the "Major condiments, e.g., catsup * * *" category under "Sauces, Dips, Gravies and Condiments" because it is used as a substitute for catsup on hot dogs.

To help manufacturers and others to identify the category in which their specific products fit, in the 1991 serving size proposal, FDA provided an extensive list of products for each product category (Ref. 20). The agency has updated this list to incorporate changes made in product categories and in the products included in each product category in response to the comments on the 1991 serving size proposal (Ref. 45). FDA will continue to update the list as necessary. Copies of the list are available from the Division of Nutrition (HFF-260), Food and Drug Administration, 200 C St. SW., Washington, DC 20204. FDA advises that those who are not sure about which product category their specific products belong should refer to this list or consult with the agency.

33. A manufacturer contended that "not having a provision for new or undefined food products is of concern" to those developing new products.

FDA agrees that new products should be provided for in this regulation. It was for this reason that FDA proposed to establish a petition process in § 101.12(h) by which a reference amount could be amended or added. New § 101.12(h) describes the information needed in the petition in order for FDA to evaluate the request for a change or addition of a product category or a reference amount of a food in Tables 1 and 2, as well as the information needed to determine a suitable reference amount for the petitioned food, if the agency concludes that the change or addition is appropriate.

From the comments on the 1991 serving size proposal and through its own observation of products in the marketplace, the agency has identified three additional product classes (dessert shells, pastry shells, and dehydrated vegetables) that were not covered in the 1991 serving size proposal. The agency intends to publish a proposal for reference amounts for these product classes in the near future.

b. Product category names

Because each product category encompasses many different types and brands of products, it is impossible to fully describe all products within each product category. Therefore, in the 1990 proposal, FDA provided a generic description of each product category. A generic description is also desirable to accommodate the brands and types of products that may be introduced in the future. Some comments on the 1990 proposal stated that because some product categories were not sufficiently descriptive, they experienced difficulty in identifying the product category in which their products fit. Thus, in the 1991 serving size proposal, FDA modified the names of some product categories to be more descriptive and also provided a few recognizable examples where it felt that it was necessary to do so. In addition, the agency provided a separate extensive list of products for each product category (Ref. 20). Several comments on the 1991 serving size proposal again requested clarifications or changes in product category names as described below.

34. An industry comment requested that FDA add "crumbcakes and similar products" to the "Coffee cakes * * *" category under Bakery Products.

FDA advises that because crumbcakes are similar to coffee cakes in their nutrient content and use in the diet, coffee cakes and crumbcakes are included in the same food code in the NFCS. Consequently, crumbcakes were included in the coffee cake group in determining the customarily consumed amount of coffee cakes. Therefore, the agency agrees with the comment that it is appropriate to include crumbcakes in the name of the coffee cake category. However, the agency finds that it would not be appropriate or desirable to add a term such as "similar products" to the product category name because such a term could be interpreted differently by different companies and may result in an inappropriate classification of a product. For example, because apple crisp has a crumb topping, like crumbcakes, it could be misclassified as belonging to the "Coffee cakes * * *" category. However, apple crisp belongs in the "Pies, cobblers * * *" category, not the "Coffee cakes * * *" category because apple crisp resembles products in the "Pies, cobblers * * *" category in nutrient content and in use in the diet as indicated by being listed in the same food group as cobblers in the NFCS. Therefore, FDA has modified the name for the "Coffee cakes * * *" category to read: "Coffee cakes, crumbcakes * * *" For clarity, FDA has also modified the name for the "Pies, cobblers * * *" category to read: "Pies, cobblers, fruit crisp * * *"

35. Another comment pointed out that game meats are missing from FDA's product category list.

Game meats belong to the major product category of "Fish, Shellfish, and Meat or Poultry Substitutes," because this category includes all meat or poultry substitutes and is the product category comparable to the meat and poultry categories in the USDA regulation. Because meat and poultry substitutes replace meat and poultry in the diet, FDA used the amount customarily consumed for meat and poultry as a surrogate for the amount customarily consumed for meat and poultry substitute products. Therefore, because game meat is a type of meat and is used interchangeably with other meat, fish, or poultry in the diet, similar to those products in the "Fish, Shellfish, and Meat or Poultry Substitutes" category, FDA has included game meat in that category. Accordingly, FDA has modified the name of this major product category, and the names of its two subcategories, to include game meats as shown below:

"Fish, Shellfish, Game Meats, and Meat or Poultry Substitutes:"

"Fish, shellfish, and game meat, canned"

"Smoked or pickled fish, shellfish, or game meat; or fish or shellfish spread"

36. A nut industry comment stated that it is not clear in which category sliced nuts fit, "Nuts, seeds, and mixtures;" or "Nuts and Seeds: Used primarily as ingredients, e.g., coconut, nut, and seed flour, etc."

The agency advises that sliced nuts belong in the "Nuts,.seeds, and mixtures" category because they were included in the analysis for the amount customarily consumed for the "Nuts, seeds, and mixtures" category. For clarity, FDA has modified the name for the "Nuts, seeds, and mixtures" category to "Nuts, seeds and mixtures, all types, sliced, chopped, slivered, and whole."

37. A manufacturer requested that FDA not use "popsicle" as part of the product category name because it is a trademark owned by a particular company.

FDA has deleted "popsicle" from the product category name. The new name for the product category is "Frozen flavored and sweetened ice and pops, frozen fruit juices: all types, bulk and novelties (e.g., bars, cups)." As discussed in section III.D.5. of this document, this category has been moved from the category for Sugars and Sweets and placed under the category for Desserts.

38. A pickle trade association stated that the product category name for relish ("Pickles, relish") suggests that the category excludes relishes that contain nonpickle ingredients. The comment argued that the category should include all relishes and requested that FDA change the category name from "Pickles, relish" to "Pickle relishes."

FDA agrees with the comment that "Pickle relishes" is a more appropriate name for the category that includes all vegetable relishes, including relishes containing nonpickle ingredients. The agency notes, however, that fruit relishes (e.g., cranberry relish) are a different type of product and are listed under "Fruits and Fruit Juice" with the reference amount of 70 g.

In addition, for clarity or for a better categorization of products, FDA on its own initiative has modified the names of the following product categories:

(1) Hushpuppies and cornbread have been deleted from the "Coffee cakes * * *" category under Bakery Products and placed in the "Biscuits * * *" category under Bakery Products.

(2) To prevent a misclassification of tortillas as taco shells because they are often used as a wrapper for tacos, the name for the taco shell category has been modified to read: "Taco shells, hard."

(3) To incorporate "frozen flavored and sweetened ice" and to reflect better the products included in the category, the name for the "Ice cream, ice milk, frozen yogurt, sherbet: All types, bulk and novelties * * *" category under Desserts has been changed to "Ice cream, ice milk, frozen yogurt, sherbet, frozen flavored and sweetened ice, frozen fruit juices: All types, bulk and novelties * * *"

(4) To reduce the number of product categories, FDA has deleted water as a separate category. For a better categorization of products, fruit-flavored drinks have been deleted from the "Juices, nectars, fruit drinks, or fruit-flavored drinks" category under Fruits and Fruit Juices. Water and fruit-flavored drinks have been combined with the category for "Carbonated beverages * * *" under Beverages. The revised name for the "Carbonated beverages * * *" category is "Carbonated and noncarbonated beverages, wine coolers, water."

These changes are intended only to clarify Table 2 and to make it more usable. They do not result in any substantive changes in the reference amounts of the products affected.

As mentioned in the previous section, to help manufacturers identify the product category in which their specific products fit, FDA has updated the list of products for each product category (Ref. 45). The agency will keep updating this list as new products are identified. Copies of the list are available from the Division of Nutrition (HFF-260), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

5. Reference amounts for specific product categories

FDA proposed, in § 101.12(b), the reference amounts for 131 product categories that it developed through the use of the general principles and procedures described in the 1991 serving size proposal. These reference amounts were presented in two tables. Table 1 contained the reference amounts for the 9 product categories that are specially formulated or processed for consumption by infants or toddlers. Table 2 contained the reference amounts for the 122 product categories in the general food supply.

FDA received more comments on the proposed reference amounts for specific product categories than on any other serving size issue. Many comments supported the proposed reference amounts. However, the majority of the comments that discussed specific reference amounts opposed one or more specific proposed reference amounts. The agency received requests for changes of the reference amounts for about 80 specific product categories. About half of the requests merely voiced their opinion on the proposed reference amounts for certain product categories (e.g., too large or too small) or provided generic types of bases for wanting the changes. The other half of the requests presented more specific reasons for each product or product category or presented data supporting their requests. FDA will first respond to the requests that provided generic types of bases and then will respond to the requests that provided more specific bases by product category.

a. Generic requests

Because many comments provided similar bases for wanting changes in the reference amounts, responding separately to them would be repetitive and would make the document needlessly lengthy. Therefore, FDA has grouped these bases and is responding to each type of basis for a change.

39. Many comments merely stated that they believed that the proposed reference amounts for specific product categories were too large or too small, but they did not present any specific arguments or data supporting their beliefs.

Section 403(q)(1)(A)(i) of the act defines serving size as "an amount customarily consumed." To determine this amount of food, FDA performed extensive analyses and evaluations of

data from four large national food consumption survey data bases, namely the 1977–1978 NFCS, 1985 CSFII, 1986 CSFII, and the 1987–1988 NFCS conducted by the USDA (56 FR 60394 at 60403). To respond to the recommendations in the IOM report and to comments requesting the use of other relevant information in addition to food consumption data, and to promote international harmonization, in addition to the food consumption data, FDA used several other sources of information listed in the proposed § 101.12(a)(5) in developing the proposed reference amounts. The agency carefully considered the food consumption data and the other information to determine the reference amounts proposed in the 1991 serving size proposal. Food consumption data and the other information used, along with the detailed description of the procedure and the basis used to determine the proposed reference amounts, were made available to the public (Ref. 2).

The law establishes an objective standard against which serving sizes are to be established. FDA cannot change the proposed reference amounts that were determined after careful and extensive consideration of food consumption data and other relevant information simply because some comments stated that the reference amounts are too large or too small without providing any data to support their assertions. Accordingly, FDA has not adopted recommendations based merely on belief or opinion.

40. A consumer organization and a few fast food companies recommended that FDA change some reference amounts to make them consistent with the average serving sizes of restaurant foods.

First, FDA advises that in determining the customarily consumed amount for each product category, it used both foods consumed at home and away from home (e.g., restaurant foods). Therefore, the serving sizes of restaurant foods were reflected in the reference amounts determined for each product category. In addition, the act mandates the nutrition labeling of retail products, not restaurant foods. Accordingly, new § 101.9(j)(2) exempts restaurant foods from the nutrition labeling regulation unless a claim is made. Therefore, it is more important for the reference amounts to be appropriate and applicable to retail products than to restaurant foods. Reference amounts that are solely based on the serving sizes of restaurant foods may not be appropriate for retail products. Furthermore, most restaurant foods are single-serving products. Based on the reference amounts in new § 101.12(b) and the definition for single-serving products, the serving sizes for restaurant foods will be one unit. Therefore, FDA has not changed the reference amounts to make them consistent with the average serving sizes of restaurant foods.

41. A manufacturer requested that FDA establish two different reference amounts, one for retail products and one for food-service products, for some product categories (e.g., 1 cup for retail soups and 3/4 cup for food service soups). The comment argued that the proposed reference amounts represent the amount customarily consumed in the home. The serving sizes used for food service products are smaller. Because these products are sold in some retail "club" stores, they will be required to bear nutrition labeling. The comment contended that if these products are required to use the same serving size as for the regular retail products, it would cause problems in providing preparation instructions and yield information directed to the food service operator because the serving size recommended for food service would differ from the serving size shown on the nutrition panel. The comment claimed that such labeling would be very confusing to the food service buyers and operators. The comment requested that food service products be allowed to use serving sizes that correspond to their traditional label instructions as long as the simplified-format of nutrition information is provided per serving based on the reference amount.

The same food cannot have different reference amounts (or label serving sizes) simply because it is intended to be sold or served for different purposes. Reference amounts of the same food sold at retail stores must be the same to facilitate nutrition comparisons of different brands regardless of where they are purchased. The reference amount for the food service products that are sold at retail stores must be based on the same reference amount as for the regular retail products.

42. Some comments recommended using a range of values rather than a fixed reference amount.

The reference amounts in § 101.12(b) will serve two purposes: (1) They will be used by manufacturers to determine serving sizes for their specific products, and (2) they will be used to determine whether food products meet the definitions for nutrient content and health claims. As explained in the 1991 serving size proposal (56 FR 60394 at 60414), both of these purposes require specific reference amounts, not a range of values. None of the comments provided any evidence that a range of values would be better than a fixed value to meet the two objectives of the reference amounts. Therefore, FDA has not adopted the recommendations for using a range of values.

43. A comment from a foreign government recommended changing the reference amounts because they differ from the amounts in its own guidelines or differ from the food consumption data developed in its country.

Although the act did not explicitly define the serving size as an amount customarily consumed by the U.S. population, it is implicit that the food consumption data used to determine this amount of food should be based on the food consumption practices by the U.S. population, not food consumption data from surveys conducted in other countries. The nutrition information on products sold in the United States is for the U.S. consumer. Moreover, the legislative history of the 1990 amendment talks about helping Americans to maintain a balanced and healthful diet and to follow the Surgeon General's guidelines (H. Rept. 101–538, supra 9–10). Moreover, one of the main sponsors of the legislation said in thanking the other main sponsor in the House that: "He has insisted that the bill be as effective as possible so that all Americans can be fully and fairly informed about the nutritional characteristics of the food that they eat" (136 Congressional Record H5841 (July 30, 1990)). Therefore, the reference amounts should be appropriate to U.S. consumers. FDA cannot change the reference amounts that reflect the food consumption practices of the U.S. population to make them consistent with the guidelines that are targeted for non-U.S. population groups or to make them agree with the data from food consumption surveys conducted in foreign countries. Accordingly, FDA has not adopted these recommendations.

b. Specific requests

In addition, FDA received many comments requesting changes in specific reference amounts. Some comments addressed meat and poultry products which are regulated by USDA. Unless such comments contained specific issues that were directed to FDA or that significantly bear on the labeling of products regulated by FDA (e.g., how to determine reference amounts for the unprepared form of the product), FDA is not responding to those comments pertaining to meat and poultry. FDA has forwarded these comments to USDA for consideration. Comments about game meats are included in this document.

Although the names and the order of the product categories in the final regulation have been changed somewhat, for the purpose of discussing the comments on specific reference amounts, the names and the order of the product categories presented in the 1991 serving size proposal are used below for ease of identifying the product category to which the comments were directed.

(1) Infant and toddler foods: other cereal and grain products, dry ready-to-eat, e.g., ready-to-eat cereals, cookies, teething biscuits, and toasts

FDA proposed 7 g as the reference amount for this product category.

44. A manufacturer of infant and toddler foods stated that 7 g is appropriate for infants but not for toddlers. Based on the published value for the median amount of ready-to-eat breakfast cereals consumed by toddlers 1 and 2 years of age as reported in the 1977–1978 NFCS, the manufacturer recommended 21 g, or 3/4 oz, as the reference amount for ready-to-eat cereals for toddlers.

FDA derived the proposed 7 g reference amount from the amount consumed by infants. Some of the products in this product category (e.g., teething biscuits, teething cookies) are primarily consumed by infants. However, FDA acknowledges that other products in the product category (e.g., cereals) may be consumed by both infants and toddlers. Therefore, the agency agrees that it is appropriate to have a separate reference amount for toddlers. However, the agency could not adopt the reference amount suggested in the comment because it was based solely on the 1977–1978 NFCS and included only toddlers 1 and 2 years of age. As discussed in section III.D.1. of this document, FDA is not using a reference amount that is solely based on the 1977–1978 NFCS. Also, new § 101.9(b)(1) defines toddlers as children 1 through 3 years of age. Therefore, the reference amount for toddlers should reflect the amount customarily consumed by toddlers 1 through 3 years of age. Following the procedures for determining the reference amount described in the 1991 serving size proposal (56 FR 60394 at 60403), FDA has determined the reference amount of cereals for toddlers 1 through 3 years of age to be 20 g (Ref. 41).

(2) Dinner, fruit, vegetable, stew or soup for toddlers, ready-to-serve

FDA proposed 170 g as the reference amount for this product category.

45. A manufacturer of infant and toddler foods stated that 170 g is too large for fruits and vegetables specially formulated or processed for consumption by toddlers. The comment recommended a separate reference amount of 100 g or 3 to 4 oz for fruits and vegetables based on the published data for the amount of fruits and vegetables consumed by toddlers 1 and 2 years of age as reported in the 1977–1978 NFCS.

FDA agrees with the comment that a separate reference amount is needed for fruits and vegetables. Detailed information on the characteristics of fruits and vegetables specially formulated or processed for consumption by toddlers was not available to FDA during the formulation of the 1991 serving size proposal. The information provided in the comment showed that fruits and vegetables specially processed for consumption by toddlers differ from fruits and vegetables specially formulated or processed for consumption by infants. Toddlers' products more closely resemble the canned fruits and vegetables in the general food supply than do fruits and vegetables for infants. The toddler products differ from the products in the general food supply primarily in the piece size, which makes them easier for toddlers to pick up with their fingers. Therefore, the agency believes that it is appropriate to use the amount of fruits and vegetables consumed by toddlers reported in the NFCS to derive the reference amount for the fruits and vegetables specially processed for consumption by toddlers.

Consistent with the discussion in section III.D.1. of this document, FDA is not using a reference amount that was suggested in the comment because it was solely based on the 1977–1978 NFCS and included only toddlers 1 and 2 years of age. Following the procedures for determining the reference amount that it described in the 1991 serving size proposal (56 FR 60394 at 60403), FDA has determined the reference amount for ready-to-eat fruits and vegetables specially formulated or processed for consumption by toddlers 1 through 3 years of age to be 125 g and 70 g, respectively (Ref. 41). Therefore, FDA has added 2 categories, "Fruits for toddlers, ready-to-serve" with a reference amount of 125 g and "Vegetables for toddlers, ready-to-serve" with a reference amount of 70 g.

(3) Infant and toddlers foods: egg/egg yolk, ready-to-serve

FDA proposed 55 g as the reference amount for this product category.

46. One comment recommended that FDA change the reference amount to 50 g because 50 g corresponds more closely to one-half of the net contents of a jar.

As discussed in the 1991 serving size proposal (56 FR 60394 at 60401), the act requires that the serving size be the amount customarily consumed. Therefore, jar size cannot be used as the basis for determining reference amounts. Furthermore, there is nothing that ties jar size to the amount customarily consumed. One may change, while the other does not. Therefore, FDA has not adopted this recommendation.

(4) Infant and toddler foods: juice, all varieties

FDA proposed 120 mL as the reference amount for juices specially formulated or processed for consumption by infants.

47. A consumer recommended that FDA change the reference amount to 125 mL because 125 mL is a rational metric size.

For the reason explained in section III.D.1. of this document, concerning the presentation of reference amounts in rational metric size, FDA has not adopted this recommendation. Accordingly, FDA has retained the reference amount as proposed.

(5) Bakery products: breads (excluding sweet quick type), biscuits, rolls, croissants, bagels, tortillas, soft bread sticks, soft pretzels (hereinafter referred to as "the original bread category" for simplicity).

FDA proposed 55 g as the reference amount for this product category.

48. Many industry comments requested that FDA divide this category into several subcategories with separate reference amounts for each subcategory. Two bakery trade associations recommended dividing the category into 4 subcategories with the following reference amounts: 45 g for bread, 50 g for rolls, 60 g for biscuits and English muffins, and 70 g for tortillas. The comments submitted published data from the 1977–1978 NFCS to support their position. In addition to these four subcategories, another industry comment suggested separate reference amounts for sliced and unsliced bread (e.g., 45 g for sliced bread and 55 g for unsliced bread). Several additional comments recommended a 45 g reference amount for bread but did not specify what the reference amount should be for other products in the bread category. The major reason stated by the industry in comments was to have a separate, lower reference amount for sliced bread so that the label serving size for sliced bread will be 1 slice, which is consistent with the serving size

in the dietary guidance documents published by Federal agencies. A nutrition professional organization also stated that the 2-slice serving size conflicts with the serving sizes in dietary guidance documents. This comment contended that consumers who hear that dietary guidance documents recommend 6 to 11 servings daily from the bread/cereal group, and then see that a label serving size is 2 slices, may be confused and think that the recommendation means 12 to 22 slices of bread a day. A few other comments suggested a 25 to 30 g reference amount for bread which is equivalent to the g weight of 1 slice of most breads. An international comment suggested changing the reference amount for bread to 45 g but keeping the 55 g reference amount for rolls because rolls are heavier than breads. One comment stated that the amount of bread customarily consumed was overestimated because FDA did not include the bread that was consumed as toast. The comment asserted that many people consume only one piece of bread as toast, and thus the amount customarily consumed would have been lower if FDA had included the bread consumed as toast in the data analysis.

FDA agrees that the 55 g reference amount could result in 2-slice serving sizes for some brands of sliced bread, and that it would be desirable to have serving sizes of sliced bread consistent with that in the dietary guidance documents published by Federal agencies. However, the agency does not agree that it should divide the original bread category into four subcategories with their own individual reference amounts. The data submitted in support of the four subcategories came from a USDA publication from the 1977–1978 NFCS (Ref. 46). These data are inappropriate for use in determining the reference amounts for several reasons.

First, the data represent the mean consumed amount per eating occasion by the total population including infants and children less than 4 years of age. New § 101.9(b)(1) defines the term "serving" or "serving size" for the general food supply as an amount of food customarily consumed by persons 4 years of age or older. Therefore, the reference amounts for the general food supply should reflect the customarily consumed amounts by individuals 4 years of age or older, not by the total population which includes infants and children less than 4 years of age.

Secondly, as discussed in the 1991 serving size proposal (56 FR 60394 at 60400), the mean is often influenced by "outliers" (i.e., extremely small or extremely large amounts). Therefore, the mean alone is not sufficient to determine the customarily consumed amount. As explained above, FDA has concluded that to determine a reliable estimate of the amount customarily consumed, all three statistical estimates that represent an amount customarily consumed (the mean, the median, and the mode) must be considered.

Thirdly, the data submitted in the comments represent estimates from the 1977–1978 NFCS. The sole use of the 1977–1978 NFCS is not appropriate for the reason stated in section III.D.1. of this document.

FDA, therefore, has reanalyzed the 1977–1978 NFCS and the 1987–1988 NFCS to determine the mean, median, and modal consumed amounts of bread per eating occasion including the bread that was eaten as toast for persons 4 years of age or older. The amounts consumed as toast were adjusted to account for the moisture loss during toasting in order to more closely determine the weight of the bread, i.e., the form sold.

The reanalysis of the food consumption data showed that both the 1977–1978 NFCS and the 1987–1988 NFCS showed somewhat lower customarily consumed amounts for breads and rolls than for other products included in the original bread category (Ref. 47). Therefore, the agency concludes that it is appropriate to divide the original bread category into two categories, one for breads and rolls and one for all other products (e.g., bagel, English muffins, tortillas). Based on the results of the reanalysis, FDA finds that 50 g is the amount customarily consumed of breads and rolls, and 55 g is the amount customarily consumed for all other products. Accordingly, FDA has divided the bread category into 2 categories with separate reference amounts.

FDA notes that the new 50 g reference amount together with the new lower limit for a single-serving unit (more than 50 percent of the reference amount) in § 101.9(b)(2)(i) would make 1 slice as the serving size for most sliced breads on the market. The agency also notes that it has added a provision in new § 101.9(b)(10)(ii) that allows voluntary labeling of a second column of values per unit (per slice in the case of sliced bread) if the serving size of a product in discrete units is more than one unit. Both of these changes should help alleviate any potential for consumer confusion, as discussed in the comments.

As for the other comments, FDA does not agree with having separate reference amounts for sliced and unsliced bread. The same food cannot have different reference amounts simply because it comes in different forms or shapes. The act directs the agency to establish uniform serving size. Therefore, the same food should have the same reference amount regardless of its form or shape. The agency also disagrees with the comments that recommended reference amounts based on the weight of 1 slice of bread because food consumption data did not support such reference amounts. The agency also does not agree with the international comment that suggested keeping the 55 g reference amount for rolls because rolls are heavier than bread. The agency notes that the act defines the serving size as an amount customarily consumed. Food consumption data of the U.S. population showed that the amount customarily consumed is not higher for rolls than for bread (Ref. 47). Therefore, FDA has not adopted these recommendations.

49. A manufacturer of "lite bread" suggested a separate category for "lite" breads with a reference amount of 40 g. The comment stated that if "lite" breads are grouped with regular breads, the serving size for "lite" breads will be 3 slices, not 2 slices.

FDA advises that § 101.12(e) of the 1991 serving size proposal, which has been combined with new § 101.12(d) (see section III.D.6. of this document), requires that the reference amount for an altered version of a food be the same as for the food for which it is offered as a substitute. Therefore, it is inappropriate to have a lower reference amount for "lite" breads. However, if the product has been modified to be an aerated product as described in new § 101.12(e), manufacturers may determine the density-adjusted reference amount for the "aerated" bread by adjusting for the difference in density of the "aerated" bread relative to the density of the appropriate reference bread. (See section III.D.6. of this document for further discussion).

50. Comments from the tortilla industry unanimously requested a separate category for tortillas because: (1) Tortillas are not used interchangeably with other products in the bread category; (2) the tortilla industry continues to grow and deserves a separate category; and (3) a separate category would "help focus guidelines more specific to tortillas rather than baked goods in general." The comments did not suggest what the reference amount for this separate category should be. A comment from a foreign government contended that tortillas should be included in the "Taco shell" category.

FDA does not agree with the comments. To minimize the number of product categories, FDA proposed to include tortillas in the bread category because the amounts customarily consumed of tortillas and other products in the bread category (e.g., bagel, English muffin) are similar. The comments did not provide data to the contrary. FDA recognizes that tortillas have uses somewhat different from other products in the bread category, and that the tortilla industry is growing. However, balancing the interest in minimizing product categories against the significance of these facts, FDA concludes that it is appropriate to list tortillas with other bakery products that have the same reference amount. Therefore, FDA is not creating a separate category for tortillas.

Also, tortillas cannot be grouped with taco shells because the reference amounts for the two foods differ by two-fold. Although they both are foods that originated in Mexico, tortillas are much higher in moisture content and thus are much heavier than hard taco shells. This difference in the moisture content is reflected in the g weight of the reference amount.

(6) Bakery products: breakfast bars and toaster pastries

FDA proposed 55 g as the reference amount for this product category.

51. Manufacturers of breakfast bars and toaster pastries commented that it is more appropriate to separate these products into two categories with separate reference amounts because they are not consumed in similar amounts or in similar manners. The comments submitted market research data that showed that less than 20 percent of the bars are actually consumed at breakfast, and almost 80 percent are consumed at lunch or as a snack. In contrast, approximately 80 percent of the toaster pastries are eaten at breakfast. The comments suggested 40 g or 41 g as the reference amount for grain-based bars including breakfast bars and granola bars. Another comment suggested a 35 g reference amount for granola bars. The comments agreed on the 55 g reference amount proposed for toaster pastries, but they contended that these products are used interchangeably with the products in the coffee cake category. The comments said that, therefore, they should be included in the coffee cake category.

FDA agrees that grain-based bars should have a separate category with their own reference amount. The agency finds that 40 g is appropriate because it is consistent with the amount of these bars customarily consumed (Ref. 2). FDA also agrees with including toaster pastries in the Coffee cake category with a reference amount of 55 g. The comments support that doing so reflects how these products are customarily consumed. Therefore, in Table 2 of new § 101.12(b), FDA has deleted the category for breakfast bars and toaster pastries and has added a new category for "Grain-based bars with or without filling or coating, e.g., breakfast bars, granola bars, rice cereal bars" with a reference amount of 40 g, after the category for French toast and pancakes under the major category for Bakery Products. The agency has also revised the name of the coffee cake category to include toaster pastries.

(7) Bakery products: brownies

FDA proposed 40 g as the reference amount for this product category.

52. Two industry comments agreed with the 40 g reference amount. One comment, however, contended that brownies should have the same reference amount as cake because brownies do not differ from cake nutritionally, technologically, or in ingredients. Another comment asserted that an 80 g reference amount for brownies is consistent with consumption data and industry practice. Another comment recommended that FDA change the reference amount for brownies to make it uniform with the reference amount for snacks.

FDA disagrees with all of the comments that requested a change in the reference amount for brownies. Products that are similar nutritionally, technologically, and in ingredients often differ in amounts customarily consumed because they differ in other characteristics that affect the amount consumed (e.g., density). For example, the customarily consumed amount of dense ready-to-eat breakfast cereals (e.g., sweetened granola cereals) is about twice that of light weight cereals (e.g., flake-type cereals). Therefore, foods do not have the same reference amount simply because they are similar nutritionally, technologically, and in ingredients. They have the same reference amount if consumption data show that they do.

Data from the 1977–1978 NFCS and the 1987–1988 NFCS showed that 40 g, not 80 g, is consistent with consumption data for brownies (Ref. 2). FDA cannot change a reference amount simply to make it consistent with industry practice. The reference amount must reflect the amount customarily consumed. Also, the agency is not adopting the recommendation for a uniform reference amount for brownies and snacks because these foods are not necessarily used interchangeably, and such a uniform reference amount is not supported by food consumption data (Ref. 2). Accordingly, FDA has retained the reference amount as proposed.

(8) Bakery products: cake

FDA proposed 4 categories with separate reference amounts based on the density of the cakes: Heavy weight, medium weight, light weight, and very light weight. The heavy weight category included cakes weighing more than or equal to 10 g per cubic inch (e.g., cheese cake, fruit cake, and pineapple-upside down cake). The medium weight category included all cakes weighing more than or equal to 6 g but less than 10 g per cubic inch (e.g., most cakes with icing or filling, carrot cake, pound cake). The light weight category included all cakes weighing more than or equal to 4 g but less than 6 g per cubic inch (e.g., most cakes without icing or filling, very light cakes with icing or filling, eclairs). The very light weight category included all cakes weighing less than 4 g per cubic inch (e.g., angel food, chiffon, or sponge cake without icing or filling).

53. All comments that addressed the reference amounts for cakes opposed the density-based categories. The comments recommended eliminating the density specifications from the product category because: (1) Density has never been used by industry, the Government, or the trade to classify cakes; (2) it is difficult to determine the density because it varies with shelf life, temperature, and atmospheric pressure; (3) the density of a commercially prepared cake and the same cake baked from a mix may be slightly different and may result in the same type of cake falling into two different categories; and (4) there is potential for the manipulation of the densities of cakes that fall near category boundaries to fit in a favorable category.

Most comments recommended that FDA regroup cakes into 3 categories based on cake types: Heavy weight, medium weight, and light weight. The comments essentially requested retaining the proposed heavy and the very light weight categories with some modifications and combining the two proposed middle categories with a reference amount of 80 g. The comments also suggested including only those fruit cakes that contain 35 percent or more of the finished weight as fruit or nuts, as opposed to all fruit cakes, in the heavy weight category. The combined medium weight category would contain all chemically leavened cakes with or without icing or filling and other cakes (e.g., Boston cream pie, eclair) that do

not belong to the heavy or light weight category. A comment submitted a detailed description and results of analysis of data from the 1987–1988 NFCS in support of the 80 g reference amount recommended for the medium weight category.

FDA recognizes that it is difficult to determine the density of cake because it varies with shelf life, temperature, and atmospheric pressure. The agency also recognizes that other problems may arise from using the density-based categories such as that the density of a commercially prepared cake and the same cake baked from a mix may have slightly different densities that could result in the same type of cake falling into two different categories, and that the product categories based on density may encourage the manipulation of the density of cakes that fall around the borderline of a category to fit in a favorable category. The agency thus agrees with the comments that it is better to group cakes by type and to combine the proposed two middle categories into one medium weight category. The agency has reanalyzed the NFCS to confirm the 80 g reference amount suggested in the comment for the medium weight category (Ref. 41). Accordingly, the product category names for cakes have been renamed by type of cakes as suggested in the comments and the proposed middle two categories have been combined into one medium weight category with a reference amount of 80 g. The revised product category names and reference amounts are as follows:

Cakes, heavy weight (cheese cake; pineapple upside-down cake; fruit, nut, and vegetable cakes with more than or equal to 35 percent of the finished weight as fruit, nuts, or vegetables)—125 g

Cakes, medium weight (chemically leavened cake with or without icing or filling except those classified as light weight cake; fruit, nut, and vegetable cake with less than 35 percent of the finished weight as fruit, nuts, or vegetables; light weight cake with icing; Boston cream pie; cupcake; eclair; cream puff)—80 g

Cakes, light weight (angel food, chiffon, or sponge cake without icing or filling)—55 g.

The agency notes that although the cake categories are named by the type of cakes, not by the density, density was used as a guideline to group the cakes into the three categories. The heavy weight category includes cakes that weigh 10 g or more per cubic inch, the medium weight category includes cakes that weigh 4 g or more per cubic inch but less than 10 g per cubic inch, and the light weight category includes cakes that weigh less than 4 g per cubic inch. The density information described here provides guidance for cakes that may enter into the future market and do not fit in the cake types described in the product category names. The agency also notes that angel food, chiffon, and sponge cake without icing or filling that are prepared by traditional recipes and preparation methods are light and usually weigh less than 4 g per cubic inch. Therefore, they are included in the light weight category. However, if angel food, chiffon, or sponge cake contains heavy ingredients (e.g., fruits, chocolate chips, and nuts) that are usually not called for in the traditional recipes of these cakes, or if these cakes are processed in such a way as to increase the density, they will not be qualified to be called light weight cakes.

54. Two comments recommended a three-category system similar to the one discussed above but suggested that the medium weight category include only cakes without icing. The comments contended that the reference amount for the medium weight cakes with icing is not necessary because icing has a separate reference amount.

The system suggested by this comment will work for cakes with icing only. Many cakes have fillings. There is no reference amount for cake fillings. The agency is unable to determine a reference amount for cake fillings because there is no information from food consumption surveys or other sources to determine the customarily consumed amount of the fillings. Accordingly, FDA has not adopted this recommendation.

55. Some comments recommended that FDA include all cheese cakes other than New York style cheese cake in the medium weight category, rather than the heavy weight category. The comments contended that the 125 g reference amount is too large for non-New York-style (aerated) cheese cakes. One comment recommended that if FDA decides not to include cheese cake in the medium weight category, cheese cake should have a separate category with its own reference amount because cheese cakes differ from other cakes in many characteristics that affect the consumption size. The comment recommended 85 g as the reference amount for cheese cakes and submitted data collected by a "mail panel" survey that supported the 85 g reference amount.

FDA acknowledges that some commercially-prepared cheese cakes have air incorporated (aerated cheese cakes) and therefore, weigh much less than the unaerated (New York style) cheese cakes. The agency agrees with the comments that these aerated cheese cakes need a separate approach.

As discussed in section III.D.6. of this document, the agency has provided guidelines for determining the reference amount for products that are modified by incorporating air. If the aerated cheese cakes mentioned in the comment meet the 25 percent minimum reduction in density relative to the density of the appropriate unaerated cheese cake, manufacturers may use the "density-adjusted" reference amount for the aerated cheese cake following the guidelines described in section III.D.6. of this document, provided that the manufacturer will show FDA detailed protocol and records of all data that were used to determine the density-adjusted reference amount for the aerated cheese cake (see section III.D.6. for further discussion). Therefore, it is not necessary to create a separate category for aerated cheese cake or to establish a separate reference amount for aerated cheese cakes. Accordingly, FDA has retained the proposed 125-g reference amount for cheese cakes.

56. Some comments recommended that FDA include pound cake without icing in the light weight category with angel food, sponge, and chiffon cake without icing. The comments argued that USDA's density data used to convert a piece of pound cake to the g weight (conversion factor) were based on home recipes. The comments contended that commercially-prepared pound cakes are much less dense than the home-prepared versions. Thus, the conversion factor used in the NFCS was too high. Consequently, the amount customarily consumed for pound cake was overestimated. One comment recommended that if FDA decides not to include pound cake in the light weight category, pound cake should have a separate category with its own reference amount because pound cake differs from other cakes in many characteristics that affect the consumption amount. The comment recommended 45 g as the reference amount for pound cakes as a separate category and submitted data collected by a "mail panel" survey in support of the 45 g reference amount.

FDA disagrees with the comments. The cakes included in the light weight category (e.g., angel food, sponge, and chiffon cake) weighs less than 4 g per cubic inch (density). Commercial pound cakes without icing are much higher in density (about 6.1 g per cubic inch) than the cakes included in the light weight category (Ref. 48). The comment did not present density data to prove that commercial pound cakes weigh less than 4 g per cubic inch. All cakes that weigh more than 4 g per cubic inch, with the exception of those included in the heavy weight cake category, are

included in the medium weight cake category.

With regard to the survey data submitted in support of a separate reference amount of 45 g, FDA notes that in this survey, respondents were asked to record the total number of servings (slices) they usually get from a specific size of pound cake but were not asked how many slices each person in the household ate at a particular eating occasion. People often consume multiple slices at a single eating occasion. In addition, the survey included only frozen pound cake manufactured by the company that submitted the comment. The survey did not include the unfrozen, ready-to-eat forms of pound cake or competitors' products. Therefore, the data submitted in the comment do not represent all forms of pound cake in the marketplace. Therefore, the agency questions the representativeness and appropriateness of the data submitted in the comment and finds that they do not support a change in the reference amount.

FDA has thus concluded that the comments did not submit adequate data to justify the inclusion of pound cake without icing in the light weight category or to establish a separate category for pound cake with a reference amount of 45 g. Accordingly, the agency has retained pound cake without icing in the medium weight cake category.

57. One comment suggested a 90 g reference amount for all cakes.

Considering the large variability in the density of cakes, a uniform reference amount, regardless of the value, would result in a serving size too large for some cakes and too small for other cakes. The 90 g reference amount suggested would make the serving size for a light cake (e.g., angel food cake) a huge piece (e.g., about 1/3 of a 10 oz (about 8 inch diameter) angel food cake), whereas the serving size for a heavy fruit cake would be a small, thin slice.

58. One comment suggested separate reference amounts for cupcakes, 55 g for iced cupcakes and 35 g for un-iced cupcakes. The comment contended that the NFCS data suggest 55 g as the reference amount for frosted cupcakes and that the 55 g reference amount agrees with the reference amount for other products that are used interchangeably with cupcakes (e.g., muffins, Danish, doughnuts, coffee cakes). One comment requested that FDA establish a reference amount for assorted cupcakes.

FDA advises that the smallest reference amount for cake is 55 g for the light weight cake category. The cakes included in the light weight category (e.g., angel food, sponge, and chiffon cake) weigh less than 4 g per cubic inch. The comment did not present density data to prove that cupcakes weigh less than 4 g per cubic inch. All cakes that weigh more than 4 g per cubic inch, with the exception of those included in the heavy weight cake category, are included in the medium weight cake category. The labels of cake mixes that belong to the medium weight cake category (e.g., chocolate, yellow, or white cake) frequently provide preparation directions for a 2-layer cake, a sheet cake, and cupcakes. These label directions suggest that cupcakes are the same cake as a 2-layer or a sheet cake included in the medium weight category but differ only in shape, i.e., cupcakes are an individually shaped form of cake. The act directs the agency to establish uniform serving sizes. Therefore, the same food should have the same reference amount regardless of its shape. Thus, the agency included all cupcakes both with and without icing (including assorted cupcakes) in the medium weight category in this final regulation with the reference amount of 80 g. Accordingly, FDA has not established a separate reference amount for cupcakes.

59. One comment requested that FDA change the reference amount for muffins prepared at home, either from scratch or from a mix, to 45 g. The comment contended that a 45 g reference amount more closely approximates the weight of the muffin made with consumer baking pans.

FDA disagrees with the comment. First, food prepared at home from scratch is not subject to nutrition labeling. Secondly, the agency cannot establish a separate reference amount for the same food depending on the equipment used for preparation (e.g., commercial equipment versus equipment used at home). The reference amount for muffins is based on what consumption data show as the amount customarily consumed. Thus, it complies with the statute. Accordingly, FDA has not adopted this recommendation.

60. One comment suggested that FDA add microwave cakes to the coffee cake category. The comment stated that because of the characteristics of microwave cooking, microwave cakes have an unusually high density (7 to 7.5 g per cubic inch) and are very rich. According to the density classification, microwave cakes belong to the proposed medium weight category with the reference amount of 110 g. The comment contended that 110 g is too large for the microwave cakes. The comment, therefore, suggested including microwave cakes in the coffee cake category.

FDA does not agree that microwave cakes should be grouped with the products in the coffee cake category because microwave cakes are not used interchangeably with the products in the coffee cake category. Microwave cakes are a kind of cake that differs from other cakes only in that they are prepared in the microwave oven rather than in the conventional-type oven. Therefore, microwave cakes belong to a cake category. The agency points out that all cakes other than those classified as heavy weight and light weight are included in the medium weight category in the final regulation. The 7 to 7.5 g per cubic inch density for microwave cakes that the comment reported is within the range of the density of cakes in the medium weight cake category (4 g or more per cubic inch but less than 10 g per cubic inch). The agency notes that the reference amount for this new medium weight category is 80 g, not 110 g. Therefore, the agency has provided the relief that the comment sought, although for different reasons.

(9) Bakery products: crackers, all varieties excluding sweet and sandwich type—includes hard bread sticks and ice cream cones

FDA proposed 15 g as the reference amount for this product category.

61. Several comments argued that it is unfair to have two different reference amounts for competing products (i.e., crackers and snacks) that are used interchangeably. The comments requested that FDA establish a uniform reference amount for snacks and "snack crackers." If not, the comments asserted that a false impression will be created that snack crackers are lower in fat than the competing snack products. Some of these comments pointed out that some products that are more appropriately classified as snacks bear the name cracker (e.g., Cracker Crisps). A manufacturer suggested defining snacker crackers as crackers to which oil has been applied after baking (postbaking oil application).

FDA agrees with the comment that many crackers are used interchangeably with products in the snacks category. The agency acknowledges that it is very difficult to draw a line between cracker and snack products. Therefore, FDA has reexamined the products included in the cracker category and has concluded that it is more reasonable to divide it into two categories: Crackers that are usually not used as snacks and crackers that are usually used as snacks, based on their customary usage, how they are positioned in the marketplace, and the

amount of the cracker that is customarily consumed.

The former category includes saltines, soda crackers, and oyster crackers. These crackers are usually used as part of the meal (e.g., with soup) rather than as snacks. Reanalysis of the data from the 1977–1978 NFCS and the 1987–1988 NFCS showed that the proposed 15-g reference amount is reasonable for crackers that are usually not used as snacks. However, the customarily consumed amount of other crackers is closer to 1 oz than to 0.5 oz. Therefore, the agency has concluded that the cracker category should be divided into two categories with separate reference amounts. Accordingly, FDA has revised the cracker category as follows:

Crackers that are usually used as snacks—30 g

Crackers that are usually not used as snacks—15 g

The agency could not use the postbaking oil application suggested in the comment to divide the cracker category into "snack crackers" and "nonsnack crackers" because manufacturers can change the practice of the postbaking oil application, and therefore, a classification system based on this application could easily become irrelevant.

(10) Bakery products: French toast, pancakes

FDA proposed 110 g as the reference amount for this product category.

62. One comment recommended that FDA combine French toast and pancakes with waffles, with a reference amount of 85 g. The comment contended that these products "make similar contributions to the diet and are customarily consumed in the same way."

FDA agrees that French toast, pancakes, and waffles are used interchangeably in the diet. However, because French toast and pancakes are denser than waffles, the amount customarily consumed in g is much larger for French toast and pancakes than for waffles. Food consumption data do not support the 85 g reference amount for French toast and pancakes suggested in the comment (Ref. 2). Therefore, these foods cannot be grouped into one category. Accordingly, FDA has retained reference amounts for French toast and pancakes as proposed.

63. One comment recommended that FDA add a new category for dry pancake mix and variety mixes with a reference amount of 55 g. The comment contended that 55 g is equivalent to the amount of mix required to make three 4-inch pancakes, which is equivalent to the reference amount proposed by FDA.

New § 101.12(c) provides that the reference amount of a product that requires cooking or the addition of water or other ingredients be the amount required to prepare one reference amount of the final product as established in new § 101.12(b). Therefore, the reference amount for dry pancake mix will be the amount of the mix required to make one reference amount of the prepared product, so there is not need to establish a reference amount for dry pancake mix. Moreover, this approach is more reasonable than that suggested by the comment because pancake mixes come both in complete and incomplete forms, and the amount to make one reference amount may differ for the different forms.

Because variety mixes are used for many different purposes, the agency agrees with the comment that a reference amount for the dry form would be desirable so that all variety mixes will have a uniform label serving size to facilitate nutrition comparisons of different brands. Otherwise, different brands may choose different uses as the basis to determine the amount of the dry mix to make one reference amount of the prepared food.

According to the product label, a major use of variety mixes is to make pancakes. Using the recipe file for the 1987–1988 NFCS (Ref. 49), the agency has estimated that about 40 g of dry mix is needed to make one reference amount of the prepared pancakes. Therefore, FDA has established the reference amount for the variety mixes to be 40 g of dry mix. Accordingly, the agency has revised the product category to read: "French toast, pancakes, variety mixes." The reference amount has been revised to read: "110 g prepared for French toast and pancakes; 40 g of dry mix for variety mixes."

(11) Bakery products: pies, cobblers, turnovers, other pastries

FDA proposed 125 g as the reference amount for this product category.

64. A comment from a trade association for bakery products supported the proposed reference amount. A few other comments opposed the 125-g reference amount. One comment requested that FDA change the reference amount to 4 oz (110 g) based on the size of 1/6 and 1/8 of pies tested. Another comment argued that the proposed reference amount would result in an extremely large serving size for some pies (e.g., 1/3 of an 8-inch frozen cream pie) and a small serving size for other pies (e.g., 1/10 of a 10-inch fruit pie). The comment recommended that FDA establish three separate reference amounts: 1/6 of a pie for 8 inch pies, 1/8 of a pie for 9-inch or larger pies, and 125 g for individual pies and pastries. The comment submitted estimates of amounts consumed per serving for various pies that it manufactures which were derived from a "Mall Intercept Method" survey conducted in 15 cities in the United States. The survey was designed to recruit people who are representative of the demographic and socioeconomic characteristics of the people who buy the test products based on the sales data for frozen pies.

FDA carefully examined all data submitted in the comments. FDA disagrees with the request to change the reference amount to 4 oz. The data submitted in support of the 4-oz reference amount do not represent food consumption data collected under actual conditions of use or an estimate representative of all types and varieties of products included in the product category.

FDA also disagrees with the comment that contended that reference amounts should be expressed in fractions of pies. The agency used fractions as the reference amount for pie crust because in this particular case, fractions are the most meaningful measure, and there is not much concern about the manipulation of the serving size for the pie crust. Because pies come in different diameters and heights, reference amounts based on fractions of pies would result in different reference amounts for different size pies of the same brand as well as for different brands of the same kind of pie. Therefore, there would be no uniform basis to evaluate the qualification for claims on pies. For example, data submitted in the comment showed that the reference amount based on fractions of pies for one brand alone could vary from 64 to 163 g. Furthermore, reference amounts based on fractions of pies may encourage the manipulation of the reference amount to produce a more favorable presentation of the nutrition information or to qualify for a claim by changing the diameter or height.

The agency, however, agrees that the 125-g reference amount would result in an unreasonably large serving size for frozen cream pies. These commercially prepared frozen cream pies differ from homemade cream pies. Commercial cream pies are aerated and thus weigh much less than homemade cream pies. Therefore, FDA believes that these pies need a separate approach that is more reasonable for aerated cream pies.

As discussed in section III.D.6. of this document, the agency has provided guidelines for determining the reference amount for products that are modified by incorporating air. If the aerated

cream pies mentioned in the comment meet the 25 percent minimum reduction in density relative to the density of the appropriate unaerated cream pie, manufacturers may use the "density-adjusted" reference amount for the aerated cream pie following the guidelines described in section III.D.6. of this document, provided that the manufacturer will show FDA detailed protocol and records of all data that were used to determine the density-adjusted reference amount for the aerated cream pie (see section III.D.6. for further discussion). Therefore, it is not necessary to establish a separate reference amount for aerated cream pies. Accordingly, FDA has retained the proposed 125-g reference amount for cream pies.

(12) Bakery products: taco shell

FDA proposed 30 g as the reference amount for this product category.

65. A comment from a trade association for bakery products supported the proposed reference amount. Another comment recommended that FDA change the reference amount to 15 g which is equivalent to 1 taco shell. The comment contended that one filled taco shell equals the reference amount for the mixed dishes not measurable with cup category (140 g).

FDA disagrees with the latter comment. The agency points out that according to the USDA manual (Ref. 31), one filled taco weighs about 70 to 80 g. Therefore, two filled tacos would approximate one reference amount for filled tacos. Accordingly, FDA has retained the reference amount as proposed.

(13) Bakery products: waffles

FDA proposed 85 g as this reference amount for the product category.

66. Two comments from a trade association for bakery products and a manufacturer supported the proposed reference amount. One comment from another manufacturer opposed the 85-g reference amount. The comment contended that the 85-g reference amount would make the serving size for some of their waffles three waffles instead of two. The comment recommended that FDA revise the reference amount for waffles to state "85 g, and not to exceed 2 waffles or 2 sets of connected waffles, if their total weight is 67 percent of the reference amount or more." The comment submitted data from a "Mall Intercept Method" survey conducted in 15 cities in the United States to support that people customarily consume 2 waffles or 2 sets of connected waffles. The comment also requested that FDA allow manufacturers to provide nutrition information per waffle or per 1 set of waffles.

FDA advises that it is inappropriate to call 2 pieces of a product that weigh 67 percent of the reference amount one serving when 3 pieces are equal to one reference amount. In addition, FDA notes that the 85-g reference amount was derived using data from large national food consumption surveys that were collected under actual conditions of use and included all types of waffle products (dry mixes and frozen) and many different brands available in the marketplace. The agency finds that it would be inappropriate to modify the reference amount to make it consistent with questionable data submitted in the comment.

The data submitted in the comment have several problems. First, they are not food consumption data that were collected under actual conditions of use. People were asked to show the number of waffles that the participants and other members of their families normally eat. People did not answer or record the number of waffles that they actually ate during the survey days. In addition, the survey tested only frozen waffles manufactured by the company that submitted the comment. Waffles come in dry mixes and frozen prepared forms. There are many different brands of waffle products in the marketplace. Therefore, it is questionable if the data submitted in the comment are representative of all waffle products in the marketplace.

Accordingly, FDA has retained the reference amount as proposed. The agency notes that new § 101.9(10)(ii) allows voluntary labeling of a second column of values per unit for products in discrete units.

(14) Beverages: all categories

Because FDA proposed a uniform 240-mL (8-fl oz) reference amount for all beverages, comments on all the categories under Beverages are considered together.

67. Comments from several manufacturers and trade associations and a comment from a nutrition professional organization supported the proposed uniform 8-fl oz reference amount for all beverages. There were no objections to the 8-fl oz reference amount for carbonated beverages, wine coolers, or water. However, two comments from the carbonated beverage industry stated that if FDA abandons the uniform 8-fl oz reference amount, they want a 6-fl oz reference amount for carbonated beverages. Comments from coffee and tea manufacturers and their trade associations opposed the 8-fl oz uniform reference amount. These comments contended that the reference amount for coffee and tea should be 180 mL (6 fl oz). Among other things, these comments argued that: (1) 6 fl oz is the serving size currently used by the industry, in recipe books and other literature, (2) hot beverages are generally not used interchangeably with cold beverages, and (3) standard coffee cups as well as the graduation on coffee makers and pots are designed for 5 1/2- to 6-fl oz serving sizes. The comments contended that changing the serving size for coffee to 8 fl oz would cause unnecessary costs to manufacturers to change the graduation on the coffee making apparatuses. Such cost increases would be passed on to consumers.

First, FDA advises that new § 101.9(j)(4) exempts plain coffee and tea from all requirements of the nutrition labeling regulation. Accordingly, the reference amount for plain coffee and tea has been deleted from Table 2 in new § 101.12(b). As for the reference amount for flavored and sweetened coffee and tea, the agency points out that food consumption data support the 8-fl oz reference amount for these coffees and teas (Ref. 2). The agency notes that unlike plain coffee, flavored and sweetened coffee are not made in coffee makers, and thus there is no concern about changing the graduation on the coffee making apparatuses which would increase the cost of coffee. Flavored and sweetened tea (e.g., iced tea mixes) is also used interchangeably with other cold beverages. Considering the weight of support for the uniform 8-fl oz reference amount for all beverages and the reasons stated here, the agency has concluded that the uniform 8-fl oz reference amount for all beverages including flavored and sweetened tea is appropriate under section 403(q)(1)(A)(i) of the act. Accordingly, FDA has retained the reference amount as proposed for all beverages under the beverages category except for plain coffee and tea. The uniform reference amount for all beverages facilitates nutrition comparisons among different beverages.

(15) Cereals and other grain products: breakfast cereals (hot cereal type), hominy grits

FDA proposed 1 cup prepared or 40-g plain dry cereal or 55-g flavored, sweetened dry cereal as the reference amounts for this category.

68. Several comments opposed the proposed reference amounts for the dry cereal form. One comment recommended that FDA change the

reference amount to 1-oz dry because this amount is more consistent with current labeling practices by manufacturers. Another comment recommended a 35-g uniform reference amount for all cereals, including hot and ready-to-eat cereals (and a 50-g reference amount for a second category if a second category is necessary). The comment did not submit any supporting data for the recommended reference amounts. A manufacturer of hot cereals recommended that FDA use a uniform reference amount of 40 g for both regular, and flavored and sweetened cereals. To support the uniform 40-g reference amount, the comment submitted estimates of the dry weight of cereals derived from the mean consumed amounts from the 1987–1988 NFCS for the two types of cereals (regular and quick hot cereals and instant hot cereals) and the conversion factors it used to determine the dry weight from the prepared weight.

Under the act, the serving size must reflect an amount customarily consumed, not the current labeling practices by manufacturers. Therefore, the agency cannot change the reference amount derived from the food consumption data, which represents the customarily consumed amount, to make it consistent with the current labeling practices.

With regard to the comment that recommended a uniform reference amount of 40 g for all hot cereals, FDA carefully examined the data submitted in support of the uniform 40-g reference amount. The data showed that the mean intake for the instant cereal was lower than the mean intake for the regular and quick cereal because many instant cereals come in single-serving packages, and the single-serving packages currently on the market generally contain less than the amount of dry cereal required to make one reference amount (1 cup) of the prepared cereal. Therefore, the mean consumed amount of flavored and sweetened cereals was lower than that of regular and of quick hot cereals.

Basing the reference amount on the data in the comment would result in using two different bases for determining the reference amount for hot cereals: (1) Regular and quick hot cereals would reflect the amount customarily consumed from multiserving containers, and (2) flavored and sweetened hot cereals would reflect the amount customarily consumed from current single-serving containers. As the comment pointed out, the flavored and sweetened hot cereals currently come in single-serving containers only. However, although the amount of hot dry cereal customarily consumed may remain the same, the single-serving container size may change, or these products may be available in multiserving containers in the future. Therefore, the agency has concluded that the reference amounts for both varieties of hot dry cereal must reflect the multiserving containers.

FDA's independent analysis, using both the 1977–1978 NFCS and the 1987–1988 NFCS showed that the amount customarily consumed for the plain dry hot cereals is 40 g (Ref. 41). The flavored and sweetened hot cereals, however, contain additional ingredients (e.g., sugar, dried fruit) and, therefore, weigh more than plain dry hot cereals on an "as packaged" basis. Based on the difference in weight of plain dry hot cereal and flavored and sweetened cereal, FDA estimated the difference in weight to be, on the average, about 15 g (Ref. 2). Therefore, the reference amount for flavored and sweetened hot cereals must include the 15-g extra weight to account for the additional ingredients. Accordingly, FDA has retained the reference amount as proposed (55 g). The agency points out, however, that according to new§ 101.9(b)(2)(i) and (b)(6), the serving sizes of all single-serving packages of hot cereals will be one package.

(16) Cereals and other grain products: breakfast cereals, ready-to-eat, all categories

FDA proposed three reference amounts for ready-to-eat cereals depending on the density or shape of the cereal: 1 cup for cereals weighing less than 3 oz per cup; 1/2 cup for cereals weighing more than or equal to 3 oz per cup; and 50 g for cereals not measurable with a cup (e.g., biscuit type).

69. Most comments objected to the reference amount in a volumetric (cup) measure because of the lack of precision in the measurement of the g weight of the cup measure. The comments preferred weight-based reference amounts. One comment stated that the volumes of small pieces of dry solids can be accidentally altered or even intentionally manipulated to reach different volumetric measurements. Cereals' shapes, sizes, ingredients, and textures, as well as handling practices, settling characteristics, measurement methods, and timing can affect the accuracy of measurements. The comment contended that measured g weights of the servings by two persons trained to follow identical procedures varied not only for servings from the top to the bottom of the boxes but at identical levels of different boxes. Overall, the g weights of the individual cup measurements differed by more than two-fold (29 to 68 g). The comment contended that because there are large variabilities in the estimates for g-weight-per-cup measure, the specific g-weight measure a manufacturer chooses to declare on the label may be arbitrary and, worse, may be manipulated in order to permit nutrient content claims.

As a solution to the problems discussed above, some comments recommended a uniform weight-based reference amount for all ready-to-eat cereals. Others recommended that the cereals be divided into two categories based on density with separate weight-based reference amounts. For a uniform reference amount, a health professional organization recommended 1 oz, and a cereal manufacturer recommended 35 g. Comments that recommended the two-category system differed in both how the two categories should be split and the reference amounts for the two categories. One comment suggested a 35-g reference amount for all cereals and, if a second category is necessary, 55 g for the second category. The comment did not provide details about what products the second category should include. Another comment recommended a 15-g reference amount for plain puffed cereal grains and a 35 to 40 g reference amount for all other cereals. Two other comments recommended a 30-g reference amount for cereals weighing less than 43-g per cup and for cereals that contain at least 8 g of fiber per oz, and a 55-g reference amount for cereals weighing 43 g or more per cup.

The comments provided a good description of the difficulties in accurately determining the g weight equivalents of the cup measures of ready-to-eat cereals. FDA acknowledges the characteristics of ready-to-eat cereals that present particular problems in determining the g-weight equivalents of household measures. The agency agrees with the comments that volume-based reference amounts present compliance problems and may result in manipulation of the serving size. Therefore, FDA has concluded that the reference amounts for ready-to-eat cereals should be in g quantities.

FDA carefully examined the weight-based reference amounts suggested in the comments. FDA does not believe that a uniform reference amount for all ready-to-eat cereals is appropriate. Regardless of the value, a uniform reference amount would result in serving sizes that are too large for some cereals and too small for others. For example, the 35-g reference amount

suggested in the comment would result in serving sizes that range from about 1/4 cup for heavy cereals (e.g., sweetened granola-type cereals) to about 3 cups for light cereals (plain puffed rice or wheat). These serving sizes are not consistent with the amounts of these types of cereals customarily consumed. Food consumption data showed that customarily consumed amounts for the heavy cereals are about 1/2 cup and for the light cereals about 1 cup (Ref. 41).

FDA also carefully examined all reference amounts for the two-category system suggested in the comments. One of the comments submitted a detailed description and results of an analysis of data from the 1987–1988 NFCS to support the 43-g per cup dividing line, with 30- and 55-g reference amounts. FDA has done an independent data analysis of ready-to-eat cereals and confirmed the validity and reasonableness of the reference amounts recommended in the comment for most cereals (Ref. 41).

However, the agency does not believe that the 30-g reference amount is reasonable for light cereals that weigh less than 20-g per cup (e.g., plain puffed rice or wheat). The 30-g reference amount would result in a serving size that is about 2 to 2 1/2 times the customarily consumed amounts of these cereals. Therefore, FDA has divided the category for cereals weighing less than 43 g per cup into 2 categories: Cereals weighing less than 20 g per cup, which primarily consist of plain puffed cereal grains, and cereals weighing 20 g or more but less than 43 g per cup. Following the principles and procedures described in the 1991 serving size proposal, FDA has determined the reference amount for light cereals to be 15 g (Ref. 41).

Accordingly, FDA has revised the product categories, and the reference amounts, for ready-to-eat cereals as follows:

Breakfast cereals, ready-to-eat weighing less than 20 g per cup, (e.g., plain puffed cereal grains)—15 g

Breakfast cereals, ready-to-eat weighing more than 20 g but less than 43 g per cup; high fiber cereals containing 28 g or more of fiber per 100 g—30 g

Breakfast cereals, ready-to-eat weighing 43 g or more per cup; biscuit types—55 g

70. Other comments on the reference amounts for ready-to-eat cereals included objections to some specific aspects of the methodology used to determine the reference amounts. One comment objected to the first step used in determining the product categories (56 FR 60394 at 60403) for cereals. This step divided the cereals into subcategories according to "other characteristics" that are likely to affect the levels of consumption of foods within the product class, i.e., in this case, the density of the cereals. Other comments objected to relying solely on the 1987–1988 NFCS in determining the reference amount for cereals measurable with a cup. Another comment stated that USDA's density information that FDA used to categorize ready-to-eat cereals differed from the manufacturers' data for at least 11 cereals.

As mentioned above, the amounts customarily consumed for ready-to-eat cereals vary by the density of the cereal. Therefore, the step that divided the cereals into subcategories by density was necessary in order to determine the appropriate amounts customarily consumed for specific types of cereals. As explained in the technical report (Ref. 2), FDA relied solely on the 1987–1988 NFCS because many new cereals have been introduced since the 1977–1978 NFCS, and the 1977–1978 NFCS did not contain food consumption data or density information for the new varieties. Also, density information in the 1977–1978 NFCS was not as useful as that in the 1987–1988 NFCS even for cereals that existed at the time of, or prior to, the 1977–1978 NFCS. Also cereals that differed in density had often been combined into one food code in the 1977–1978 NFCS. In the 1987–1988 NFCS, however, USDA greatly expanded the list of ready-to-eat cereals and their density information. FDA continues to believe that ready-to-eat cereals need to be divided into subcategories, and that it is necessary to rely solely on the 1987–1988 NFCS to estimate the amounts customarily consumed for the cereals currently on the market and to reflect the more recent data on density.

With regard to the discrepancy in measurements of densities of ready-to-eat cereals between USDA and manufacturers' data, the comment did not specify the cereals for which there was a discrepancy, or how large the discrepancies were. USDA's density information is the most current and the best data available to FDA. These density measurements were done without any knowledge about a possible use in nutrition labeling. Therefore, there was no manipulation of the measurements to provide a favorable nutrition profile or to be able to make a claim. In light of the extreme difficulties in measuring the g weights of cup measures and the lack of well-established standard procedures for measuring the g weights of cup measures for ready-to-eat cereals, FDA will use USDA's measurements for compliance purposes to check for proper categorization of ready-to-eat cereals. USDA's density data can be found in Reference 45.

If a manufacturer does not agree with USDA's density data, the manufacturer can petition FDA for a reevaluation of the density of a particular cereal. The manufacturer should submit density data that includes a detailed description of the methodology used (e.g., materials and equipment used, procedures followed), name and qualification of the operator, records of all individual measurements, the mean and the standard deviation of the measurements, and any other information that may help FDA to evaluate the density of the product in question. Density measurements should be repeated a sufficient number of times to produce a reliable estimate. In determining the density, manufacturers should also follow FDA's general Guidelines for Determining the Gram Weight of the Household Measure mentioned in new § 101.9(b)(7).

(17) Cereals and other grain products: flours or cornmeal

FDA proposed 30 g as the reference amount for this product category.

71. One comment opposed the 30 g reference amount for bread. The comment contended that their research showed that 55 g (2 oz) of flour is needed to make 2 slices of homemade bread. The comment stated that they used 2 slices as the amount customarily consumed because the 1977–1978 NFCS showed that consumers typically consume 2 slices of bread per eating occasion regardless of the density. Because the primary use of flour is homemade bread, and homemade bread is typically more dense than commercially-made bread, the comment argued that more flour is needed to make 2 slices of homemade bread than 2 slices of commercial bread. The comment did not submit the protocol for the research upon which it relied or data in support of the suggested change in the reference amount.

FDA disagrees with the comment. The agency notes that the comment's assumption that the amount customarily consumed in g is larger for homemade bread than for commercial bread is wrong. Data from the 1977–1978 NFCS and the 1987–1988 NFCS showed that the amount customarily consumed of homemade bread is not greater than 55 g (Ref. 41). The 30-g reference amount is the amount of flour required to make 55 g of bread. Accordingly, FDA retained the reference amount as proposed.

(18) Cereals and other grain products: grains, e.g., rice, barley, plain

FDA proposed 140 g prepared or 45 g dry as the reference amount for this product category. The agency notes that the product category name in the 1991 serving size proposal (56 FR 60394 at 60418) had a typographical error and included seasoned rice. A correction notice was published on March 6, 1992 (57 FR 8179).

72. Several comments from the rice industry stated that the proposed reference amount was based on the 1977–1978 NFCS data which are outdated. The comments argued that rice consumption patterns have changed since the 1977–1978 NFCS, and that the proposed 140-g reference amount does not reflect the amount of rice customarily consumed today. The comments contended that rice products introduced since the 1977–1978 NFCS (e.g., rice mixes) are customarily consumed in 1/2-cup servings. None of the comments submitted food consumption data to support this claim. One comment pointed out that the 140-g prepared reference amount yields different cup measures for different types of rice, and therefore, the label serving size will differ for different types of rice. The comment contended that rice is easily and conveniently measured with a cup, and that a reference amount that is expressed in a volume measure would yield more consistent label serving sizes for different types of rice. The comment recommended 3/4 cup prepared as the reference amount and submitted the g weights per cup measures of different types of rice in support of the 3/4-cup reference amount. A few comments requested that FDA delete the reference amount for the dry form because the customarily consumed amounts are more consistent on a prepared basis among different types and forms of rice.

FDA advises that it used both the 1977–1978 NFCS and the 1987–1988 NFCS to determine the reference amount for plain rice (Ref. 2). In the 1991 serving size proposal, seasoned rice mixes were included in the Mixed dishes measurable with cup category (see further discussion on seasoned rice mixes under the Mixed dishes measurable with cup category).

FDA disagrees that the reference amount for cooked rice should be expressed in cups. Although cup is the household measure most appropriate for expressing the label serving size for rice, its use in defining the reference amount for rice is not desirable for several reasons. First, cooked rice has several unique characteristics that make it difficult to accurately determine the g weight of the cup measure. For example, cooked rice is not free-flowing, and when cooked, some rice becomes sticky. Secondly, there is no well-established procedure for determining the g weight of the household measure. Therefore, if the reference amount is expressed in cups, the parenthetical metric measure that is used for compliance monitoring would be inaccurate. Thus, the agency has concluded that it is more important to have the reference amount in the most accurate measure possible, i.e., in g. In addition, comments on the 1990 proposal wanted a uniform "standard" serving size (equivalent to the reference amount in the 1991 serving size proposal) for pastas and rice. Changing the reference amount for rice to 3/4 cup would make the reference amounts for these two foods nonuniform. Accordingly, FDA has retained the reference amount of cooked rice as proposed (140 g).

FDA also disagrees that the reference amount for the dry form should be deleted. Because the weight of the cooked rice depends on the amount of water used in the preparation, the amount required to make one reference amount in cooked form can vary widely. The reference amount on a cooked basis also opens a door to a manipulation of the reference amount for dry rice. Therefore, if the reference amount for rice is expressed only on a cooked basis, FDA cannot effectively monitor the compliance. Consequently, the agency rejects this recommendation and has decided to retain the reference amount for the dry form as proposed.

(19) Cereals and other grain products: pastas, without sauce

FDA proposed 140 g prepared or 55 g dry as the reference amount for the product category.

73. A comment from a trade association for pasta products supported the proposed reference amount. One comment contended that because FDA relied on the 1977–1978 NFCS and the 1987–1988 NFCS, refrigerated filled pastas were not adequately represented. The comment argued that the refrigerated filled pastas (e.g., tortelloni, tortellini, and ravioli) were introduced to the market in 1987, and the comment further argued that a study of consumer "habits and attitudes" done by a company showed that people eat smaller portions of meat and cheese filled pastas compared to "cut pasta." Therefore, the comment recommended a 100 g reference amount for filled pasta and claimed that 100 g most closely agrees with the amount customarily consumed of filled pasta. The comment did not submit the results of the consumer "habits and attitudes" study or data supporting the claim that 100 g represents the amount customarily consumed for filled pasta.

FDA advises that this category includes only plain pastas. Filled pastas contain components from two or more food groups, pasta and filling from another food group (e.g., cheese, meat). Filled pastas are included in the Mixed dishes measurable with cup category (Refs. 2 and 20). Because the refrigerated filled pastas were introduced into the market in 1987, there were more reportings of these products in the 1987–1988 NFCS than in the 1977–1978 NFCS. The 1987–1988 NFCS had a total of 67 individual eating occasions of ravioli and tortellini. The customarily consumed amount was 1 cup or about 200 g without sauce (Ref. 41), not 100 g. Accordingly, FDA has retained filled pasta under the Mixed dishes measurable with cup category, with a reference amount of 1 cup. For clarity, the agency has revised the product category name to read: "Pastas, plain."

74. A few comments stated that the proposed 140 g reference amount is too large for lasagna noodles because lasagna noodles are used only as an ingredient of lasagna. One comment recommended 2 oz prepared as the reference amount for lasagna noodles. The comment contended that 2-oz prepared would be consistent with the amount of lasagna noodles required to make one reference amount of lasagna, but the comment did not explain how it arrived at this amount. Another comment recommended 1-oz dry as the reference amount for lasagna noodles. The comment contended that this amount is reasonable because it is half of the reference amount for the dry form of other pastas in the category.

FDA acknowledges that lasagna noodles have a specific usage, i.e., they are customarily consumed as an ingredient of lasagna. However, other pastas in this category are also used primarily as an ingredient of other foods (e.g., spaghetti noodles in spaghetti, macaroni noodles in macaroni and cheese or macaroni salad). Because neither comment explained or submitted data in support of the recommended reference amount for lasagna noodles, FDA has independently estimated the amount of lasagna noodles that are required to make one reference amount (1 cup) of lasagna. Using the recipe file for the 1987–1988 NFCS (Ref. 49) and the percent yield information reported by USDA (Ref. 18), the agency has estimated that about 3.5-oz prepared or about 1.5-oz dry lasagna noodles are

needed to make 1 cup of lasagna (Ref. 50). These values are considerably larger than the 2 oz prepared and 1 oz dry that were suggested in the comments. The data from the 1977–1978 NFCS and the 1987–1988 NFCS showed that customarily consumed amounts of products in this category vary widely, and the 3.5-oz cooked lasagna is well within one standard deviation of the mean customarily consumed amount (Ref. 41). Considering the large variability in customarily consumed amounts of pastas, the relatively small difference between the amount of lasagna required to make one reference amount of lasagna and the reference amount for the pasta category, and that lasagna is not the only pasta used as an ingredient, the agency has concluded that a separate reference amount specific for lasagna noodles is not warranted. Accordingly, FDA had retained the reference amount as proposed.

(20) Dairy products and substitutes: cheese, grated hard, e.g., Parmesan and Romano

FDA proposed 5 g as the reference amount for this product category.

75. One comment contended that the 5-g reference amount is too small and requested that FDA change it to 1 tbsp. FDA advises that 5 g is equivalent to 1 tbsp. in terms of volume. Accordingly, FDA has retained the reference amount as proposed.

(21) Dairy products and substitutes: eggnog

FDA proposed 120 mL as the reference amount for this product category.

76. One comment requested that FDA change the reference amount to 8 fl oz to make it consistent with the reference amounts for other beverages.

FDA does not believe that a uniform 8-fl oz reference amount is necessary for eggnog. Eggnog differs from other beverages. It usually is not used interchangeably with other beverages. Eggnog is a special type of beverage that is customarily served at special occasions (e.g., holidays and parties) and is customarily consumed in amounts smaller than other beverages, such as soft drinks. Comments on the 1990 proposal supported the 120 mL (4 fl oz) reference amount. Food consumption data did not provide a reasonable basis to increase the reference amount to 8 fl oz. Therefore, FDA has retained the reference amount as proposed.

(22) Dairy products and substitutes: milk, evaporated, undiluted

FDA proposed 15 mL as the reference amount for this product category.

77. Several comments from the dairy industry opposed the proposed reference amount. The comments contended that: (1) Evaporated milk is used interchangeably with condensed milk in recipes, (2) the proposed reference amount reflected the use of evaporated milk in coffee, and (3) evaporated milk is used more often as an ingredient of other foods, and 30 mL is closer than 15 mL to the amount used as an ingredient. The comments requested that FDA change the reference amount to 30 mL. One comment submitted data from a recent survey on the use of evaporated milk involving 2,000 households that showed that about 70 percent of the households surveyed used evaporated milk as an ingredient in recipes as opposed to about 35 percent of the households that used it in coffee. The comment also submitted results from a study done by a manufacturer that showed the amounts of evaporated milk consumed per serving of the recipes most frequently used by consumers.

FDA carefully examined the arguments and data submitted in the comments. The agency agrees that evaporated milk is used primarily as an ingredient of other foods, and that the amount customarily consumed as an ingredient is generally larger than the proposed reference amount. The data submitted in the comment showed that the amount of evaporated milk, as an ingredient, consumed per serving ranged mostly from 20 to 50 mL. The mid-range of these values is 35 mL (about 1 fl oz). Because the major use of evaporated milk is as an ingredient, the agency has concluded that the reference amount for evaporated milk should reflect the amount used as an ingredient. Following the principles in expressing the reference amounts for fluids described in the 1991 serving size proposal (56 FR 60394 at 60406), the agency has determined the reference amount for evaporated milk to be 30 mL. Accordingly, FDA has revised the reference amount to 30 mL.

(23) Dairy products and substitutes: milk, milk-based drinks, e.g., instant breakfast, meal replacement, cocoa

FDA proposed a uniform 240 mL (8 fl oz) as the reference amount for all beverages.

78. Comments from several manufacturers and trade associations and a comment from a nutrition professional organization supported the proposed uniform 8-fl oz reference amount for all beverages. A few comments requested that FDA create a separate category for hot cocoa or hot cocoa and cocoa beverages with a reference amount of 6 fl oz. The comments contended that 70 percent of the servings of hot cocoa mix sold are in single-serving envelopes that yield a 6-fl oz serving, and that hot cocoa sold from vending machines also has a 6-fl oz serving.

Cocoa beverages are a type of flavored and sweetened milk beverages. FDA does not believe that it is appropriate to have two different reference amounts for flavored and sweetened milk beverages, one for cocoa beverages and one for other flavored and sweetened milk (e.g., chocolate milk, malted milk). Cocoa beverage mixes are available both in single-serving and multiserving containers. These beverage mixes are consumed both hot or cold and interchangeably with other hot or cold beverages. Food consumption data showed that the amount customarily consumed for cocoa beverages is 8 fl oz (Ref. 41). FDA also notes that the 6-fl oz single-serving envelopes in a multiserving container are single-serving units according to new § 101.9(b)(2)(i), and therefore, the serving size will be one envelope. Considering the weight of the support for the uniform 8-fl oz reference amount for all beverages, food consumption data, and the other reasons stated here, the agency concludes that 8 fl oz is the appropriate reference amount for cocoa beverages under the act. Accordingly, FDA has retained the reference amount as proposed.

(24) Dairy products and substitutes: yogurt

FDA proposed 225 g as the reference amount for this product category.

79. Two comments requested that FDA change the reference amount to 170 g (6 oz). One comment argued that the mean consumed serving from the 1987–1988 NFCS was 6.9 oz, and this value rounded to the nearest container size would be 6 oz. Another comment contended that recent data from a marketing survey on yogurt sales showed that 6 oz rather than 8 oz would be a more appropriate reference amount. The comment stated that on a pound-volume basis, the survey showed that 40 percent of all yogurt was packaged in 6-oz containers or smaller, and approximately 60 percent was packed in 8-oz containers. The comment claimed that when these data were converted to a per serving basis, they showed that 52 percent of yogurt was eaten from 6-oz containers or smaller. The comment did

not submit actual survey data or explain how the 52-percent estimate on a per serving basis was derived.

FDA disagrees with all requests for a change in the reference amount for this category. As for the comment that requested a change based on the mean intake of yogurt from the 1987–1988 NFCS, FDA advises that it is not using the mean alone or a reference amount that is solely based on the 1987–1988 NFCS for the reasons explained in section III.D.1. of this document, unless there is a valid reason for doing so (e.g., trends that are confirmed by another survey that had a high response rate, or information was not available in the 1977–1978 NFCS).

As for the comment that requested a change based on the sales volume of single-serving yogurt containers, FDA notes that sales data are not consumption data and do not necessarily equate to consumption data. For example, some people could have consumed two 4-oz containers of yogurt which makes the consumed amount 8 oz, while the sales data would have counted two 4-oz containers. It is not clear how the comment derived the percent estimates on a serving basis from the sales data. FDA's independent analysis of the sales data from the same source as the comment showed that both on a pound basis and on a serving basis, 8-oz containers were clearly the major container size (Ref. 51). On a pound basis, containers that were 6 oz or smaller accounted for about 21 percent of the total weight, whereas 8-oz containers accounted for about 59 percent. On a serving basis, the respective values were about 27 and 54 percent (Ref. 51). Therefore, the sales data also supported the 8-oz reference amount derived from food consumption data.

Accordingly, FDA has retained the reference amount as proposed.

(25) Desserts: ice cream, ice milk, frozen yogurt, sherbet: all types, bulk and novelties (e.g., bars, sandwiches, cones)

FDA proposed 1/2 cup (4 fl oz) as the reference amount for the product category. The reference amount included the volume of coatings and wafers for the novelty type varieties.

80. Several comments recommended that FDA divide this category into two categories, one for bulk products and one for novelties. Some comments agreed with the 1/2-cup (4-fl oz) reference amount for bulk products. A few other comments asserted that the reference amount for bulk products should be larger. One comment suggested 6 oz, and another comment suggested 1 cup. Most comments recommended a 2.5-fl oz (an average size of 1 novelty) as the reference amount for novelties. The comments contended that novelty type products are consumed by piece, and the serving size should be 1 piece. The comments argued that the proposed reference amount of 4 fl oz would make the serving size 2 bars for some novelties packaged in multiserving containers.

First, FDA notes that food consumption data showed that the customarily consumed amount for novelty-type products was 2.5 oz. When converted to volume, 2.5 oz is equivalent to about 4 fl oz (Ref. 2). Bulk products and novelty-type products are the same type of products in different shapes. Some novelty-type products come without coating or wafers, and thus the bulk-type and the novelty-type differ only in shape. It is inappropriate to have two reference amounts for two forms of the same food that are used interchangeably. If FDA did have two separate reference amounts as suggested in the comments, one for bulk products (e.g., 4 fl oz) and one for novelty-type products (e.g., 2.5 fl oz), nutrition information and the evaluation for the qualification for claims for these two types of products would be based on different amounts. Consequently, although a bulk product might not be able to qualify for a claim, a similar novelty-type product might be able to do so because of the smaller reference amount. This result would be misleading.

Therefore, based on available consumption data, the agency has concluded that a uniform 1/2-cup reference amount is appropriate for both the bulk and the novelty-type products (Ref. 2). The 1/2-cup reference amount is also consistent with the reference amount for other desserts (e.g., custard, pudding, and gelatin desserts), which are often used interchangeably with products in this category as a dessert. The 1/2 cup reference amount is desirable for several other reasons: (1) It is in agreement with most serving sizes in dietary guidance documents, (2) it is consistent with the Canadian serving size guidelines, (3) it is the serving size currently used by many manufacturers, and (4) it was supported by many comments on the 1990 proposal.

The agency notes that new § 101.9(b)(2)(i) allows optional declaration of nutrition information on a single unit basis for products in discrete units that are more than 50 percent but less than 67 percent of the reference amount. Therefore, the serving size for most novelty-type products will be one unit.

For all the above reasons, FDA has retained the reference amount as proposed.

(26) Desserts: custard, gelatin or pudding

FDA proposed 1/2 cup as the reference amount for this product category.

81. Two comments opposed the proposed 1/2-cup reference amount. The comments argued that the powdered mix type of puddings comprised only about 52 percent of the retail food store sales of puddings in 1990. More recently, ready-to-eat puddings have taken the lead in terms of market share and are growing at a faster rate as compared to dry-mix type puddings. The comment stated that the reference amount should reflect the recent sales trend in puddings, or that FDA should establish a separate reference amount of 4 oz for ready-to-eat puddings. The comments contended that ready-to-eat puddings either come in 4 oz single-serving containers or in bulk containers that are multiples of 4 oz. Therefore, the customarily consumed amount of the ready-to-eat puddings is 4 oz. The comments argued that a volumetric measure is appropriate for dry pudding mixes but is inappropriate for ready-to-eat puddings.

FDA recognizes the recent trend in the availability of ready-to-eat puddings. However, the agency is not establishing separate reference amounts for different forms of the same food because the act directs the agency to establish uniform serving sizes. Therefore, it would be inconsistent with the act to have different reference amounts for different forms of the same food that are used interchangeably. The act also relates serving size to the amount of the food customarily consumed, not the form in which the food is sold. The comments did not present any food consumption data to prove that the amount of all forms of puddings customarily consumed is 4 oz, not 1/2 cup. The agency notes that sales data are not consumption data and do not necessarily equate to consumption data.

In addition, the agency points out that direct interpretation of the sales data often result in the wrong conclusion. For example, the comments compared sales data for ready-to-eat puddings and dry-mix type puddings on an as packaged basis. These two types of puddings cannot be compared directly on an as packaged basis because ready-to-eat puddings are in a prepared form, whereas dry-mix type puddings are not. Before these two types of products can be compared, they should be on an equal basis in weight, i.e., both types

should be on a prepared basis. FDA's independent analysis of the recent sales data showed that when the two types of products were compared on a prepared basis, dry-mix type puddings are still the major type of puddings in the marketplace, accounting for about 88 percent of the total prepared weight of all types of puddings sold (Ref. 51), as they were when the NFCS's were conducted. The results of this analysis reconfirmed that the 1/2 cup reference amount, which reflects the customarily consumed amount of the dry-mix type puddings, is still valid because the dry-mix type is still the major type of puddings used in the United States. Finally, the agency notes that according to new § 101.9(b)(2)(i), 4-oz containers of ready-to-eat puddings in the multiserving package are single-serving units, and under that section of the regulations, the serving size for the 4-oz container will be one container, i.e., 4 oz. Accordingly, FDA has retained the reference amount for puddings as proposed (1/2 cup).

(27) Egg and egg substitutes: egg mixture, e.g., egg foo young, scrambled egg, omelet

FDA proposed 110 g as the reference amount for this product category.

82. One comment contended that the reference amount for this category should be 100 g. The comment argued that it is inappropriate to add the weight of 2 eggs (100 g) and then an arbitrary amount of 10 g for the reference amount of egg mixtures. Another comment stated that the reference amount for an omelette should be related to the number of eggs used per omelette. For example, a "one egg omelette" should have a smaller reference amount than a "two egg omelette."

First, FDA points out that it did not arrive at the proposed reference amount by adding the weight of 2 eggs and then arbitrarily adding 10 g. According to the act, the serving size is an amount customarily consumed. The proposed reference amount represents the customarily consumed amount of the foods belonging to this category determined from food consumption data, following the procedures described in the 1991 serving size proposal (56 60394 at 60403) (Ref. 2). Secondly, the same food cannot have two different reference amounts, one for the egg mixture containing one egg and one for the egg mixture containing two eggs because, under the act, the reference amount is the amount of the food customarily consumed. These mixtures are used interchangeably. Therefore, FDA is establishing the same reference amount for both. Accordingly, FDA has not adopted these requests.

(28) Fats and oils: butter, margarine, oil, shortening

FDA proposed a uniform 1 tbsp. reference amount for this product category.

83. Comments on this reference amount were split fairly evenly for and against the proposed 1 tbsp. reference amount. Comments from the margarine and oil industry and a few others, including a consumer, supported the 1-tbsp. reference amount. Comments from the dairy industry and others, including a nutrition professional organization, opposed the proposed reference amount. Two comments recommended that FDA change the reference amount to 1 tsp. to be consistent with the serving size in the diabetic exchange list or to be consistent with dietary guidance recommendations which recommend lowering the total fat in the diet.

FDA has examined all arguments for and against the proposed uniform 1-tbsp. reference amount. FDA advises that it cannot change the reference amount to make it consistent with the serving size in the diabetic exchange list because, as explained in the 1991 serving size proposal (56 FR 60394 at 60407) and in section III.B. of this document, the serving size for the diabetic exchange list is designed to meet the needs of a special subgroup of the population having medical problems. It is not intended for the general public. As for the recommendation to change the reference amount to 1 tsp. to be consistent with the dietary guidance recommendations, FDA points out that the serving size on the product label is not the amount recommended for consumption. In section III.D.1. of this document, the agency has explained in detail why the serving sizes in the dietary guidance documents are not appropriate for nutrition labeling purposes. The agency also points out that food consumption data showed that 1 tsp. is not the customarily consumed amount of foods in this category. The amount customarily consumed for most products in this category is 1 tbsp. (Ref. 2). The comments to the 1991 serving size proposal merely reiterated the reasons stated in the comments on the 1990 proposal. No new arguments or data have been presented to persuade the agency to change the proposed uniform 1 tbsp. reference amount. Therefore, FDA finds no basis to change the reference amount, and it has retained the reference amount as proposed.

(29) Fats and oils: dressings for salad

FDA proposed 30 g as the reference amount for this product category.

84. Two comments suggested that FDA change the reference amount to 15 g (equivalent to 1 tbsp.). One comment argued that 30 g is too large and precludes dressings for salads "from claims where they would be considered as good sources of oils that would reduce serum cholesterol."

FDA advises that the serving size declared on the product label is by statute an amount customarily consumed. The amount customarily consumed for dressings for salad is 2 tbsp., not 1 tbsp. (Ref. 2). The agency cannot change a reference amount so that certain products can make a claim. Accordingly, FDA has retained the reference amount as proposed.

(30) Fish, shellfish, and meat or poultry substitutes: entrees (cooked) with sauce, e.g., fish with cream sauce, shrimp with lobster sauce

FDA proposed 140 g as the reference amount for this product category.

85. Two comments requested that FDA establish a uniform 85-g reference amount for all fish products with or without sauce. One comment contended that the proposed reference amount of 140 g is too high. The comment did not submit data to support this claim. The other comment contended that it will be difficult to categorize products into two categories, with and without sauce.

FDA advises that the serving size declared on the product label is, by statute, an amount customarily consumed. The amount customarily consumed for the products in this category (that is, with sauce) is 140 g, not 85 g (Ref. 2). No consumption data that would support a different reference amount were presented. The agency notes that it has provided an extensive list of products for each product category to assist manufacturers to locate the product category in which their specific products fit (Ref. 44). Accordingly, FDA has retained the reference amount as proposed.

(31) Fish, shellfish, and meat or poultry substitutes: entrees (cooked) without sauce, plain or fried fish and shellfish, fish and shellfish cake

FDA proposed 85 g as the reference amount for this product category. Many comments on the reference amount for this category specifically addressed the reference amount for meat and poultry products. FDA has forwarded these comments to USDA for consideration in the development of the final regulation for nutrition labeling of meat and

poultry products. The agency is responding to comments that included discussions on the reference amounts of FDA regulated products.

86. Comments from a nutrition professional organization and a nutrition professional supported the proposed 3-oz reference amount. However, FDA received a large number of comments from consumers stating that the 3-oz "serving size" is too small for "meat, poultry, and fish." These consumer comments did not state what the serving size for "meat, poultry, and fish" should be. (Although FDA does not regulate meat and poultry, the comments were responding to a prestructured questionnaire distributed by a consumer organization that discussed the serving sizes of meat, poultry, and fish together. Many other consumer comments that were not recorded on the prestructured questionnaire also stated that the 3-oz serving size is too small for meat and poultry, but they did not mention fish. Thus, the agency is not sure that the comments recorded on the questionnaire apply to the reference amount for fish. Therefore, the agency has presented the food names as they appeared in the questionnaire.) Two comments from consumer organizations requested that FDA establish two separate reference amounts for fish and shellfish. They suggested 1.4 or 1.5 oz for "shrimp" and 4 oz for fish based on the published data for the median consumed amount per eating occasion from the 1977–1978 NFCS. One industry comment requested that FDA create a new category for fish sticks with a reference amount of 70 g. The comment submitted data on the mean, percentiles, and modal consumed amounts from the 1987–1988 NFCS in support of the 70-g reference amount.

FDA has carefully examined all arguments against the 3-oz reference amount and the data submitted in support of the requested changes of the reference amount. FDA believes that comments from consumers indicated a misunderstanding of the meaning and purpose of the serving size on the product label. The serving size on the product label is not the amount recommended as the serving size for any individual. It represents an amount customarily consumed by the U.S. population that manufacturers are to use to present the nutrition information on their products. Therefore, the serving size on the product label may be too small or too large for some individuals. FDA plans to followup the publication of the nutrition labeling regulations with consumer education to assist consumers in using nutrition information on the label. Consumer education will include information on how nutrition information based on labeled serving size should be adjusted for the individual's own serving size.

As for the request for two separate categories for fish and shellfish, FDA finds that separate categories are inappropriate. As explained in the 1991 serving size proposal (56 FR 60394 at 60403), the agency grouped similar foods to determine reference amounts for product categories, not for specific foods. This grouping allows for product comparisons among similar foods that are likely to be used interchangeably. In determining the reference amount for this product category, fish and shellfish were grouped together because they are used interchangeably as entrees. Two separate reference amounts for fish and shellfish would undermine nutrition comparisons of these products that are used interchangeably in the diet. Although, if determined separately, the amount customarily consumed would be lower for shellfish than for fish (Ref. 41), it is also the case that the 1977–1978 NFCS and the 1987–1988 NFCS showed that about 40 to 50 percent of people consumed 3 oz or more shellfish per eating occasion, the amount of fish consumed per eating occasion by most people (Ref. 47). The two separate reference amounts suggested in the comment (1.5 oz for shellfish and 4 oz for fish) could also give a false message about the nutrient contents of fish and shrimp to the people who consume fish and shellfish in similar amounts. For example, shrimp is known to be high in cholesterol. On the same serving basis, shrimp is about three times as high in cholesterol as most finfish (Ref. 52). However, if shellfish has a serving size that is about one-third of the serving size for finfish as suggested in the comment, there will be little difference in the cholesterol content per serving. This information would be a disservice to the public, particularly to those consumers who have been told by their physician to limit their cholesterol intake. In addition, the agency points out that it is not using a reference amount that is derived solely from the 1977–1978 NFCS for the reasons stated in section III.D.1. of this document.

Therefore, to reduce consumer confusion and to promote uniform serving sizes for nutrition comparisons of products that are used interchangeably, the agency has concluded that fish and shellfish should have the same reference amount.

As for the request for a separate category for fish sticks, FDA advises that a separate category for fish sticks is not justified.

FDA's independent data analysis for fish sticks from the 1977–1978 NFCS and the 1987–1988 NFCS showed that the amount customarily consumed is 85 g, not 70 g (Ref. 41). Also, as discussed in section III.D.1. of this document, unless there is a good reason for relying solely on the 1987–1988 NFCS, FDA has used both the 1977–1988 NFCS and the 1987–1988 NFCS. Data submitted in the comment were based solely on the 1987–1988 NFCS without any explanation.

Having carefully examined all arguments and data submitted in the comments, FDA has concluded that the proposed 85-g reference amount is the amount of fish customarily consumed. Accordingly, the agency has retained the reference amount as proposed.

87. Proposed § 101.12(c) requires that the reference amount of uncooked seafood be the amount required to prepare 85 g of cooked seafood. A seafood trade association stated that they are very concerned that their members will be unable to determine the serving sizes for uncooked seafood needed to produce the reference amount. The comment contended that the amount of uncooked seafood required to make one reference amount is affected by many uncontrollable variables such as methods of cooking (e.g., frying in oil or conventional and microwave cooking) and cooking time. The comment asserted that given these uncertainties, the serving size should be based on an "as packaged" basis for processed foods that require no further preparation other than cooking.

FDA recognizes the variability in cooking methods and time used to prepare seafoods. The agency agrees that this variability makes it difficult to determine the serving size of the uncooked seafood. Therefore, the agency has concluded that it should establish a reference amount for uncooked seafoods except for those fish and shellfish that are allowed to provide nutrition information on a cooked basis in new § 101.9(j)(11) and § 101.45. Using USDA's cooking yield information (Ref. 18), FDA has estimated the reference amount for uncooked fish and shellfish as 110 g (Ref. 53). Accordingly, the description "(cooked)" has been deleted from the product category name and the reference amount has been changed to read: "85 g cooked; 110 g uncooked." A footnote has been added to inform manufacturers that the 110 g uncooked reference amount does not apply to the raw fish and shellfish subject to § 101.45 and packaged single-ingredient fish and shellfish in new § 101.9(j)(11).

(32) Fish, shellfish, and meat or poultry substitutes: fish and shellfish, canned

FDA proposed 85 g as the reference amount for this product category.

88. Two comments opposed the proposed reference amount. One comment from a trade association contended that the category should be divided into subgroups with separate reference amounts: 56 g for canned tuna and bonito and 100 g for canned salmon. The comment contended that these reference amounts are more consistent with the current industry practices and equal to the contents of single-serving containers on the market. A comment from a seafood trade association requested that FDA change the reference amount to 55 g to make it consistent with the reference amount for luncheon meats. The comment submitted data showing that the largest use of tuna is as an ingredient in sandwiches.

FDA advises that it cannot change the reference amount simply to make it consistent with current industry practices or to make it equal to the contents of single-serving containers on the market. The agency's review of the data submitted in the comment showed that the major usage of tuna is as an ingredient in sandwiches. One of the general principles in determining the reference amount in new § 101.12(a)(7) states that the reference amount should reflect the major usage of the food. In the United States, more tuna is consumed than other canned fish (Ref. 47), and its major use is as an ingredient in sandwiches. The amount of the sandwich cutomarily consumed is one sandwich, and about 2 oz tuna (on a drained weight basis) is used to make one sandwich (Ref. 47). Thus, the agency has concluded that the reference amount for canned fish should be changed to 55 g to reflect the use as an ingredient in sandwiches. The 85-g reference amount proposed in the 1991 serving size proposal was based on all uses of tuna and other canned fish, including their use as an entree and for fish salad.

Accordingly, FDA has revised the reference amount to 55 g.

(33) Fish, shellfish, and meat or poultry substitutes: smoked or pickled fish or shellfish

FDA proposed 55 g as the reference amount for this product category.

89. A comment from a seafood trade association stated that smoked/pickled fish are specialty foods consumed as appetizers, not as a "center-of-the-plate item." Therefore, the comment said, the reference amount should be closer to the reference amount for snacks (30 g). The comment did not submit any data to support the 30 g reference amount that it recommended.

FDA advises that food consumption data did not support a 30-g reference amount. The 55-g proposed reference amount reflects the amount customarily consumed for smoked or pickled fish or shellfish (Ref. 2). Accordingly, FDA has retained the reference amount as proposed.

(34) Fruits and fruit juice: dried

FDA proposed 40 g as the reference amount for this product category.

90. A comment from a Federal agency recommended that FDA change the reference amount to 30 g. The comment contended that the proposed reference amount is too large for some dried fruit (e.g., dried apple rings, dried apricots).

FDA advises that the serving size declared on the product label is, by statute, an amount customarily consumed. Food consumption data showed that the amount customarily consumed for the products in this category is 40 g, not 30 g (Ref. 2). The comment did not present any data to support that 30 g better reflects the customarily consumed amounts of products in this category. Accordingly, FDA has retained the reference amount as proposed.

(35) Fruits and fruit juice: fruits used primarily as ingredients, e.g., avocado, cranberries, lemon, lime

FDA proposed 55 g as the reference amount for the product category.

91. One comment from a Federal Government agency opposed the 55 g reference amount. The comment stated that the proposed reference amount is too large, but the comment did not suggest what the reference amount should be. A comment from a trade association for avocadoes requested that FDA change the reference amount of avocados to 1 oz. The comment contended that USDA's g weight conversions (conversion factors) of small, medium, and large avocados were too high and did not reflect the California avocados which account for over 90 percent of the total U.S. avocado crop. In addition, the percent yield values used to determine the edible portion of avocados in the NFCS were too high. The comment submitted corrected conversion factors from a "National Retail Weight Study" sponsored by a trade association, an extensive list of the updated percent yield values, and results of a reanalysis of the NFCS data using the corrected conversion factors and the updated percent yield values. The data supported a 1-oz reference amount rather than 2 oz.

FDA carefully examined all of the data submitted in the comment. The results of the "National Retail Weight Study" showed that the conversion factors for small, medium, and large avocados were considerably lower than the values used in the NFCS. The updated percent yield values for 200 avocados of three California avocado varieties were significantly lower than the yield values used in the NFCS. The results of the comment's reanalysis of the 1987–1988 NFCS data using corrected conversion factors, and the updated percent yield values showed that the mean was about 2 oz, the median was about 1 oz, and the primary mode, that which accounted for over 50 percent of the total number of eatings, was 1 oz. The data submitted in the comment clearly showed that the customarily consumed amount is closer to 1 oz than to 2 oz. Because data from the 1987–1988 NFCS showed a decreasing trend in the amount of avocado consumed since the 1977–1978 NFCS, and the trend was confirmed by the CSFII (Ref. 40), the agency is relying on the data from the 1987–1988 NFCS submitted in the comment. Therefore, the agency has concluded that avocados should have a separate category with a reference amount of 30 g. Accordingly, FDA has divided the "Fruits used primarily as ingredients * * *" category into two categories: "Fruits used primarily as ingredients, avocado" with a reference amount of 30 g and "Fruits used primarily as ingredients, others (cranberries, lemon, and lime)" with a reference amount of 55 g as proposed.

(36) Fruits and fruit juice: all other fruits (except those listed as separate categories), fresh, canned or frozen

FDA proposed 140 g as the reference amount for this product category.

92. Several comments from the industry stated that the 140-g reference amount (equivalent to 5 oz) is too large. The comments requested that FDA change the reference amount to the g-equivalent of 1/2 cup.

FDA advises that it cannot use the g-equivalent of the 1/2 cup measure as the reference amount for two reasons: (1) For fruits that can be measured with a cup (e.g., canned or frozen fruits), food consumption data showed that the amount customarily consumed is about 5 oz, not 1/2 cup (Ref. 2), and (2) for the fruits that cannot be measured with a cup (e.g., most fresh fruits), the g-equivalent for the 1/2 cup measure cannot be determined. Food consumption data showed that the amount of fresh fruits is also about 5 oz

(Ref. 2). Accordingly, FDA has retained the reference amount as proposed.

(37) Fruits and fruit juice: juice, nectar, fruit drinks, or fruit-flavored drinks

FDA proposed 240 mL (8 fl oz) as the reference amount for the product category.

93. Comments from several manufacturers and trade associations (including a juice manufacturer and trade associations for juices) and a comment from a nutrition professional organization supported the proposed uniform 8-fl oz reference amount for all beverages. Comments from two other trade associations requested that FDA change the reference amount for juices to 6 fl oz. One comment stated that 6 fl oz is the amount that represents long established industry practice, and that 6 fl oz is a more appropriate reference amount when extended to multiserving containers. The comment submitted no data to support its claims, however. A manufacturer contended that FDA has no authority to manipulate the customarily consumed amount of food in order to standardize the reference amount. The comment argued that FDA's own data from the 1977–1978 NFCS (Ref. 2) indicated that 4 fl oz is the amount customarily consumed, and therefore, FDA must change the reference amount to 4 fl oz. A consumer asserted that 250 mL (8.45 fl oz) is a more appropriate reference amount because most small size juices are sold in 250 mL packs.

The agency notes that data from the 1977–1978 NFCS suggested 6 fl oz (not 4 fl oz as claimed by one comment) to be the customarily consumed amount. The agency notes that the comment that asserted that 4 fl oz is the amount customarily consumed misread the data. Data from the 1977–1978 NFCS had a mean of 6.3 fl oz, the median of 6 fl oz and 3 modes (4 fl oz, 6 fl oz, 8 fl oz). However, data from the 1987–1988 NFCS suggested that 8 fl oz is the customarily consumed amount for juices. Also, both the 1977–1978 NFCS and the 1987–1988 NFCS showed that 8 fl oz is the customarily consumed amount for fruit juice drinks and fruit-flavored drinks that are used interchangeably with fruit juices. Therefore, the agency has concluded that 8 fl oz is the most reasonable reference amount for all fruit juices and drinks.

As for the consumer comment, the agency advises that food consumption data did not support a 250-mL reference amount. The agency notes that the 250 mL packs of juice are single-serving containers and, therefore, will be labeled as 1 serving

Considering the weight of support for the uniform 8 fl oz reference amount for all beverages and for the other reasons stated above, the agency has concluded that 8 fl oz is the appropriate reference amount under section 403(q)(1)(A)(i) of the act for all beverages including fruit juices and fruit drinks. The uniform reference amount for all beverages facilitates nutrition comparisons of different beverages. Accordingly, FDA has retained the reference amount as proposed.

(38) Legumes: bean cake (tofu)

FDA proposed 85 g as the reference amount for the product category.

94. A comment from a consumer organization stated that, because the sample size for tofu in the 1977–1978 NFCS was so small (n=12), an accurate estimate of the amount customarily consumed could not be derived from this survey. The comment contended that because tofu is used as a substitute for meat and poultry, the reference amount should be equivalent to the reference amount for meat and poultry.

FDA agrees that the sample size for tofu in the 1977–1978 NFCS was too small to give a reliable estimate of the amount customarily consumed. However, for other reasons explained in section III.D.1. of this document, the agency is not using a reference amount that is based solely on the 1977–1978 NFCS. The 1987–1988 NFCS had a larger sample size for tofu (n=31), and all three statistical values from the 1987–1988 NFCS data that FDA uses in determining the amount customarily consumed (the mean, the median, and the mode) showed that 3 oz is the amount of tofu customarily consumed (Ref. 2). Therefore, the agency has concluded that 3 oz is a reasonable reference amount for tofu. The 3 oz reference amount is the same as the reference amount for fish, shellfish, game meats, and meat or poultry substitutes without sauce regulated by FDA and the reference amount for meat and poultry regulated by USDA. Accordingly, FDA has retained the reference amount as proposed.

(39) Legumes: beans, plain or in sauce

FDA proposed 1/2 cup as the reference amount for the product category.

95. Two comments, from a trade association and a manufacturer, supported the proposed 1/2-cup reference amount. However, the comments requested that FDA change the 1/2 cup reference amount to a g weight. One comment opposed the use of drained weight for plain canned beans. The comment contended that nutrition information on the canned beans should be based on an as packaged basis, including the liquid.

In light of the difficulty in determining the g weight of the household measure, FDA has concluded in section III.D.2. of this document that volume-based reference amounts should be converted to weight-based reference amounts where a weight-based reference amount is feasible. The agency has reexamined foods in this product category and has concluded that the weight-based reference amount can be determined for this category. By taking the average of the g weights per 1/2 cup of cooked plain beans reported by USDA (Ref. 54), the agency has determined that the reference amount for beans that are not canned in liquid or in sauce to be 90 g (Ref. 55).

Regarding the comment that requested nutrition information of canned beans on an as packaged basis, including the liquid, the agency, as discussed in section III.H.2. of this document, has concluded that the nutrition information of canned beans will be based on an as packaged basis including the liquid because a large percentage of people do use the liquid in the canned food. By taking the average of the g weights per 1/2 cup of canned beans including the liquid reported by USDA (Ref. 54), the agency has determined that the reference amount for canned beans, including the liquid, is 130 g (Ref. 55). Also, by taking the average of the g weights per 1/2 cup of beans with sauce (e.g., pork and beans, baked beans) reported by USDA (Ref. 54), the agency has determined that the reference amount for beans in sauce is 130 g (Ref. 55).

Accordingly, FDA has revised the reference amount to read: "130 g for beans in sauce or canned in liquid; 90 g for others."

(40) Miscellaneous category: batter mixes, bread crumbs, meat, poultry, and fish coating mixes, dry

FDA proposed 30 g as the reference amount for this product category.

96. An industry comment opposed the 30 g reference amount for coating mixes. The comment stated that because of the varying densities of the products and the varying surface areas of the products they coat (e.g., meat and fish), 30 g of coating mix will coat between 3 and 8 oz of meat. The industry suggested including coating mixes with seasoning mixes with a reference amount equal to the amount of the product required to prepare one portion of the end product (e.g., the amount necessary to coat 3 oz of meat or fish).

FDA recognizes that coating mixes vary in density, and that the amount needed to coat the surface areas depends on the type of the mixes and the products they coat. These products are made for use in a specific end dish (e.g., coating mix for fish). Thus, a reference amount that is the amount required to prepare one reference amount of the end product would be more consistent with the amount customarily consumed of coating mixes.

Therefore, the agency has concluded that the reference amount for coating mixes should be changed to the amount to make one reference amount of the final dish as listed in new § 101.12(b). In the case of multiple uses, manufacturers should determine the major use of the coating mix based on food consumption data, marketing survey data on the consumer usage of the product, or in the case of a new product, promoted use, and use that major use to determine the reference amount. The agency agrees that coating mixes should be grouped with seasoning mixes because they are a type of seasoning mixes. Accordingly, FDA has revised the seasoning mixes category to read: "Meat, poultry and fish coating mixes, dry; seasoning mixes, dry, e.g., chili seasoning mixes, pasta salad seasoning mixes."

(41) Miscellaneous category: chewing gum

FDA proposed 3 g as the reference amount for the product category.

97. Two comments from the chewing gum industry stated that the reference amount for chewing gum should be one piece because, according to a recent marketing research study, people consume chewing gum piece by piece, not by weight. The comment contended that because chewing gum products vary so widely in the piece size, it is not possible to fix a standard weight that adequately encompasses the serving size. The comment also argued that much of the chewing gum consumed weighs less than 2 g per piece. Another comment argued that a 3 g reference amount is too small because it corresponds to 3/4 stick or 1 7/8 chiclets. The comment requested that FDA change the reference amount to 4 g.

FDA agrees that chewing gums vary widely in the piece size, and that chewing gums are usually consumed by piece. However, the agency cannot use one piece as the reference amount. Some chewing gums come in very small pieces (mini-size chewing gums weighing about 1 g per 10 to 12 pieces), and people usually chew several pieces at a time. Therefore, it is not appropriate to call one piece of these mini-size chewing gums a serving. The reference amount is needed to determine the serving size of these mini-size chewing gums.

As explained in section III.D.5.a. of this document, for compliance monitoring, the agency also needs a fixed value as the reference amount, not a measure that varies from brand to brand (e.g., piece). The wide variability in the piece size makes the determination of the reference amount difficult. Based on the piece size of the chewing gums commonly available in the Washington, DC metropolitan area, the agency has determined 3 g to be a reasonable reference amount (Ref. 2). The agency acknowledges that there are some chewing gums that weigh less than 2 g per piece. The new lower limit for the single-serving unit in new § 101.9(b)(2)(i), however, will make all chewing gums that weigh more than 1.5 g per piece one serving.

The agency also recognizes that there are many chewing gums that weigh more than 200 percent of the reference amount. Although they weigh more than the upper limit of the single-serving unit, marketing data submitted in the comment show that gums are intended to be single-serving products. Therefore, footnote 9 of Table 2 informs the manufacturer that the serving sizes of all chewing gums that weigh more than 3 g, that can reasonably be consumed at a single-eating occasion, is 1 piece.

As for the comment that recommended the 4-g reference amount, a 4-g reference amount would make the serving sizes of all chewing gums weighing 2 g or less, 2 or more pieces. Chewing gums, with the exception of the mini-size chewing gums, are customarily consumed one piece per eating occasion. In light of the many chewing gums weighing less than 2 g per piece mentioned in the comment, the agency has concluded that a 4 g reference amount is too large. The agency also notes that FDA's measurements showed that commonly available chewing gums weigh about 3 g per stick (Ref. 2).

Accordingly, FDA has retained the 3-g reference amount as proposed.

(42) Miscellaneous category: salad and potato toppers, e.g., salad crunchies, salad crispins, substitutes for bacon bits

FDA proposed 7 g as the reference amount for the product category.

98. One comment opposed the proposed reference amount. The comment recommended that FDA change the reference amount to 5 g (approximately 2 tsp.). The comment contended that a 5-g reference amount is supported by "consumer-based consumption data" collected by the comment. The comment submitted no data, however, to support this claim.

FDA advises that food consumption data showed that the customarily consumed amount for products in this category is 7 g (Ref. 2). The 7 g reference amount also approximates 1 tbsp., a convenient household measure, and is consistent with the reference amount for croutons that are used as a salad topper. The comment did not submit any data. Thus, there is no basis for the agency to change the reference amount to 5 g. Accordingly, FDA has retained the reference amount for this category as proposed.

(43) Miscellaneous category: salt, salt substitute, seasoning salt (e.g., garlic salt)

FDA proposed 1 g as the reference amount for this product category.

99. One comment agreed with the proposed reference amount because it is in the best interest of the consumers. A comment from a trade association for spice products agreed with the proposed reference amount of 1 g for seasoning salts. However, the comment requested that FDA allow manufacturers to voluntarily declare the sodium content per 1/4 tsp. Another comment objected to the weight-based reference amount. The comment contended that it had developed a low-density salt product that provides a salt taste similar to that of regular salt in a smaller g amount, because the low-density salt is processed to dissolve faster and more completely than the regular salt. Because the low-density salt weighs significantly less than salt, a weight-based reference amount (e.g., 1 g) would result in a serving size of the low-density salt 2 1/2 to 3 times larger than that of salt. Therefore, the comment requested that FDA change the reference amount to a volume-based reference amount (e.g., 1/4 tsp.). The comment did not submit any data to support that regular salt and the low-density salt are consumed equally on a volume basis.

FDA advises that the reference amount for sugar substitutes is "an amount equivalent to one reference amount for sugar in sweetness." Both sugar and salt are used as flavoring agents. People use them to attain the level of sweetness or saltiness that they desire. Therefore, like sugar the reference amount for a salt substitute (e.g., low-density salt) should be the amount necessary to provide a salty taste equivalent to one reference amount of salt. Salt is used both in cooking and at the table. Although regular salt may not completely dissolve when added at

the table, it will dissolve completely when used in cooking. Because, as the name indicates, the low-density salt is lighter than the regular salt, 1/4 tsp. of the low-density salt will contain less salt than 1/4 tsp. of the regular salt. Therefore, when used in cooking, a larger volume of the low-density salt than the regular salt will be required to achieve the same salty taste. Thus, low-density salt and regular salt may not be used on an equal volume basis at least in cooking. Accordingly, the agency rejects the request for a volume-based reference amount.

100. A comment from a consumer organization stated that the reference amount should be expressed as 1,000 milligrams (mg), instead of 1 g, to be consistent with the sodium content listed in the nutrition information panel. The comment contended that most Americans are unfamiliar with the metric system, so they will not understand that 1 g is equal to 1,000 mg.

FDA does not agree with the comment. Whether the reference amount is expressed 1 g or 1,000 mg, the serving size on the product label by statute has to be in a common household measure (e.g., 1/4 tsp.). The nutrition information on the label tells consumers how much sodium is in one serving (1/4 tsp.) of salt. It is not necessary for consumers to know that 1 g equals 1,000 mg to use the nutrition information on the product label. Therefore, the agency has concluded that it is not necessary to change the reference amount to 1,000 mg.

(44) Mixed dishes: measurable with cup, e.g., casserole, hash, macaroni and cheese, pot pie, spaghetti with sauce, stew, etc

FDA proposed 1 cup as the reference amount for the product category.

101. Many comments agreed with the proposed reference amount. One manufacturer agreed with the 1-cup reference amount for mixed dishes that are served as main dishes. However, the comment contended that 1/2 cup is a more appropriate reference amount for mixed dishes that are served as side dishes (e.g., potato dishes, pasta salad, potato salad). The comment contended that the 1987–1988 NFCS supported the 1/2-cup reference amount for these products. The comment did not submit data to support this claim.

FDA advises that pasta salad and potato salad have a separate category under Salads with a reference amount of 140 g which is equivalent to about 3/4 cup. Because the comment did not submit data to support the 1/2-cup recommendation, the agency is unable to verify the 1/2-cup reference amount claimed by the comment for the mixed dishes that belong to this product category. However, the agency notes that both the 1977–1978 NFCS and the 1987–1988 NFCS showed that the customarily consumed amount for products that belong to the "Mixed dishes measurable with cup" category is 1 cup, not 1/2 cup (Ref. 2). The agency recognizes that mixed dishes are used for both a main dish and a side dish. However, FDA rejects the suggestion to establish two different reference amounts for the same type of food for three reasons. First, one of the uses of the reference amount is to determine the appropriateness of nutrient content and health claims made on food products. Such a determination cannot be made for the same food on two or more different bases (i.e., reference amounts), e.g., a smaller reference amount (1/2 cup) to evaluate a claim for a side dish and a larger reference amount (1 cup) to evaluate a similar claim on a similar product labeled as a main dish.

Secondly, there is no assurance that a product labeled as a side dish will not be consumed as a main dish, and vice versa. Thirdly, this suggestion is not in the best interest of the consumers. Two reference amounts for the same type of products will interfere with the goal that there be uniformity among serving sizes declared on similar products by different manufacturers.

In the 1991 serving size proposal (56 FR 60394 at 60402), the agency stated that it would not object to manufacturers providing a second column of nutrition information as a side dish or as a main dish. The agency advises that the second column of information is allowed only if the serving size as a side dish or as a main dish meets the requirement for the second column in new § 101.9(b)(11), i.e., if the serving size for the second column differs from the serving size for the required column by at least two fold. However, the agency wants to make it clear that it will use the appropriate reference amount in new § 101.12(b) to evaluate whether a mixed dish that does not qualify as a meal product or a main dish product as defined in new § 101.13(l) and (m) meets FDA standards for any claim made for the product.

102. Several comments requested that FDA use a weight-based reference amount or include g weight equivalent of 1 cup in the reference amount (e.g., 1 cup (235 g)). One manufacturer suggested a 7.5 oz reference amount. Another manufacturer requested that the same reference amount be used for canned mixed dishes and frozen mixed dishes and suggested a 7.5-oz reference amount.

Although mixed dishes measurable with a cup are consumed in similar quantities by volume (e.g., 1 cup), it is not possible to have one uniform g-weight equivalent reference amount (e.g., 235 g) or weight-based reference amount (e.g., 7.5 oz) because mixed dishes come in many different forms and combinations of ingredients. Therefore, the g-weight-per-cup measure will vary greatly for different dishes. Accordingly FDA has retained the volume-based reference amount.

With regard to the comment that recommended that the same reference amount be used for both canned and frozen mixed dishes, FDA advises that although the reference amounts in new § 101.12(b) are expressed in the prepared ready-to-eat weight, they apply to all forms of the products in the product category: Dry, canned, frozen, refrigerated, and ready-to-eat. Therefore, both canned and frozen (fully-cooked "heat and serve") mixed dishes have the same reference amount. The reference amount for uncooked frozen mixed dishes would be the amount of such a product necessary to prepare one reference amount established in new § 101.12(b).

103. A manufacturer requested that FDA use a uniform 6-oz (170 g) reference amount for both mixed dishes measurable with a cup and mixed dishes not measurable with a cup to provide more continuity and consistency in reference amounts for products that qualify as "meal-type" products.

FDA advises that the serving size on the product label is, by statute, an amount customarily consumed. Both the 1977–1978 NFCS and the 1987–1988 NFCS showed that the amounts customarily consumed for the mixed dishes measurable with a cup and the mixed dishes not measurable with a cup differ considerably (Ref. 2). Therefore, it is not possible to have a uniform reference amount that reflects the amount customarily consumed for the two categories. Accordingly, the agency rejects this request.

104. One comment recommended that FDA delete seasoned flavored rice mixes from this category and include it in the rice category. The comment contended that flavored rice mixes differ from all other products in the mixed dishes category, which all contain two or more components from at least two different food groups. Rice mixes contain only rice and seasoning.

FDA agrees with the comment that many flavored rice mixes are mixtures of rice and seasoning. However, some varieties do contain two or more components from two or more food

groups. For example, dry spanish rice mix contains rice and tomato. Also, seasoned flavored rice comes both canned and in dry mixes. The canned flavored rice (e.g., canned spanish rice) contains a large amount of tomato.

The agency included seasoned flavored rice mixes in the Mixed dishes measurable with cup category instead of the plain rice category for the following reasons: First, the amount of seasoned flavored rice customarily consumed was generally higher in g than that of plain rice (Ref. 2), and therefore, the 140 g reference amount for the plain rice was not appropriate for seasoned flavored rice.

Secondly, "seasoned flavored rice" includes a diverse variety of rice products. Some are clearly mixed dishes and others are not. Because the customarily consumed amount in volume of seasoned flavored rice (1 cup) was similar to that of other products in the "Mixed dishes measurable with cup" category (1 cup), the agency included all seasoned flavored rice in the "Mixed dishes measurable with cup" category in the proposal.

FDA concludes that seasoned flavored rice fits best in the "Mixed dishes measurable with cup" category because the amount customarily consumed is the same for both of these products. Accordingly, the agency rejects the request.

(45) Mixed dishes: not measurable with cup, e.g., burrito, egg roll, enchilada, pizza, pizza roll, quiche, all types of sandwiches

FDA proposed 140 g for pizza and products without sauce and 195 g for products topped with sauce as the reference amounts for the product category.

105. Some manufacturers contended that unlike other products included in this category that are consumed as a main dish (e.g., burritos, enchiladas, sandwiches, and pizza), pizza rolls and egg rolls are not customarily consumed as the main part of a meal, and thus pizza rolls and egg rolls should not be classified as a mixed dish not measurable with a cup. The comments asserted that these products are designed and promoted as snacks. The comments recommended that FDA either include pizza rolls and egg rolls in the category "Entrees without sauce" or create a separate category for appetizers with a reference amount of 85 g. Another manufacturer agreed with the 5-oz reference amount for pizza as a meal, and they also agreed that the claim evaluation should be based on the 5-oz reference amount. However, the comment requested that FDA establish a separate reference amount (e.g., 70 g) for presenting the nutrition information when pizza is used as a snack. The comment stated that the manufacturer should have the right to decide if the product is a meal or a snack.

FDA advises that the "Entrees without sauce" category under the major category for Fish, Shellfish, Game Meat, or Meat or Poultry Substitutes includes products whose major ingredients are fish, shellfish, game meat, or meat or poultry substitutes such as plain or fried fish and shellfish, fish and shellfish cake, and meatless hamburger. Pizza rolls and egg rolls do not belong to the "Entrees without sauce" category because the major ingredients of these rolls are not fish, shellfish, game meat, or meat or poultry substitutes. The NFCS included pizza rolls and egg rolls in the same group as pizza which is classified as mixed dishes not measurable with cup in § 101.12(b). Therefore, the agency has concluded that pizza rolls and egg rolls belong to the category of mixed dishes not measurable with cup.

With regard to a separate category for pizza rolls and egg rolls as appetizers, FDA finds no basis to justify a separate category. As explained in the 1991 serving size proposal (56 FR 60394 at 60403), the agency grouped similar foods to determine reference amounts for product categories, not specific foods. This grouping allows for product comparisons among similar foods that are likely to be used interchangeably. The agency included pizza rolls and egg rolls in the category for mixed dishes not measurable with cup because they are frequently used interchangeably with other products in this category as entrees. Although pizza rolls and egg rolls may be promoted as a snack or appetizer, and the amount of these rolls customarily consumed may be smaller than the amount customarily consumed for other products in the mixed dishes not measurable with cup category (e.g., pizza) that are used primarily as an entree, food consumption data show that a large percentage of people consumed 4.5 to 9 oz (Ref. 47) of pizza rolls or egg rolls per eating occasion, which are amounts that are appropriate for use as an entree, not an appetizer. To promote uniform serving sizes for nutrition comparisons of products that are used interchangeably, FDA has concluded that pizza rolls and egg rolls should have the same reference amount as other products in the mixed dishes not measurable with cup category. Accordingly, FDA rejects this request.

106. A consumer organization contended that the reference amount for pizza should be 7 oz. The comment stated that the 5-oz reference amount is too small because: (1) The average weight of single-serving pizzas in supermarkets is 6.6 oz, (2) two slices of pizza at a popular pizza restaurant averages 7.3 to 7.4 oz, and (3) a personal pan pizza served at a popular pizza restaurant is 9 oz. The comment also argued that the reference amount for vegetable burgers should be 7 oz because the average weight of hamburgers in fast-food restaurants is 7 oz. The comment contended that the "serving size" should reflect what is commonly consumed at fast food restaurants as well as at home.

FDA advises that all sizes of pizzas mentioned in the comment will be one serving based on the 5-oz reference amount and the single-serving container definition in § 101.9(b)(6). There is no need to change the reference amount which is based on consumption data, not the weight of products on the market (Ref. 2).

As explained in section III.D.5.a. of this document, FDA included the pizza and hamburger consumed at the fast food restaurants in arriving at the 5-oz reference amount. Therefore, there is no need to change the reference amount to reflect the amount consumed at fast food restaurants.

Accordingly, FDA has retained the reference amount as proposed.

(46) Nuts and seeds: nuts, seeds and mixtures

FDA proposed 40 g as the reference amount for the product category.

107. Many comments were received from the nut industry requesting that FDA change the proposed reference amount to 1 oz or 28 g or 30 g. The comments contended that nuts are used interchangeably with snacks and thus should have the same reference amount as snacks to facilitate nutrition comparisons of different types of snacks. The comments argued that 1 oz is the historical serving size, and airline single-serving packets are less than 1.5 oz. Many of these comments stated that a research study conducted by a consulting firm on the comments' behalf uncovered a series of potential biases built into the protocol for using consumption data for the purposes of determining a reference amount. The comments claimed that many of the g-weight equivalents of cup measures in the NFCS data base used to convert the cup measures of nuts to the g weights were too high. Consequently, the g amounts reported in the NFCS that FDA used to estimate the reference amount for the nut category were overestimated. The comments contended that reanalysis of the NFCS data, using their

own "correct" g-weight equivalents per cup measures, showed that 1 oz is closer to the customarily consumed amount than 1.5 oz. Some comments submitted the g-weight equivalents of cup measures used in the reanalysis and detailed descriptions and data from the reanalysis. Other biases in determining the reference amounts for nuts described in the comments included: (1) FDA's analysis did not include all food codes in the nuts and seeds category, and (2) FDA used mean weights that were between two modal values when one modal value was twice as large as the other.

One comment contended that estimates of nut consumption from the NFCS are not accurate because the amounts consumed were reported in an approximate measure (e.g., cups). To obtain more accurate estimates of the consumption, the comment conducted an independent "in-home usage" survey in 20 cities across the United States, using a diary method in which the respondents recorded the number of nuts that they consumed at each eating occasion. The survey tested four different nuts commonly consumed in the United States and included 568 households. The survey was designed to parallel, as closely as possible, the demographic and socioeconomic characteristics of the nut users in the United States. The comments contended that the results of this survey showed that the amount of nuts customarily consumed is 1 oz, not 1.5 oz. The comment submitted detailed descriptions of the survey methodology and the methodology for the sample selection and the determination of the number of nuts per oz, and detailed data.

FDA carefully examined all arguments and data submitted in the comments. In the absence of well-established procedures, the agency acknowledges that NFCS data may have inaccuracies, as data from food consumption surveys usually do. The agency also recognizes the difficulties in determining the g-weight equivalents of cup measures of solid foods such as nuts. However, the agency advises that the comments' own reanalysis of the NFCS data using the comments' own estimates of the g-weight equivalents of cup measures did not give any better estimates of the nut consumption. The comments' reanalysis of the NFCS underestimated the nut consumption reported in the NFCS because the technique used to determine the g-weight equivalent of cup measures did not measure a volume of nuts equivalent to 1 cup as defined in new § 101.9(b)(5)(iv), i.e., 240 mL (Ref. 47). Therefore, FDA cannot use the results of the reanalysis of the 1987–1988 NFCS submitted by the many comments.

However, the agency agrees that the methodology used in the independent "in-home usage" survey (counting the number of nuts) estimated the nut consumption more accurately than the NFCS. The survey also had a much larger sample size (number of individual eating occasions) than the NFCS. The survey's sample size was 8 times as large as that in the 1987–1988 NFCS. The methodology used to determine the number of nuts per oz that was then used to convert the number of nuts consumed to g weight was sound. Data from this survey showed that the amount of nuts customarily consumed is closer to 1 oz than 1.5 oz. Accordingly, FDA has revised the reference amount to 1 oz.

FDA does not agree that FDA's estimate of the customarily consumed amount for nuts was biased because the analysis did not include all food codes in the nuts and seeds category. To facilitate data analysis given severe time constraints, FDA, in some cases, selected foods having a high frequency of consumption to represent the category instead of using all foods appropriate for the category. In response to a similar comment on the 1990 proposal, the agency presented evidence that inclusion or exclusion of infrequently consumed food did not affect the determination of the amount customarily consumed (Ref. 19). In response to the above comment on the 1991 serving size proposal, FDA reanalyzed the data analysis including all food codes for nuts, seeds and mixtures (excluding boiled peanuts which the comment said was inappropriate), and the results showed that the inclusion of all food codes did not make a significant difference (Ref. 41).

With regard to the comment that stated that FDA's estimate of the customarily consumed amount for nuts is inappropriate because it used mean weights that were between two modal values, the agency advises that the comment misinterpreted the way FDA derived the reference amount from the survey data. When the sample sizes were adequate, but the three statistical estimates that represent an amount customarily consumed (mean, median, and mode) did not agree, the agency considered all three values in deciding the reference amount (56 FR 60394 at 60405). Nuts had adequate sample size, but the three values differed. Therefore, the agency considered all three values to determine the reference amount for nuts. When all three values were considered together, 1.5 oz was determined to be the customarily consumed amount which happened to be closer to the mean value than to either of the two modes. The agency did not arbitrarily take the mean weights that were between two modal values.

After a careful examination of all arguments and data submitted in the comments and for the reasons explained above, FDA has concluded that the amount of nuts customarily consumed is 1 oz. Therefore, the agency has revised the reference amount for nuts to 30 g (equivalent to 1 oz).

(47) Nuts and seeds: nut and seed butter, paste, or cream

FDA proposed 30 g as the reference amount for this product category.

108. A manufacturer pointed out that several new product developments within the peanut butter market, of which FDA was not likely aware during the development of the 1991 serving size proposal, have resulted in a range of product densities among existing products. The comment stated that consumers eat peanut butter according to volume. The comment contended that the weight-based reference amount makes the serving size for whipped butter 3 tbsp., instead of 2 tbsp. Therefore, the proposed weight-based reference amount would severely undermine manufacturers' incentive to produce a peanut butter lower in fat. The comment pointed out that when products within the product category differ widely in density, FDA expressed the reference amount in volume, not in weight. The comment contended that because the densities of different brands of peanut butter differ widely, FDA should express the reference amount for peanut butter in volume, not in weight. The comment, therefore, requested that FDA change the reference amount to a volume-based reference amount (e.g., 2 tbsp.). The comment submitted data showing the differences in the densities of the regular and whipped peanut butter.

FDA acknowledges that it was not aware of the new line of whipped peanut butter during the deliberation of the 1991 serving size proposal. The agency also agrees that it has expressed the reference amount in volume, not in weight, when the density of the products within the product category vary widely and the amount customarily consumed is more uniform in volume. The agency also acknowledges that commonly used cookbooks show that peanut butter is used by volume (e.g., tbsp. and cups), not by weight (Refs. 43 and 44). Therefore, the agency has concluded that the reference amount for

peanut butter should be changed to a volume-based reference amount to encompass the differing densities of the different brands of peanut butter. Accordingly, FDA has changed the reference amount for the "Nut and seed butter * * *" category from 30 g to 2 tbsp. (volume equivalent to 30 g). However, manufacturers that make whipped peanut butter must comply with other labeling requirements for aerated food in new § 101.12(e).

(48) Potatoes and sweet potatoes/yams: French fries, hash browns, skins, or pancake

FDA proposed 70 g as the reference amount for this product category.

109. Two comments stated that French fries come in many different sizes and styles (e.g., shoestrings, thin crinkles, regular crinkles, dinner fries), and that they are prepared in many different ways (e.g., deep fat frying, microwave cooking, skillet frying, conduction oven hearing). The variation in the size and style of the cut and in the preparation method makes it difficult to determine the serving size of frozen French fries because the yield differs for different sizes, styles, and preparation methods. The comment requested that FDA establish a reference amount of 85 g for the uncooked form of the products. The comment submitted data on the cooking loss for different types of french fries that showed that the weight loss varied from about 15 to 40 percent for different sizes, styles, and quantities cooked.

FDA recognizes that there are many differing sizes, styles, and preparation methods for French fries and agrees that a reference amount for the uncooked frozen product would promote uniformity in the serving sizes of frozen french fries. Based on the average percent cooking yield of 78 percent reported by USDA (Ref. 18), FDA estimated that 89-g frozen French fries would be needed to make the 70 g of prepared French fries that are customarily consumed. The 89-g reference amount approximates 3 oz in a household measure. Therefore, the 85-g reference amount (equivalent to 3 oz) suggested in the comment is reasonable for the uncooked frozen French fries. Accordingly, FDA has revised the reference amount to read: "70 g prepared; 85 g for frozen unprepared French fries."

(49) Potatoes and sweet potatoes/yams: plain, fresh, canned, or frozen

FDA proposed 110 g as the reference amount for this product category.

110. A trade association requested that FDA change the reference amount to the g weight of 1/2 cup because it is the amount currently used by the industry on canned potato products. The comment also opposed the requirement that the nutrient content be based on the drained weight of the product. The comment contended that nutrition labeling for this product has been traditionally labeled on the contents of the entire container.

FDA advises that the serving size declared on the product label is, by statute, an amount customarily consumed. Food consumption data showed that the amount customarily consumed for plain potatoes is 110 g, not the g equivalent of 1/2 cup (90 g drained solids) as recommended in the comment (Ref. 2). Therefore, FDA rejects this request.

Consistent with the agency decision on the nutrition information on an "as packaged" basis for canned beans, potatoes, and vegetables discussed in section III.H.2. of this document, FDA has revised the reference amount for canned potatoes to include the liquid. Using the average yield of 68 percent reported by USDA (Ref. 18), the agency has determined the reference amount for canned potatoes including the liquid, to be 160 g. Accordingly, FDA has revised the reference amount to read: "110 g for fresh or frozen; 160 g for canned in liquid."

(50) Salads: pasta or potato salad

FDA proposed 140 g as the reference amount for the product category.

111. One comment recommended that FDA change the reference amount to a volume-based reference amount. The comment contended that consumers measure these products on a volume basis, and therefore, a volume measure is more consumer friendly than a weight measure. The comment recommended 1/2 cup for the reference amount.

FDA advises that it is not necessary to change the reference amount to a volume-based reference amount to make it consumer friendly. Reference amounts appear only in the Code of Federal Regulations, and consumers usually do not see them. Although the reference amount is in g, the label serving sizes of products in this category will be expressed in cup measures because cup is the common household measure most appropriate for products in this category. Manufacturers should determine the cup measure that most closely approximates 140 g of their product.

112. A few comments claimed that the proposed reference amount is too large. The comments contended that most single-serving containers of these products hold 3.5 oz, and that manufacturers do not make single-serving containers that hold 5 oz (140 g). One comment claimed that serving scoops measure 3.5 oz. The comments recommended that FDA change the reference amount to 100 g.

The serving size on the product label is, by statute, an amount customarily consumed. Food consumption data showed that the customarily consumed amount of products in this category is 140 g, not 100 g (Ref. 2). Therefore, the agency cannot change the reference amount to make it consistent with the single-serving container size or the serving scoop size. The agency notes that the serving size of a 3.5 oz single-serving container will be the content of the container, not 140 g. However, the 140 g reference amount, not 3.5 oz, will be used to evaluate the qualification of this single-serving container for claims.

(51) Salads: all other salad, e.g., egg, fish, shellfish, bean, fruit, or vegetable salad

FDA proposed 100 g as the reference amount for this product category.

113. One comment requested that FDA expand the salads category to have a separate reference amount for "entree" type salads (e.g., pasta and seafood salad, tuna salad) and to reflect changes in the past decade in the availability and variety of salads in the supermarkets and restaurants. The comment contended that these major changes in salad consumption have occurred since the 1977–1978 NFCS, and therefore, the changes were not reflected in that survey.

FDA advises that it used both the 1977–1978 NFCS and the 1987–1988 NFCS in determining the reference amount for salad proposed in the 1991 serving size proposal. Therefore, by using data from the 1987–1988 NFCS, the changes in the salad consumption practices since the 1977–1978 NFCS were factored into the determination of the reference amounts for salads. The agency also points out that § 101.9(j)(2) and (j)(3) exempt deli foods and restaurant foods (e.g., salad bars). Accordingly, FDA has retained the reference amount as proposed.

(52) Sauces, dips, gravies, and condiments: all categories

FDA grouped these products into five categories with separate reference amounts.

114. One comment stated that some sauces might be more appropriately grouped in different categories. The comment contended that because barbecue sauce and marinade are more similar to catsup than to dips in their usage, they "might" be included in the

major condiments instead of with the hollandaise and tartar sauce. The comment continued that cocktail sauce is used in the same manner as tartar sauce and would more appropriately be grouped with tartar sauce. Worcestershire sauce might be more appropriately included with major condiments because it is used in a similar manner to steak sauce and soy sauce. The comment did not submit any data to substantiate the suggested regrouping of sauces.

FDA advises that it has classified products in this category according to the similarity in the customarily consumed amounts as reported in the 1977–1978 NFCS and the 1987–1988 NFCS. As explained in section III.D.5.a. of this document, the agency cannot recategorize products merely because someone believes that the products need to be regrouped. Accordingly, FDA rejects this suggestion.

(53) Sauces, dips, gravies, and condiments: barbecue sauce, Hollandaise sauce, tartar sauce, other sauces for dipping (e.g., mustard sauce, sweet and sour sauce), all dips (e.g., bean dips, dairy-based dips, salsa), marinade

FDA proposed 2 tbsp. as the reference amount for this product category.

115. Several comments stated that the 2-tbsp. reference amount is too large for marinades. The comments contended that most of the marinade is discarded after use, so the amount consumed is only about 1 tbsp. or less. The comments recommended that FDA include marinade in the "Major condiments" category because the amount of marinade consumed is closer to the reference amount for this category than that of the proposed category.

FDA acknowledges that much of the marinade is discarded after use. There is no good estimate about what percentage of the marinades used is actually consumed, but the amount consumed is certainly less than the amount used. The smaller reference amount for related products is 1 tbsp. Therefore, the agency has concluded that 1 tbsp. is more reasonable for marinades than 2 tbsp. Accordingly, FDA has moved marinades to the "Major condiments" category.

(54) Sauces, dips, gravies, and condiments: major main entree sauces, e.g., spaghetti sauce

FDA proposed 1/2 cup as the reference amount for this product category.

There was no request for a change in the reference amount for this product category. However, to follow the decision made in section III.D.2. of this document for converting the volume-based reference amount to the weight-based reference amount, the agency has changed the reference amount from 1/2 cup to 125 g (Ref. 55) using the g-weight-per-cup measure for spaghetti and marinara sauce reported by USDA (Ref. 56).

(55) Sauces, dips, gravies, and condiments: minor main entree sauce (e.g., pizza sauce, pesto sauce), other sauces used as toppings (e.g., gravy, white sauce, cheese sauce), cocktail sauce

FDA proposed 1/4 cup as the reference amount for this product category.

116. One comment stated that the 1/4-cup reference amount seems large, and that a 2-tbsp. reference amount may be more appropriate. The comment also suggested that cocktail sauce is used in the same manner as tartar sauce, so it would be more appropriate to include it in the Barbecue sauce category.

FDA advises that the serving size on the product label is, by statute, an amount customarily consumed. Food consumption data showed that the customarily consumed amount of cocktail sauce is 1/4 cup (Ref. 2). Accordingly, FDA has retained the reference amount as proposed.

(56) Sauces, dips, gravies, and condiments: major condiments, e.g., catsup, steak sauce, soy sauce, vinegar, teriyaki sauce, etc.

FDA proposed 1 tbsp. as the reference amount for this product category.

117. One comment requested that FDA change the reference amount to 2 tbsp. because it believed that 2 tbsp. is more consistent with the usage of these condiments. The comment submitted no data to support this change in the reference amount.

FDA advises that the 1 tbsp. reference amount was based on the amount customarily consumed of these condiments (Ref. 2). As explained in section III.D.5.a. of this document, the agency cannot change the reference amount because someone believes it is too small. Accordingly, FDA has retained the reference amount as proposed.

(57) Sauces, dips, gravies, and condiments: minor condiments, e.g., horseradish, hot sauce, mustard, worcestershire sauce, etc.

FDA proposed 1 tsp. as the reference amount for this product category.

118. One comment argued that 1 tsp. of hot sauce is too large. The comment contended that the average amount consumed is 1/2 tsp. for the regular hot sauce and 1/4 tsp. for extra hot sauce. The comment did not submit any data to support the suggested reference amounts.

FDA advises that the 1977–1978 NFCS and the 1987–1988 NFCS showed that the amount customarily consumed of hot sauce is about 1 tsp. (Ref. 2). The comment did not submit food consumption data to support that the amounts customarily consumed are 1/2 tsp. for the regular hot sauce and 1/4 tsp. for the extra hot sauce. Accordingly, FDA has retained the reference amount as proposed.

(58) Snacks: all varieties, chips, pretzels, popcorns, extruded snacks, fruit-based snacks (e.g., fruit chips), grain-based snack mixes

FDA proposed 30 g as the reference amount for the product category.

119. Many comments from the popcorn industry opposed the weight-based reference amount. The comments stated that popcorn kernels differ in their expansiveness. More expansive hybrid kernels produce a larger volume than less expansive kernels. Therefore, the comments said, the proposed 30-g reference amount would result in different serving sizes in volume (cups) for different brands of popcorns on a popped basis. The comments contended that popcorn typically is consumed by volume rather than weight and requested that FDA establish a separate volume-based reference amount for popcorn. The comments recommended 3 cups popped as the reference amount.

One comment contended that when products within the product category differ widely in density, FDA expressed the reference amount in volume, not in weight. As an example, the comment argued that FDA proposed the reference amount for ready-to-eat breakfast cereals in cups, instead of g. The comment contended that because the densities of different brands of popcorns differ widely, FDA should also express the reference amount for popcorn in volume, not in weight. Some comments claimed that consumers will be confused when they see different volume serving sizes on different brands that represent the same serving size because they weigh the same. The comments did not submit any food consumption data to support their contention that more expansive popcorns and less expansive popcorns are consumed in equal volume on a popped basis, or data to substantiate the claim that the different volume serving sizes on different brands of popcorn would be confusing to consumers.

FDA recognizes that popcorns differ in their expansiveness, and that the

weight-based reference amount would result in different volume serving sizes for different brands of popcorn because the expansiveness of popcorn kernels depends on the variety of corn and its moisture content (Ref. 57). However, the agency advises that it cannot have a volume-based reference amount (cups) for popcorn because the g weight of the cup measure of popcorn cannot be determined accurately. Expansiveness of unpopped corn depends on the popping method (Ref. 57). Many factors such as handling and shipping practices, measurement methods, and timing of measurement can affect the accuracy of the g weight of the cup measure of popped corn. As discussed in sections III.D.5. and III.F.1. of this document, there is no well-established standard procedures for determining the g-weight equivalents of the household measures. This inaccuracy in volume-based reference amount makes compliance monitoring impossible. The agency notes that in light of the difficulty in accurately measuring the g-weight equivalents of the household measures, it has decided to convert volume-based reference amounts to the weight-based reference amount where feasible (see section III.D.2. of this document). As a result, the reference amount for ready-to-eat breakfast cereals in the final regulation is in g, not in cups.

Because none of the comments submitted food consumption data to support their contention that more expansive and less expansive popcorns are consumed in equal volume, the agency is not sure that popcorns having different expansion ratios are consumed in equal volume. Furthermore, the agency points out that popcorns come in many different varieties: Plain, flavored, and carameled with or without nuts. The uniform 3 cup reference amount suggested in the comments may not be applicable to all popcorns. Food consumption data showed that the customarily consumed amount of carameled popcorn is 1 cup (Ref. 41).

As for the comments that claimed that consumers will be confused to see serving sizes that differ in the number of cups on different brands of popcorn, the comments did not submit any data to substantiate this claim. Therefore, the agency is not sure of its validity. However, the agency recognizes that many consumers may consume popcorn by volume rather than weight. For the benefit of consumers who consume popcorn on a volume basis and would like to know the nutrient contents of different brands of popcorn on an equal volume basis, the agency would not object to manufacturers providing voluntary labeling of a second column of values on a per cup popped basis (see § 101.9(b)(10)(iii)). This voluntary second column per cup applies only to popcorn and not to other snacks.

For the reasons explained above, the agency has concluded that the weight-based reference amount for popcorn should be retained. Accordingly, FDA has retained the 30-g reference amount as proposed in new § 101.12(b), Table 2.

120. Some comments stated that it is not clear whether the reference amount for popcorn refers to the weight of the kernels before popping or to the weight of the finished product because popcorn is sold both in popped and unpopped form. The comments contended that the reference amount for popcorn should be on a popped basis.

As explained in the preamble (56 FR 60394 at 60407) and in footnote 2 to Tables 1 and 2 in the 1991 serving size proposal, the reference amounts in § 101.12(b) are for the ready-to-serve or almost ready-to-serve (e.g., heat and serve, brown and serve) form of the product. Therefore, the 30 g reference amount is for the popped popcorn. New § 101.12(c) provides that the reference amount of a product that requires cooking or the addition of water or other ingredients is the amount required to prepare one reference amount of the final product as established in new § 101.12(b). Therefore, the reference amount for the unpopped popcorn would be the amount of unpopped corn that is required to make 30 g popped corn.

121. One comment recommended that FDA change the reference amount for all "bulk snacks measurable by a cup" other than popcorn to 1 cup. The comment claimed that NFCS data showed that the mean consumption of snacks is "38.1 g" which reasonably supports the 1 cup reference amount that it recommended.

As stated above, the serving size on the product label is, by statute, an amount customarily consumed. Food consumption data show that the customarily consumed amount for snacks is 30 g (Ref. 2). The g-weight-per-cup measure reported by USDA (Ref. 31) showed that the g weight of 1 cup of snacks, other than popcorn, that are measurable by a cup vary widely. For example, one cup of cheese balls weighs 35 g, whereas one cup of corn nuts weighs 91 g. Therefore, the 1 cup reference amount suggested in the comment does not reflect the amount customarily consumed of snacks, and FDA rejects this recommendation.

122. A manufacturer of "dried fruit snacks" (pressed dried fruit) stated that each individual piece of the dried fruit snack comes in 0.5 to 1 oz pieces. The 30-g reference amount would make the serving size of many of these products two pieces. The comment requested that FDA change the reference amount for the "dried fruit snacks" to 0.5 or 0.75 oz. The comment did not submit any food consumption data to support the suggested reference amounts.

The serving size on the product label is, by statute, an amount customarily consumed. Because the 1977–1978 NFCS did not have dried fruit snacks listed, the agency used the 1987–1988 NFCS to determine the amount customarily consumed for all types of pressed dried fruit. The analysis showed that the customarily consumed amount for pressed dried fruit is about 1 oz, not 0.5 or 0.75 oz (Ref. 41). Therefore, FDA rejects the request.

(59) Soups: all varieties

FDA proposed 1 cup as the reference amount for the product categories.

123. A manufacturer requested that FDA define the reference amount for soups in g. The manufacturer contended that a volume-based reference amount will cause an enormous additional laboratory and administrative burden for the manufacturer.

In light of the difficulty in determining the g weight of the household measure, FDA has concluded in section III.D.2. of this document that the volume-based reference amount should be converted to the weight-based reference amount where the weight-based reference amount is feasible. Because the g-weight-per-cup information is available, and products in this category are relatively uniform in density, the agency has concluded that a weight-based reference amount can be determined for this category. Using the g-weight-per-cup measure reported by USDA (Ref. 58), the agency has determined the average weight per cup for soups to be 245 g (Ref. 55). Accordingly, FDA has revised the reference amount to 245 g.

(60) Sugars and sweets: baking candies (e.g., chips) and hard candies

FDA proposed 15 g as the reference amount for the product category.

124. Several comments from the hard candy industry opposed the uniform 15 g reference amount for all hard candies. The comments stated that the entire package of breath mints or the entire roll of roll candies would be one serving with a 15 g reference amount. The comments contended that some hard candies (e.g., breath mints, hard roll candies) are consumed in much smaller quantities than other hard candies and

should have separate smaller reference amounts.

The comments differed with respect to specific recommendations for the reference amounts. Comments from the breath mint industry stated that breath mints are consumed for the purpose of "freshening" one's breath, not as a candy. Most of these comments recommended one piece as the reference amount for breath mints because breath mints are customarily consumed one piece at a time. One comment stated that a recent consumer survey showed that 60 percent of those surveyed customarily consumed one piece of the breath mint per eating occasion. The comment did not submit any data to support the statement. Another comment recommended that the reference amount should be one piece for hard roll candies and three pieces for "bite-size" hard candies, including breath mints. The comment submitted data from a marketing research survey to support the recommended reference amounts. This survey showed the number of candies that people put in their mouth at a time.

One comment argued that although breath mints and hard candies are often consumed one piece at a time, several pieces are consumed together during what should be considered one eating occasion. Therefore, the reference amount for these candies should not be one piece. The comment did not submit any supporting data.

One comment recommended that FDA divide hard candies into three categories by the piece size and establish a separate reference amount for each size category. Another comment from a manufacturer of hard candies recommended a 4-g reference amount for hard candies that weigh 4 g or less, based on the candy consumption data that it collected through an independent "home use test" mail survey. The comment also suggested placing these candies under the Miscellaneous category with baking decorations. The manufacturer submitted detailed descriptions of the survey methodology and demographic and socioeconomic distributions of the survey respondents, the methodology used to determine a piece weight, and detailed piece weight and consumption data. The survey tested four different "mini candies and mints" that weigh 2.4 g or less per piece. The survey included 1,333 households, covering all 9 U.S. census divisions, that have used the "test candies" or similar candies. The survey was designed to parallel, as closely as possible, the demographic and socioeconomic characteristics of the U.S. population ages 4 and older.

A comment from a Federal agency suggested a 10-g reference amount because it believed that the 15-g reference amount was too large. No data were submitted to support the suggested 10-g reference amount. A comment from a foreign government recommended that FDA change the reference amount to 30 g. The comment stated that, in the case of baking chocolate, 30 g closely approximates 1-oz squares of baking chocolate and is equivalent to the weight of chocolate chips in 3 to 5 cookies.

FDA recognizes that the hard candy category encompasses a wide variety of hard candies which may differ in amounts customarily consumed. Because the NFCS grouped all hard candies in one food code, the agency was unable to establish separate reference amounts for different types of hard candies. The NFCS showed that the amount customarily consumed for all hard candies was 1/2 oz. Consequently, the agency proposed a 15-g reference amount for the hard candy category.

FDA carefully examined all arguments and data submitted in the comment. With regard to the comments that requested a 1-piece reference amount for breath mints, the comments did not submit any food consumption data to support that 1 piece is the customarily consumed amount. Therefore, FDA has not adopted this request.

With regard to the comment that requested a 1-piece reference amount for hard roll candies and a 3-piece reference amount for "bite-size" hard candies, the data from the marketing research survey that were submitted in support of these reference amounts do not represent the customarily consumed amount. The survey asked how many pieces of the test candies people put in their mouth at a time. The survey, however, did not ask how many candies the people wound up eating per eating occasion. To determine the amount consumed per eating occasion, information on the number of candies people put in their mouth at a time and the number of times this process was repeated. Consequently, the data submitted are inappropriate. Therefore, FDA rejects this request.

With regard to the comment that requested dividing hard candies into three categories by the size of the candy and establishing a separate reference amount for each size, the comment did not submit food consumption data to show that the customarily consumed amounts of hard candies by size. In addition, dividing hard candies into three categories by the size of candy can encourage manipulation of the candy size to fit in a more favorable category. Therefore, FDA rejects this request.

FDA examined carefully the data from the "home use test" mail survey. The data were collected under the actual conditions of use and represented the consumption by the U.S. population 4 years of age or older. The survey had a sample size over 10 times that of the 1977–1978 NFCS and over 40 times that of the 1987–1988 NFCS for the hard candy consumption. The results of this survey supported that the customarily consumed amount is 2 g for breath mints and 5 g for roll-type hard candies. The survey also showed that the customarily consumed amount of mini-size candies in dispenser-type packages is less than 5 g. Although the survey only tested the comment's own brand, this study is the only food consumption data available to the agency for specific types of hard candies that were collected under actual conditions of use, and the manufacturer is a major producer of the types of candies tested.

Therefore, the agency has concluded that breath mints, roll-type candies, and mini-size candies in dispenser-type packages should have separate reference amounts. Accordingly, FDA has divided hard candies, based on the type of candy, into three categories each with their own reference amount as shown below:

Hard candies, breath mints—2 g

Hard candies, roll-type and mini-size in dispenser-type packages—5 g

Hard candies, others—15 g

With regard to the comment from the Federal agency, the comment did not submit any food consumption data to support the 10-g reference amount. With regard to the comment from the foreign government, the agency also notes that because the reference amount for cookies is 30 g, the reference amount for baking candies (e.g., chocolate chips), which are only part of the cookie, cannot be 30 g. Therefore, FDA rejects these requests.

(61) Sugars and sweets: all other candies

FDA proposed 40 g as the reference amount for this product category.

125. A few comments recommended a 1-oz reference amount. The comments contended that a uniform 1-oz reference amount would allow for fast and accurate nutrition comparisons of different candies.

Food consumption data showed that 40 g (not 1 oz) is the amount customarily consumed of candies (Ref. 2). The agency notes that regardless of what the reference amount is, most candies come in discrete units, and

therefore, the serving size for most candies will be in the number of pieces according to new § 101.9(b)(2)(i). Because the piece size varies for different candies, the serving sizes for candies will differ. Therefore, a uniform 1-oz reference amount is not going to facilitate nutrition comparisons of different candies any better than the 40-g reference amount. Accordingly, based on these factors and the fact that the comment did not present any data to show that the amount customarily consumed is any different than the amount that the agency proposed, FDA has retained the reference amount as proposed.

126. One comment from a manufacturer requested that FDA create a separate category for specialty fine chocolates/pralines with a reference amount of one piece. The comment contended that these specialty fine chocolates/pralines are unique and deserve a separate category because: (1) The proposed reference amount would make the serving size of these candies three to four pieces, yet these candies are individually wrapped and intended and promoted to be consumed one piece at a time, (2) purchasers of these candies do not "customarily consume" three to four pieces at a time, and (3) unlike other candies that come in several sizes, the manufacturer's chocolates/pralines come only in one size. A comment from another manufacturer stated that the 40-g reference amount is too large for "after dinner mints," and that FDA should establish a separate reference amount for "after dinner mints." Two comments from a foreign country stated that the proposed reference amount is too large for fine bonbons. The comments did not suggest what the reference amount for bonbons should be or submit any data to support their claim.

FDA advises that the serving size on the product label is, by statute, an amount customarily consumed. None of the comments submitted food consumption data that show that the customarily consumed amounts of these candies differ from the proposed reference amount. Therefore, FDA has rejected this request.

(62) Sugars and sweets: confectioner's sugar

FDA proposed 1/4 cup as the reference amount for this product category. The agency notes that the reference amount in the 1991 serving size proposal (56 FR 60394 at 60419) had a typographical error and stated that the reference amount is 2 tbsp. A correction notice was published on March 6, 1992 (57 FR 8179).

No objections have been raised on the proposed reference amount. As discussed in section III.D.2. of this document, the agency has decided to change the volume-based reference amount to the weight-based reference amount where feasible. Accordingly, FDA has changed the 1/4-cup reference amount to the g-weight equivalent to 1/4 cup, i.e., 30 g, using the g-weight-per-cup measure in the USDA Agriculture Handbook (Ref. 57).

(63) Sugars and sweets: honey, jams, jellies, fruit butter, molasses

FDA proposed 1 tbsp. as the reference amount for this product category.

127. A comment from a trade association for jelly and preserves supported the proposed reference amount. Comments from a trade association and a consumer organization requested that FDA change the reference amount to 2 tsp. for honey. One comment contended that the reference amount for honey should be the same as the reference amount for sugar because these products are used interchangeably. In addition, the comment asserted that data from the 1977–1978 NFCS supported the 2-tsp. reference amount for honey because the median consumption was 2 tsp., and the mode was 1 tsp.

FDA acknowledges that honey is used interchangeably with sugar in some foods (e.g., tea). However, honey has many uses. It is also used interchangeably with jam and jelly on toasts and in sandwiches, as shown by the manufacturers' suggested uses on the label. The agency notes that the 1977–1978 NFCS and the 1987–1988 NFCS together reveal that the customarily consumed amount of honey is 1 tbsp., not 2 tsp. (Ref. 2). As explained in section III.D.1. of this document, the agency is not using a reference amount that is based solely on the 1977–1978 NFCS. The agency also notes that the 1977–1978 NFCS showed the mean consumed amount was 3.3 tsp. with two modes (not one as claimed in the comment), one at 1 tsp. and one at 3 tsp. (equivalent to 1 tbsp.). The comments thus have not shown that a separate 2 tsp. reference amount for honey is appropriate. Accordingly, FDA has retained the reference amount as proposed.

128. A manufacturer requested adding "Nutella" to this category. "Nutella," imported from Europe, is a chocolatey spread made from sugar, milk powder, cocoa, pulverized toasted hazelnuts, cocoa butter, and vegetable oil. The company promotes it for use with fruit, crackers, breads, or desserts and asserted that it is used like jams and jellies and, therefore, should be included in this category with a reference amount of 1 tbsp. The company submitted a home use survey conducted by an independent research group to support its assertion.

Because this product is not a commonly consumed food in the United States, it was not listed in the USDA NFCS, which FDA relied on as the source for information on food consumption practices of the U.S. population. As a result, "Nutella" was not included in the "List of products for each product category" that FDA referenced in the 1991 serving size proposal (Ref. 20). According to the description provided in the comment, the product resembles chocolate syrups used as a dessert topping, except that "Nutella's" consistency is thicker than chocolate syrup. The survey data submitted by the manufacturer showed that the major use of 'Nutella" is as a dessert topping with ice cream as opposed to a substitute for jam and jelly with bread. Twenty-seven percent of the 157 respondents surveyed stated that their favorite way of using "Nutella" is with ice cream, whereas only 8 percent named bread. FDA concludes, based on the product characteristics and the usage data provided in the comment, that "Nutella" belongs to the "Other dessert toppings * * *" category under Dessert Toppings and Fillings, not the "Honey, jams, jellies, * * *" category under Sugars and Sweets with a reference amount of 2 tbsp. FDA has revised the product category name for dessert toppings to include the dessert spread. The modified name reads: "Other dessert toppings, e.g., fruits, syrups, spreads, marshmallow * * *" If the company believes that FDA misclassified its product, it can petition FDA to reclassify the product category, but the petition must be accompanied with information specified in § 101.12(h), including food consumption data (the amount customarily consumed) under actual conditions of use.

(64) Sugars and sweets: popsicles, snow cones

FDA proposed 85 g as the reference amount for this product category.

129. Two comments recommended moving popsicles to the frozen dessert category because they are frozen desserts, and they are used interchangeably with products in that category (e.g., ice cream, frozen yogurt, sherbet). The comments differed, however, in the recommended reference amount. One comment recommended a 1/4-cup or 2.5-fl oz reference amount for popsicles because the nutrition

information for these products has been traditionally declared on a volume basis. The other comment recommended a 1/2-cup reference amount, the same as for other frozen desserts in the "Ice cream, ice milk * * *" category (the ice cream category).

First, FDA notes that the product category name has been changed to read: "Frozen flavored and sweetened ice and pops, frozen fruit juices: all types, bulk and novelties (e.g., bars, cups)" (referred to as frozen pops for simplicity) (see section III.D.4.b. of this document).

With regard to the placement of these products, in the 1991 serving size proposal, the agency listed the frozen pops under Sugars and Sweets following the categorization system for the NFCS. The agency agrees with the comments that frozen pops are used as a substitute for other frozen desserts, as shown by how they are positioned in the marketplace, and by how they are grouped in common food composition books (Refs. 37 and 59). Therefore, the agency has concluded that frozen pops should be moved to the Desserts category.

With regard to the request for changing to a volume-based reference amount because the nutrition information on these products has been traditionally declared on a volume basis, the agency advises that according to the act, the serving size should be in a common household measure that is appropriate to the product (section 403(q)(1)(A)(i) of the act). Products in the frozen pops category, with the exception of frozen ice, come in discrete units (e.g., bars), and therefore, the serving size will be the number of pieces, not the volume (e.g., fl oz or 1/2 cup) that is customarily consumed. Consequently, under the act, the nutrition information on frozen pops (excluding frozen ice) will be provided on a piece, and not a per fl oz or per cup, basis. Therefore, the comments' arguments do not justify changing the weight-based reference amount to a volume-based reference amount. Unlike the products in the ice cream category, which are difficult to express in weight because they tend to be highly aerated and differ in density, frozen pops are usually not aerated, are high in moisture, and are relatively uniform in density. Thus, the reference amount can be expressed in g. For compliance monitoring purposes, the weight-based reference amount is more effective than the volume-based reference amount. Therefore, the agency has decided to retain the weight-based reference amount for frozen pops.

With regard to the request to change the reference amount to 4 fl oz to make it the same as the reference amount for other frozen desserts, the agency advises that the customarily consumed amount in volume is not the same for the frozen pops and the products in the ice cream category. The 3-oz customarily consumed amount for frozen pops is equivalent to about 2.6 to 2.8 fl oz because of their high density. Consequently, the agency cannot change the reference amount of frozen pops to 4 fl oz to make it the same in volume as the reference amount for the ice cream category.

Accordingly, FDA has retained the reference amount as proposed.

(65) Sugars and sweets: sugar

FDA proposed 8 g as the reference amount for this product category.

130. Two industry comments requested that FDA change the reference amount to 1 tsp. One comment contended that the available food consumption data do not provide a good estimate of the amount of sugar customarily consumed. The comment stated that the concept of an eating occasion is not suited to a serving size determination for sugar because of the multiple uses of sugar that result in its being consumed in several foods at one eating occasion and in multiple servings of food with added sugar (e.g., coffee) as part of that eating occasion. For example, sugar may be added to coffee, cereal, and grapefruit at breakfast. The amount of sugar consumed per eating occasion in this case would be the total amount of sugar added to all three foods. In addition, many people consume multiple servings of coffee per eating occasion, and the sugar consumed in the multiple servings must be summed to arrive at the amount consumed per eating occasion. The comment also pointed out that the 1977–1978 NFCS and the 1987–1988 NFCS assumed a 2-tsp. serving size when the quantity consumed was not provided by the respondent. The comment contended that this assumption contributed to the conclusion that 2 tsp. is the amount customarily consumed. The comment submitted results of its analysis of data from the 1987–1988 NFCS to show the impact that the use of the default serving size and the consumption of multiple servings had on the determination of the customarily consumed amount of sugar. The comment urged FDA to utilize other relevant information in determining the reference amount, such as the 1-tsp. serving size currently used by the industry and in single-serving packets currently available in grocery stores and restaurants. The comment also contended that: (1) The 1 tsp. serving size has been used by industry for over 12 years, (2) the 1 tsp. serving size is well understood and accepted by consumers, and (3) 1 tsp. is the most convenient and practical measure of sugar.

FDA carefully examined all arguments and data submitted in the comment in support of the 1-tsp. reference amount. FDA acknowledges that because the determination of the serving sizes of foods was not one of the major objectives of the NFCS, data were not collected in a manner to accurately determine all serving sizes, and the NFCS does not accurately reflect the amount of sugar customarily consumed per eating occasion. The agency acknowledges that the amount customarily consumed per eating occasion derived from the NFCS may have been overestimated because the amount of sugar consumed per eating occasion may have included the sugar used in several foods rather than in separate eating occasions. The agency also acknowledges that a major home use of sugar in the United States is to sweeten coffee and tea. The data submitted in the comment showed that a large percentage of people consumed multiple servings of coffee (i.e., 2 or more times the reference amount). The amount of sugar consumed in these multiple servings of coffee would be more than what is used in one reference amount of coffee. Consequently, the amount of sugar customarily consumed in coffee would have been overestimated each time more than 1 cup was consumed.

For the reasons explained above, the agency has concluded that the 2-tsp. customarily consumed amount, derived from the NFCS, is an overestimate of the true customarily consumed amount for sugar. The true customarily consumed amount for sugar is less than 2 tsp. Therefore, the agency has concluded that NFCS data are insufficient to determine the amount customarily consumed for sugar.

As stated in § 101.12(a)(5), when food consumption survey data are insufficient, the agency considered other sources of information including serving sizes recommended in comments and serving sizes used by manufacturers. Because: (1) The next smallest reference amount less than 2 tsp. that corresponds to a common household measure is 1 tsp., (2) 1 tsp. serving size has been used for over 12 years and thus consumers are likely to be familiar with the 1 tsp. serving size, (3) several comments both on the 1990

and the 1991 serving size proposals supported 1 tsp. serving size, and (4) food consumption data did not provide a reasonable basis to change the current industry practice, the agency has concluded that 1 tsp. is the most reasonable reference amount for sugar. Accordingly, FDA has revised the reference amount to 4 g (equivalent to 1 tsp.).

(66) Sugars and sweets: syrups

FDA proposed 60 mL as the reference amount for this product category.

131. An industry comment requested that FDA change the reference amount for light and dark corn syrups to 30 mL. The comment contended that these syrups are used for different purposes than the syrups used on pancakes and waffles. The comment submitted data from a "strategic study" showing that these syrups are used as cooking ingredients rather than poured on pancakes or waffles.

FDA has examined the data submitted in the comment. The agency agrees that the data submitted in the comment show that light and dark corn syrups are used as cooking ingredients rather than poured on pancakes or waffles. Because these syrups are consumed as an ingredient of other foods, NFCS did not have food consumption information for these syrups per se. Using the recipe file for the 1987–1988 NFCS (Ref. 49), the agency has estimated the average amount of these syrups consumed in one reference amount of the final dishes that contain these syrups is about 30 mL. Therefore, the agency has concluded that 30 mL (equivalent to 30 g) is a more reasonable reference amount for light and dark corn syrups than 60 mL (Ref. 50). Accordingly, FDA has revised the reference amount to read: "30 mL for syrups used primarily as an ingredient (e.g., light or dark corn syrup); 60 mL for all others."

(67) Vegetables primarily used for garnish or flavor, e.g., pimento, chili pepper, green onion, parsley: fresh or canned

FDA proposed 30 g as the reference amount for this product category.

132. One comment contended that pimiento/pimento is a specialty canned food item and is an ingredient that is used only in small quantities to enhance the flavor and color of various dishes. The comment argued that because pimento is never used by itself as a vegetable, the 30-g reference amount is too large for pimentos. A nutrition professional organization stated that the proposed reference amount reflects use as a vegetable, not a garnish or flavor.

FDA has reexamined the reference amount for this category. In the interest of minimizing product categories, in the 1991 serving size proposal, the agency included pimento, chili pepper, green onion, and parsley in one group. Because pimento is used primarily as an ingredient of other foods, and the analysis to determine the amount of pimento customarily consumed is time consuming, the agency did not determine the customarily consumed amount for pimento per se due to time constraints. In response to the comment, FDA has determined the amounts of pimento and parsley customarily consumed. The results of the data analysis supported a smaller reference amount (4 g) for pimento and parsley than for chili pepper or green onion (Ref. 41). Therefore, the agency has concluded that this product category should be divided into two categories: Vegetables primarily used for garnish or flavor, e.g., pimento, parsley with a reference amount of 4 g, and chili pepper, green onion with a reference amount of 30 g. FDA has revised § 101.12(b) accordingly.

(68) Vegetables: all other vegetables without sauce: fresh, canned, or frozen

FDA proposed 85 g as the reference amount for this product category.

133. Comments from two trade associations supported the reference amount. One comment opposed the use of the nutrition information on a drained weight basis. The comment presented data showing that a large percentage of consumers consume the liquid in canned vegetables.

As discussed in section III.H.2. of this document, the agency has decided that nutrition information on canned vegetables should be on an "as packaged" basis including the liquid. The 85-g proposed reference amount represents the amount customarily consumed for the solids only, and therefore, it is still applicable to fresh and frozen vegetables without sauce. To reflect the decision in section III.H.2. of this document, the reference amount for canned vegetables has to be reestimated to include the liquid. Using the information on the percent yield of the drained solids for canned vegetables reported by USDA (Ref. 18), the agency has determined that the amount customarily consumed for canned vegetables including the liquid is as follows: 95 g for vacuum packed vegetables and 130 g for vegetables canned in liquid (Ref. 55).

In the 1991 serving size proposal, pumpkin and winter squash were included in the vegetables with sauce category because although pumpkin and winter squash do not contain sauce, the customarily consumed amount was closer to the 110 g than the 85-g reference amount. In the final regulation, the agency has grouped pumpkin and winter squash with vegetables canned in liquid under the category of vegetables without sauce because the customarily consumed amounts of these vegetables are similar. In addition, FDA has moved cream-style corn and canned or stewed tomatoes from footnote 5 of Table 2 in the 1991 serving size proposal to the reference amount column in the final regulation because the reference amount for these two vegetables is the same as that for the vegetables canned in liquid, and therefore, the footnote is no longer necessary. The revised reference amount reads: "85 g for fresh or frozen; 95 g for vacuum packed; 130 g for canned in liquid, cream-style corn, canned or stewed tomatoes, pumpkin, or winter squash."

134. One comment recommended that vegetables with pasta and vegetables with rice be included in the vegetable category, not in the Mixed dishes category. The comment contended that the dietary guidance documents recommend 1/2 cup for vegetables, rice, and pasta, so there may be consumer confusion if 1/2 cup is not used for these foods when combined.

Vegetables with pasta and vegetables with rice are neither rice nor pasta nor vegetables. They are clearly mixed dishes because they contain two foods from two different food groups (the grain product group and the vegetable group). The comment did not submit any data to show that, for these products, a serving size other than 1/2 cup would cause consumer confusion.

Accordingly, FDA has rejected this comment.

(69) Vegetables: all other vegetables with sauce: fresh, canned, or frozen

FDA proposed 110 g as the reference amount for this product category.

135. A comment from a consumer recommended that FDA change the reference amount to 100 g because 100 g is a more rational metric size than 110 g.

FDA advises that for reasons explained in section III.D.1. of this document, it is not changing the reference amount to make it more rational in metric quantity. Accordingly, FDA has retained the reference amount as proposed.

(70) Vegetables: vegetable juice

FDA proposed a uniform 240-mL (8 fl oz) reference amount for this product category.

136. Comments from several manufacturers and trade associations and a comment from a nutrition professional organization supported the proposed uniform 8-fl oz reference amount for all beverages. One comment from a manufacturer requested that FDA establish a separate category for vegetable juice with a reference amount of 6 fl oz.

Considering the weight of support for the uniform 8-fl oz reference amount for all beverages and the benefit of the uniform reference amount that facilitates nutrition comparisons of different beverages, the agency has decided to retain the uniform 8-fl oz reference amount for all beverages, including vegetable juice. Vegetable juice is frequently used interchangeably with fruit juice and other beverages. Food consumption data also did not show that the customarily consumed amount for vegetable juice differs from that of fruit juice or of many other beverages (Ref. 2). The comment did not submit data that would support a different result. Accordingly, FDA has retained the reference amount as proposed.

(71) Vegetables: olives

FDA proposed 15 g as the reference amount for this product category.

137. One comment requested that FDA change the reference amount to 30 g. The comment contended that 30 g is the serving size that is currently used on packaging, and because pickles and olives have similar consumer usage patterns, the reference amount for olives should be the same as the reference amount for pickles.

FDA disagrees with the comment. The agency advises that the serving size on the product label is, by statute, an amount customarily consumed. Both the 1977–1978 NFCS and the 1987–1988 NFCS showed that the customarily consumed amount of olives is closer to 0.5 oz, not 1 oz. The comment did not present any data to show that 0.5 oz is not the customarily consumed amount. Accordingly, FDA has retained the reference amount as proposed.

6. Reference amounts for imitation or substitute food, altered food, and foods for special dietary use

To prevent the manipulation of serving sizes for nutrient content claims, FDA proposed in § 101.12(d) that the reference amount for an imitation or substitute food be the same as that of the food for which it is offered as a substitute. In addition, the agency proposed in § 101.12(e) that the reference amount for an altered version of a food, such as a "low calorie" version, be the same as for the food for which it is offered as a substitute.

FDA received about a dozen comments on this proposal from manufacturers, trade associations, and professional organizations. About one-third of the comments supported the proposal. The rest of the comments opposed it.

138. Comments opposing the proposal stated that one way that industry is reducing the fat and calorie content of foods is through a new technology that incorporates air into the product (referred to as "aerated food" for simplicity). Many aerated foods weigh significantly less than their regular counterparts. Comments stated that there is no concern when the reference amount is established in volume, but that there is a concern when a weight-based reference amount is used. For example, using a reference amount of 85 g for waffles, 3 aerated waffles would be compared to 2 regular waffles of the same size and shape. Therefore, the calorie and fat content of the aerated food would not be lower than that of the regular food when compared on an equal weight basis. Manufacturers would thus be unable to use a nutrient content claim for the aerated foods.

These comments argued that the proposal would diminish manufacturers' incentive to develop "nutritionally improved" foods and prevent consumers from benefitting from low fat, low calorie alternatives. The comments suggested that when the reference amount is determined by weight, FDA should allow the manufacturers to use "the volume measure (e.g., common household volumetric or dimensional measure or number of discrete units) equivalent to the volume measure of the manufacturer's regular product pursuant to the reference amount," e.g., 2 waffles for both the aerated and the regular food.

FDA has given careful consideration to all arguments and suggestions presented in these comments. Although the comments claimed that the amount customarily consumed for the regular and the aerated food is the same in volume, not in weight, no food consumption data were presented with the comments or are available from other sources to verify the claim. It is possible that people eat three aerated waffles, instead of two, to attain satiety. Therefore, FDA is not certain that the amount customarily consumed for the aerated foods and their regular counterpart is the same in volume.

At the same time, in light of the current dietary guidelines for reducing fat and calorie intakes (Refs. 60 through 62), FDA acknowledges that it is desirable to have a wide selection of low fat and low calorie foods available to consumers. Some consumers may benefit from having such aerated foods if they consume an equivalent volume of aerated food as they would have the regular food, e.g., two instead of three aerated waffles. However, FDA does not believe that the solution suggested in the comments is appropriate or desirable considering the wide variability in the unit size and shape of the regular products in discrete units. This variability would make it difficult to determine a reference point, i.e., volume equivalent to the reference amount of the regular counterpart.

FDA finds that the most reasonable solution to this problem is to allow the manufacturers to determine the reference amount in g for the aerated food by adjusting for the difference in density of the aerated food relative to the density of the regular counterpart (density-adjusted reference amount). For example, if the density of the aerated food is 30 percent lower than the density of the regular counterpart, the reference amount for the aerated food would be 30 percent less than the reference amount of the regular counterpart. For example, the reference amount for regular waffles is 85 g, so the reference amount for aerated waffles, which are 30 percent lower in density, would be 60 g. A manufacturer may use the density-adjusted reference amount to determine the label serving size and the qualification of the aerated food for nutrient content and health claims, provided that, upon request, the manufacturer will show FDA the detailed protocol and records of data described below. FDA will consider regulatory action under sections 402(b) and 403 of the act on any misuse of this allowance.

Such density-adjusted reference amounts may not be done for cakes. Although the product categories for cakes in the final regulation are identified by types of cakes, not by density, the three cake categories in Table 2 in new § 101.12(b) were determined according to the density of various cakes. FDA took the differences in the densities of different types of cakes having different degrees of air incorporation into consideration in determining the reference amounts for cakes. Therefore, further adjustment of the reference amounts for aeration is not permissible for cakes.

For the aerated food to qualify to use the density-adjusted reference amount, the product must be sufficiently lower in density than the regular counterpart. The agency finds that a 25-percent

reduction in density is a reasonable cutoff level for this purpose. The 25-percent minimum reduction is consistent with the minimum percent reduction requirement to qualify for a "less" or "reduced" claim in the regulation entitled "Food Labeling; Nutrient Content Claims, General Principles, Petitions, Definition of Terms" (hereinafter referred to as the nutrient content claims regulation), published elsewhere in this issue of the **Federal Register**. In estimating the difference in density, manufacturers must use an appropriate reference food as described in new § 101.13(j)(ii)(A) of the nutrient content claims regulation, published elsewhere in this issue of the **Federal Register**, for the regular counterpart.

In expressing the weight-based reference amounts for the regular foods in new § 101.12(b), FDA rounded the values to the nearest 5-g increment to avoid the appearance of an overly exact g-weight. Under § 101.12(e), this procedure must also be followed in determining the reference amount for the aerated food. Manufacturers must use the rounded density-adjusted reference amount to determine the serving size and whether the aerated food qualifies for a claim. The table below shows an example of the calculated density-adjusted reference amount and the corresponding rounded reference amount to be used for aerated waffles that have been reduced in density by 25 to 35 percent. As the table shows, aerated waffles with density reductions of 27 to 32 percent must use 60 g, not 58 to 62 g, as the reference amount.

Reference Amount for the Regular Waffle: 85 g

Percent reduction in density	Calculated Density-adjusted reference amount	Reference amount for "aerated" food
(%)	(g)	(g)
25	64	65
26	63	65
27	62	60
28	61	60
29	60	60
30	60	60
31	59	60
32	58	60
33	57	55
34	56	55
35	55	55

To use a density-adjusted reference amount, manufacturers must have the following available for inspection by FDA upon request: (1) A detailed protocol and records of all raw data and calculations used to determine densities of both the regular and the aerated products; (2) records of the sample size, the mean, and the standard deviation for the density measurements of the regular and the aerated products; and (3) records of all data, calculations, and procedures used to arrive at the "density-adjusted" reference amount for the aerated product. The protocol must contain identification and descriptions of all materials used (e.g., equipment) to determine the density. In determining the differences in the densities of the regular and the aerated products, manufacturers must also observe the following: (1) The regular and the aerated product must be the same in size, shape, and volume. To compare the densities of products having nonsmooth surfaces (e.g., waffles), manufacturers must use a device or method that ensures that the volumes of the regular and the aerated products are the same. One way to ensure the same volume is to use the same equipment to make the regular and the aerated products; (2) sample selections for the density measurements must be done in accordance with the provisions in § 101.9(g); (3) density measurements of the regular and the aerated products must be conducted by the same trained operator using the same methodology (e.g., the same equipment, procedures, and techniques) under the same conditions; and (4) density measurements must be replicated a sufficient number of times to ensure that the average of the measurements is representative of the true differences in the densities of the regular and the aerated products.

Manufacturers must use a descriptive term such as "whipped" or "aerated" as part of the product name (e.g., whipped peanut butter, aerated waffle) so that consumers are properly informed that extra air has been incorporated into the product. The use of this term is necessary, under section 201(n) and 403(a) of the act, to disclose a material fact.

To incorporate the labeling requirements for aerated foods, FDA has combined § 101.12(d) and (e), redesignated as § 101.12(d), and added the requirements for aerated products in § 101.12(e).

139. A manufacturer of medical foods stated that several aspects of the serving size regulation (e.g., expressing the serving size in the common household measure) are not accurate enough for medical foods.

FDA advises that the serving size regulations do not apply to medical foods because section 403(q)(5)(A)(iv) of the act exempts medical foods from all requirements of nutrition labeling. The agency intends to develop regulations for proper labeling and uses of medical foods in a future **Federal Register** document.

7. Reference amounts for products consisting of 2 or more foods having individual reference amounts

FDA proposed in § 101.12(f) that the reference amount for products packaged and presented to be consumed together (e.g., peanut butter and jelly combination, cracker and cheese pack, pancakes and syrup pack) be the sum of the reference amounts for the individual foods in the package.

140. FDA received only a few comments on this aspect of the proposal. Comments from nutrition professional organizations agreed with the proposal. A consumer organization disagreed with the proposal and stated that the proposal is reasonable only for foods that are not packaged in single-serve containers such as peanut butter and jelly. The comment contended that for foods in single-serve containers (e.g., cheese-and-cracker snack trays, yogurt and granola, pancakes and sausage, waffles and fruit sauce, spaghetti and tomato sauce,, macaroni and cheese, or rice with vegetables), the reference amount should be based on the weight of the entire package.

First of all, FDA wishes to clarify that the proposal applies to the products that contain two or more foods having individual reference amounts that are not listed in proposed § 101.12(b). Although this fact was mentioned in the preamble (56 FR 60394 at 60407), FDA did not state it in the codified language in proposed § 101.12(f). To clarify its intent, FDA has revised § 101.12(f) to read:

> The reference amount for products that represent two or more foods packaged and presented to be consumed together * * * shall be the sum of the reference amounts for individual foods in the package if the reference amount for the product is not listed in paragraph (b) of this section.

Some of the examples mentioned in the comment (spaghetti and tomato sauce, macaroni and cheese, rice with vegetables) are mixed dishes measurable with a cup that have reference amounts in new § 101.12(b). As explained previously, FDA does not believe that it is consistent with the act to have different reference amounts for the same product in different package sizes, one for single-serving packages and one for multiserving packages. The reference amount for the same product must be the same regardless of the package size.

In addition, the agency points out that the package of yogurt and granola is one food. It simply is another variety of flavored yogurt. Like frozen entrees in pouches, yogurt and granola are

packaged in separate containers for technical reasons (e.g., better preservation of the texture), but they are combined before consumption and eaten as one food. The reference amount for yogurt and granola is 225 g, the same as for any other yogurts.

141. An industry comment stated that the reference amount is not necessary for "meal-type" products because claims on these products will be evaluated on a per 100 g basis.

The agency disagrees with the comment. Reference amounts are also used to determine the label serving sizes of specific products for presenting nutrition information. Many "meal-type" products (reclassified and redefined as "meal product" and "main dish product" in the final nutrient content claims regulation published elsewhere in this issue of the **Federal Register**) (e.g., lasagna, pizza) are available both in single-serving and multiserving containers. Reference amounts provide a basis on which to determine the label serving sizes of these products in multiserving containers and whether these products are qualified to be called single-serving.

142. A consumer organization requested that FDA establish reference amounts for "frozen meals" (e.g., breakfast, lunch, or dinner trays) based on the average weight of the products in the marketplace or on the "industry-wide average."

The agency notes that the "frozen meals" mentioned in the comment currently come only in containers clearly intended for a single serving, and therefore, the nutrition information for these products will be based on the entire content of the package. The agency also notes that the reference amount is not needed to evaluate whether these products are qualified for claims because the qualification for claims on these products will be based on 100 g of the product and not on the reference amount as discussed in the final nutrient content claims regulation published elsewhere in this issue of the **Federal Register**. If a reference amount is needed for "frozen meals," new § 101.12(f) can be used to determine the reference amount for specific frozen meals. Breakfast, lunch, or dinner trays contain two or more distinct products which have reference amounts in new § 101.12(b). According to new § 101.12(f), the reference amounts of these products are the sum of the reference amounts of the individual foods in the tray. For example, the reference amount of a dinner tray containing fish, french fries, and mixed vegetables will be the sum of the reference amounts of fish (85 g), french fries (70 g if cooked), and mixed vegetables (85 g), i.e., 240 g. Therefore, there is no need to establish separate reference amounts for these "frozen meals."

8. Miscellaneous issues related to reference amounts

143. Some industry comments stated that restaurants should be permitted to declare nutrition information according to their own specifications for serving size.

Restaurant foods are not required to bear nutrition labeling. However, when nutrient content or health claims are made for restaurant foods, the restaurateur must provide nutrition information in compliance with the nutrient content or health claims regulations published elsewhere in this issue of the **Federal Register**. Meals, entrees, or other menu items served in restaurants are analogous to single-serving products. Therefore, in most cases, the restaurateur must have a reasonable basis for believing, based on the amount served, that the food qualifies for the claim. However, if nutrient content claims are made relative to a competitor's product, it is important that like amounts be compared.

144. A trade association recommended that FDA allow manufacturers to deviate from the reference amounts if such deviation is supported by food consumption data.

The act requires that FDA establish standards providing that uniform serving sizes information will be furnished on the food label (H. Rept. 101–538, supra, 7). The reference amounts are part of the standards. Manufacturers cannot deviate from the reference amount simply because they believe that such deviation is supported by food consumption data. If the uniformity expected by Congress is to be maintained, the information on the need for revised or separate reference amounts must be evaluated by FDA through the petition process that it has established in new § 101.12(h) before changes in, or deviations from, the reference amounts can occur.

E. Procedures for Converting the Reference Amount to Serving Size

For the purpose of converting the reference amounts for multiserving products into label serving sizes, FDA grouped these products into three categories according to the shape and characteristics of products and the way products are usually served. The three categories were: (1) Products in discrete individual units (e.g., muffin, sliced bread, apple), (2) products in large discrete units that are usually divided for consumption (e.g., cake, pie, pizza, melon, cabbage), and (3) nondiscrete bulk products (e.g., breakfast cereals, flour, sugar). The agency proposed separate procedures for each category to ensure that the serving size declared on the label is most appropriate for the specific type of product.

FDA received about 20 comments on issues related to these procedures. About one-third of the comments agreed with the proposed procedures. The remaining two-thirds suggested other ways of determining label serving sizes for specific products or requested modification or clarification of certain specific aspects of the procedures. FDA will first respond to the "general" types of comments and then discuss the comments on procedures for each specific category.

145. A foreign manufacturer stated that the reference amounts should be used only to ascertain that the serving size chosen by the manufacturer is reasonable, and that they should not be used to determine the label serving size. The comment argued that products packed in foreign countries are packaged according to "whole number" metric amounts and do not translate easily into U.S. household units. The comment requested that FDA show a certain amount of flexibility. A domestic comment stated that several of the reference amounts are "atypical in retail practice" in the United States even though they may represent consumers' consumption practice. The comment, therefore, suggested that FDA permit industry to use the reference amount as a guideline and require them to justify, with marketing data, those serving sizes that substantially deviate from the reference amount. A few consumer comments, on the other hand, requested that FDA not allow the manufacturers to deviate from the "standard serving size."

The 1990 amendments direct FDA to establish standards, not guidelines, to define serving sizes. As alluded to above, the House report on the 1990 amendments, in explaining section 2(b)(1)(B) states: "It is critical to the successful implementation of this legislation that the FDA develop meaningful serving size requirements * * *." (H. Rept. 101–538, supra, 18). Accordingly, FDA established the standards described above to define how to determine the label serving size that is most appropriate for a specific product. FDA believes that the standards provide enough flexibility to both domestic and foreign manufacturers to permit them to determine the serving sizes most

appropriate for their products from the reference amounts in new § 101.12(b).

FDA does not agree with the comment that products packaged in foreign countries according to "whole number" metric amounts cannot easily be translated into common U.S. household measures. Some domestic products are also packaged according to "whole number" metric amounts (e.g., 1- or 2-liter (L) bottles of soft drinks). FDA allows the number of servings per container to be expressed in an approximate number. Therefore, it should not be difficult to translate the products packaged according to "whole number" metric amounts into common U.S. household measures. For example, the serving size and the number of servings for a 1–L container of soft drink can easily be translated to the common U.S. household measure by dividing the 1-L (1,000 mL) net quantity of the product by the 240-mL reference amount for soft drinks and expressing an approximate number of servings, e.g., serving size: 1 cup (240 mL); number of servings per container: about 4.

FDA notes that the act links serving size to food consumption practices, not to the "typical retail practice" or marketing data. Therefore, FDA cannot use information (e.g., "typical retail practice" or marketing data) other than food consumption data as the primary basis for reference amounts when appropriate food consumption data are available. The agency has considered serving sizes used by the industry (i.e., retail practice) in developing the reference amounts in this final rule. When appropriate food consumption data were not available, the agency gave more weight to other information listed in new § 101.12(a)(5), including serving sizes currently used by the industry, in arriving at the reference amount.

146. An industry comment asked that FDA clarify how to determine the label serving size if there are more than one use of a product.

The reference amounts in new § 101.12(b) reflect the major usage of the products in each product category. If there is more than one use for a product, manufacturers should use the major usage of the product to determine the label serving size. For example, the label serving size for a cake mix which has directions for a 2-layer cake and cupcakes should be based on the 2-layer cake. Manufacturers should determine the major usage of the product based on food consumption data, marketing survey data on the consumer usage of the product, or, in the case of a new product, promoted use.

147. An industry comment requested that FDA clarify how to determine the label serving size if the label serving size determined according to the procedures in proposed § 101.9(b)(2) and the incremental rules in proposed § 101.9(b)(5) falls exactly half way between two sizes, e.g., exactly 2.5 tbsp.

FDA notes that the common standard procedure for rounding is to round up values 0.5 or larger. FDA is not aware of any reason not to follow this procedure. Therefore, for clarity, FDA has added a new § 101.9(b)(5)(v), on rounding rules as follows:

When a serving size, determined from the reference amount in § 101.12(b) and the procedures described in this section, falls exactly half way between two serving sizes, e.g., 2.5 tbsp, manufacturers shall round the serving size up to the next incremental size.

148. Several comments suggested different serving sizes for celery or for other of the 20 most frequently consumed raw fruits and vegetables identified in § 101.44.

FDA advises that serving sizes for the 20 most frequently consumed raw fruits and vegetables, including celery, are provided in Appendix A to the regulation entitled "Food Labeling; Guidelines for Voluntary Nutrition Labeling; and Identification of the 20 Most Frequently Consumed Raw Fruits, Vegetables, and Fish; Definition of Substantial Compliance" (56 FR 60880 as amended at 57 FR 8174, March 6, 1992). Retailers who wish to use different serving sizes for these fruits and vegetables may do so subject to the provisions of § 101.45. FDA urges such retailers, and retailers who wish to provide the nutrition information of raw fruits and vegetables not included in § 101.44, to use the reference amount specified in new § 101.12(b) for the fruit or vegetable category appropriate for the specific fruits or vegetables and to follow the procedures described in this section to determine the label serving size.

1. Products in discrete individual units

FDA proposed in § 101.9(b)(2)(i) that "for products in discrete units (e.g., muffin, sliced bread, apple), the serving size shall be the number of units that most closely approximates the reference amount for the product category. If a unit weighs 67 percent or more, but less than 200 percent, of the reference amount, the serving size shall be one unit. If a unit weighs 200 percent or more of the reference amount, the manufacturer may declare the whole unit as one serving if the whole unit can reasonably be consumed at a single-eating occasion."

149. Several industry comments opposed the lower limit of the single-serving unit because single units of many products in discrete units weigh less than 67 percent of the reference amount. One comment requested changing the lower limit from 67 percent to 50 percent because food consumption data (e.g., 1977–1978 NFCS) show that a significant proportion of "eatings" (e.g., up to 25th percentile) were about one-half or less of the average quantity consumed. Therefore, the comment contended, a unit that weighs 50 percent of the reference amount should be able to declare one serving per unit. Another comment requested changing the lower limit from 67 percent to 50 percent and allowing single-serving declaration on a single unit that weighs less than 50 percent of the reference amount if a single unit can reasonably be consumed at a single-eating occasion. The latter comment stated that this approach is analogous to the optional declaration as a single serving of a single unit that weighs 200 percent or more of the reference amount if the whole unit can reasonably be consumed at a single-eating occasion. Some comments recommended that FDA let the manufacturers determine whether a unit that weighs less than 67 percent is a single serving.

FDA carefully examined all requested changes for the lower limit of a single-serving unit. The agency has examined the amount of food consumed per eating occasion for several products that come in discrete units and find that a significant number of people consume between 50 and 67 percent of the reference amount per eating occasion (Ref. 63). Considering that: (1) Many single units fall between 50 and 67 percent of the reference amount, (2) a significant number of people consume between 50 and 67 percent of the reference amount per eating occasion, and (3) serving sizes in dietary guidance documents are often based on a single unit, FDA believes that it is reasonable to let manufacturers have the flexibility to determine whether a unit that weighs more than 50 percent but less than 67 percent is a single serving. However, a unit that weighs 50 percent of the reference amount is, by definition, one-half of a serving, not one serving. Therefore, products that weigh 50 percent or less cannot be called one serving. Accordingly, FDA has revised § 101.9(b)(2)(i) to allow optional declaration of a serving based on a single unit of a product if the unit weighs more than 50 percent but less than 67 percent of the reference amount.

150. Several industry comments requested that FDA permit the use of an oz measure for the serving size for products that naturally vary in piece

size (e.g., shrimp, pickles) instead of the number of discrete units. A seafood trade association stated that great difficulty and financial burden would be placed on the industry if serving sizes of seafoods have to be expressed in the number of discrete units. The comment pointed out that seafoods such as shrimp, scallops, oysters, clams, lobster, and fillet of fish vary naturally and substantially in size. For example, processed breaded shrimp products are made in as many as 12 to 15 sizes because of the natural variation in shrimp size. The comment stated that if a manufacturer packed these products in three different sized packages, up to 45 different labels would be necessary to accurately designate serving sizes based on discrete units, and the cost of printing different labels would be prohibitive.

A pickle trade association also stated that the size and shape of cucumbers naturally vary widely because of numerous factors, including the variety, weather conditions, and maturation when harvested. Therefore, according to the comment, pickles, even in the same grade established by the USDA, vary considerably in size and weight. The comment contended that the serving size cannot be declared by the number of pickles because of the inherent variability in pickle sizes. If the serving size of pickles were required to be declared in the number or fraction of pickles, the comment continued, pickle manufacturers would have to have a different label for each pickle size. The comment contended that such a result would represent an unnecessary burden and cost. Therefore, the comment recommended that the serving size for pickles should be declared in terms of oz.

FDA recognizes the wide variability in the unit size of seafoods and agricultural commodities such as pickles where the size is determined by nature, not the manufacturer. The costs incurred in ensuring that the number of discrete units in the serving size declaration for these naturally-variable products is appropriate would be unreasonable because of the numerous labels for each product size, and the costs would likely be passed on to the consumer. The agency, therefore, believes that the most reasonable solution to this problem is to express the serving size in an oz measure most closely approximating the reference amount, followed by the g equivalent weight and the approximate number of pieces for small pieces (e.g., shrimp) or the dimension for a large piece (e.g., fillet of fish) in parenthesis. For example, serving sizes may be declared as 3 oz (84 g/about 5 shrimp) for cooked shrimp, 3 oz (84 g/about one fillet) for cooked fish fillet, 1 oz (28 g/about 1 pickle) for small pickles, and 1 oz (28 g/about 1/2 pickle) for large pickles. This approach will satisfy the act by providing the declaration in household measures in terms of oz. It also provides a uniform g weight within and across brands. This approach also facilitates nutrition comparisons among brands. Because many consumers stated that they do not understand oz measure, the approximate number of pieces or the dimension allows consumers to visualize the serving size in more easily identifiable units. Therefore, FDA has revised § 101.9(b)(2)(i) to exempt products that vary naturally in the unit size such as pickles, shellfish, whole fish, and fillet of fish. In addition, the agency has added a statement that serving sizes for these products shall be expressed in the amount in oz that most closely approximates the reference amount for the product category, and a second statement that refers manufacturers to § 101.9(b)(5) for instructions on how to express the serving size in oz. The agency notes that this exemption does not apply to processed products, such as fish sticks and fish squares, where manufacturers can control the piece size.

FDA recognizes that unit sizes of products in individual discrete units (e.g., fish sticks, muffins, sliced products) for which the size of the product is controlled by the manufacturer, not by nature, also vary somewhat from unit to unit within the package as well as from batch to batch for the same container size. This variation is also true for products in large discrete units (e.g., cake, pizza). Therefore, the g weight of a unit or a fraction will vary from unit to unit as well as from batch to batch. It is thus impossible to label accurately the g weight that is equivalent to the household measure in each package. FDA concludes that the most reasonable solution for this problem is to state the average g-weight equivalent of the unit or the fraction that represents the serving size. To determine the average g-weight equivalent of the household measure, manufacturers must follow the sampling procedures in § 101.9(g)(2) for nutrient analysis. The g-weight equivalent of a unit or a fraction for each package can be determined by dividing the net weight of the package in g by the number of units or fractions in the package or by actually weighing the units or the fractions. In determining the average g-weight equivalent, the measurements should be replicated a sufficient number of times to ensure that the average of the measurements is truly representative of the g-weight equivalent of the serving size in household measure. FDA urges manufacturers to maintain records of all data and calculations used to determine the average g-weight equivalent to substantiate the parenthetical metric quantity declared on the label.

151. A comment from a maraschino cherry trade association stated that according to the 1991 serving size proposal, the serving size for maraschino cherries would be 1 cherry. However, maraschino cherries naturally vary in size ranging from 4 g for a small cherry to 7 g for a large cherry depending of the locality of growth and the crop year. The comment contended that because of this natural variation in the size of cherries, the maraschino cherry packers would have to keep changing the labels to have the accurate serving size information. In addition, the comment stated that the number of servings per container vary because of the variation in the cherry size. The comment requested that FDA allow the maraschino cherry packers to use a range of values (e.g., 4 to 7 g) for the parenthetical metric measure for the serving size and exempt the maraschino cherries from the declaration for the number of servings per container.

As for pickles, FDA recognizes the wide variability in the unit size of agricultural commodities where the size is determined by nature, not the manufacturer. As stated above, the costs incurred in ensuring that the number of discrete units in the serving size declaration would be unreasonable because of the numerous labels necessary for each product size. Unlike pickles, however, cherries cannot have a serving size expressed in oz because the reference amount for cherries (4 g) is too small to express in oz. Therefore, the agency finds that the most reasonable solution to this problem is to declare the serving size as one cherry and the parenthetical metric measure as the g-weight equivalent of one medium cherry (e.g., 1 cherry (5 g)). The number of servings per container would then be declared as the usual number of servings per size of container (e.g., usually 20 servings), and the nutrition information would thus be provided for one medium cherry. The agency recognizes that different size containers hold different numbers of cherries. Therefore, this approach will require the manufacturer to have one set of labels for each size of container. Accordingly, new § 101.9(b)(2)(i) has been further revised to include the special serving

size requirement for maraschino cherries.

152. Several industry and professional comments stated that the serving size for products in discrete units (e.g., sliced bread, frozen novelties) should be one unit.

FDA disagrees with the comments. Products in discrete units vary widely in unit size. For example, the unit size for sliced bread varies from about 0.3 oz to 1.2 oz and from 0.4 oz to 6 oz for muffins. If one unit were defined as the serving size, there would be no uniformity in the serving sizes for products in discrete units. Furthermore, single units of some of these products are too small to be reasonably considered a serving.

The act defines serving size as an amount customarily consumed. Reference amounts established by this regulation represent FDA's best estimate of the amounts customarily consumed for the 139 product categories. To provide flexibility and to ensure that the serving size in common household measures is meaningful for specific types of products, FDA has provided procedures in new § 101.9(b)(2) to convert the reference amounts to the label serving size. Therefore, unless one unit represents the serving size for the product as determined from the reference amount in new § 101.12(b) using the procedures in new § 101.9(b)(2), one unit cannot be used on the labels as the serving size.

153. Some comments requested that FDA clarify serving sizes of packages within packages.

FDA advises that packages within a package (i.e., individually wrapped products in a multiserving container) are considered to be products in discrete units. Each individually wrapped package (e.g., fun size candy bars, roll candies, tiny box of raisins) is one unit. The serving size of these products is the number of individual units whose total net content most closely approximates the reference amount. FDA has revised § 101.9(b)(2)(i) to clarify this point by adding individually packaged products within a multiserving package to the list of examples of products in discrete units.

154. A manufacturer suggested that FDA change the single-serving unit criteria from "67 percent or more, but less than 200 percent" of the reference amount to "2/3 or more, but less than twice" the reference amount. The comment asserted that this modification would avoid a difference of opinion as to whether 66.67 percent should be rounded to 67 or should be considered less than 67 percent for a single-serving determination.

As discussed earlier, the common standard procedure for rounding is to round up values 0.5 or larger. Thus, 66.67 percent is considered to be 67 percent. Therefore, defining the lower cutoff point as 67 percent is as clear as defining it as 2/3, and defining the upper limit as less than 200 percent is as clear as defining it as less than twice. Since the proposed language and the suggested change are equally clear, the agency has concluded that it is not necessary to modify the proposed regulatory language. Accordingly, FDA has retained the language for the single-serving unit criteria as proposed.

155. A consumer organization requested that FDA clarify whether, for products in discrete units, manufacturers must list the nutrition information on the basis of units that constitute the label serving size (e.g., 2 slices) or for the underlying reference amount (e.g., 2 1/2 slices). The comment contended that FDA should require nutrition information for products in discrete units to be listed based on the former approach.

FDA agrees that clarification is needed. Accordingly, the agency is revising § 101.9(b)(2)(i) to state that, except for products that naturally vary in size, the serving size of discrete-unit products is the number of whole units that most closely approximates the reference amount for the product category. This revision makes it clear that the serving size is to be expressed in whole number of units which was the original intent in the proposal.

156. A manufacturer requested that FDA clearly state in the preamble to the final regulation that a slice of cheese, whether or not wrapped individually, like sliced bread, constitutes a discrete unit for purposes of determining serving size. The manufacturer stated that this fact was evident, but ambiguous, in light of specific examples of discrete units cited in the 1991 serving size proposal.

Because it is impossible to provide the entire list of the products that are sold in discrete units, FDA provided a few examples of products that are sold in discrete units in § 101.9(b)(2)(i) of the 1991 serving size proposal. They included muffins, sliced bread, and apples. The specific examples given in the 1991 serving size proposal were to provide some idea of what is meant by products in discrete units. The agency included "sliced bread" as an example to convey the message that a slice of sliced products is a discrete unit product. A slice of sliced cheese is thus a discrete unit product. For clarity, FDA has modified the "sliced bread" example to read "sliced products such as sliced bread."

2. Products in large discrete units that are usually divided for consumption

FDA proposed in § 101.9(b)(2)(ii) that for products in large discrete units that are usually divided for consumption (e.g., cake, pie, pizza, melon, cabbage), the serving size is the fractional slice of the food (e.g., 1/12 cake, 1/8 pie, 1/4 pizza, 1/4 melon, 1/6 cabbage) that most closely approximates the reference amount for the product category.

157. A manufacturer recommended that the fractional slice should be "geometrically friendly" to consumers. The comment stated that some fractional slices may not be easy for the consumers to cut or visualize. For example, a cake cannot be easily cut into seven even slices. The comment provided two separate lists of "geometrically friendly" fractions in support of their position, one "for products that are not cut in two directions" (e.g., round cakes) and one for "products that must be cut in two directions" (e.g., sheet cakes). A few other comments also expressed a concern about odd fractional serving sizes.

FDA recognizes that the proposal could result in an odd fractional slice such as 1/7 of a cake or pie. The agency agrees with the comment that the serving size for products in large discrete units should be expressed in fractions friendly to consumers. Although manufacturers may have a means to cut these products in odd fractions, consumers generally would have difficulty in cutting them into certain odd fractions such as 1/7.

To rectify this problem, the agency carefully examined all possible fractional slices including those suggested in the comment. FDA could not directly adopt the two sets of fractional schemes suggested in the comment because the agency cannot require that some products be cut in one direction and others in two directions. Contrary to the assumption in the comment, some large, round cakes are often cut in two directions. The fractional list provided by the manufacturer was also inconsistent in that it suggested that a square cake could not be divided into five pieces but listed 1/20, which is a multiple of 5, as "geometrically friendly" for a square or rectangular product.

For the reasons outlined above, FDA cannot directly adopt the list of fractions suggested by the comment. However, the agency agrees with the concept of friendly fractions and is responding to the spirit of the comment by adopting a two-part scheme for identifying them. The scheme involves

establishing a base set of fractions and describing a process for generating a continuing set of smaller divisions of the base set. For the base set, FDA has selected integer increases of fractions up to and including 6 (1/2, 1/3, 1/4, 1/5, and 1/6). The agency has not included 1/7, which both FDA and the comment recognize would be difficult to cut and which the comment did not include in either of it's suggested lists. This base set is consistent with the comment's list of fractions for round products but not for square and rectangular products, which excluded 1/5 as geometrically unfriendly. The agency acknowledges that dividing a product into five pieces is more difficult than other fractions in the base set. However, the difference between a serving size of 1/4 and 1/6 of a product is substantial and therefore could result in a serving size that is too large or too small. The comment also included 1/5 as a friendly fraction for round products. Thus, the agency has included a 1/5 fraction to provide a more reasonable serving size for products that contain between 450 and 550 percent of the reference amount.

The process for generating a continuous set of friendly fractions is based on creating further divisions of the base set. FDA and the comment both agree that it is easy to divide objects into two or three pieces. Therefore, the process selected for generating additional fractions involves dividing any of the base set or any newly created fractions by 2 or 3. Thus under this scheme, the set of friendly fractions includes 1/2, 1/3, 1/4, 1/5, 1/6, 1/8, 1/9, 1/10, 1/12, 1/16, 1/18, 1/20, 1/24, 1/32, 1/36, etc. The only fraction included in the comment list and not included here is 1/28 because it involves a division by 7 and that was not acceptable to the comment or FDA. Therefore, the agency excluded 1/28 from the friendly fractions.

To incorporate the friendly fractions in the regulations, FDA has revised § 101.9(b)(2)(ii) to read: "For products in large discrete units that are usually divided for consumption * * * the serving size shall be the fractional slice of the food * * * that most closely approximates the reference amount for the product category. In expressing the fractional slice, manufacturers shall use 1/2, 1/3, 1/4, 1/5, 1/6, or smaller fractions that can be generated by further division by 2 or 3."

F. Declaration of Serving Size on the Product Label

1. Label statement of serving size

FDA proposed in § 101.9(b)(7) that a label statement regarding a serving shall be the serving size expressed in common household measures followed by the equivalent metric quantity in parenthesis. In addition, FDA proposed that serving sizes may be declared in oz and fl oz (U.S. measure), in parenthesis, following the metric measure where other common household measures are used as the primary unit for serving size, e.g., 1 cup (28 g)(1 oz).

158. Over 100 comments addressed this issue. The majority supported the use of common household measures as the primary unit for the serving size. About one-third of the comments agreed that the equivalent metric quantity should be required, and that manufacturers should be allowed to voluntarily list the equivalent U.S. measure. Comments disagreeing with the proposal varied widely as to how serving sizes should be stated.

Several comments stated that the U.S. measure should be mandatory in addition to or instead of the metric measure. Others objected to voluntary declaration of the U.S. measure in addition to the common household measure, arguing that it was unnecessary, would crowd the label, and would be confusing to consumers. However, none of the comments presented any supporting data or evidence.

Several comments opposed the use of the metric measure arguing that U.S. consumers are not familiar with metric measurements, that a g is not commonly used in food preparation, and that declaration of the exact metric weight might mislead consumers by implying an accuracy that is often unachievable for food products. Some suggested making the metric measure optional. Other comments favored allowing only one of the three measures; some of these expressed no preference and others specifically supported one of the three. However, many comments from professional organizations and consumers supported listing the metric measure parenthetically. These comments noted that the world is progressively moving toward the metric system, and it is important for Americans to become familiar and feel comfortable with metric measurements. They stated that using metric measurements to declare serving sizes would educate consumers about the metric system.

The 1990 amendments require that serving size be expressed in a common household measure that is appropriate to the specific food. The Omnibus Trade and Competitiveness Act of 1988 (Pub. L. 100–418) declares that the metric system is the preferred measurement system for U.S. trade and commerce. Federal agencies are required to use the metric system in procurement, grants, and other business-related activities to the extent economically feasible by the end of fiscal year 1992. As discussed in the 1991 serving size proposal, FDA needs a precise quantity statement (e.g., metric measure), in addition to the common household measure, for compliance purposes because of the variability in the quantity of different brands in common household units. After carefully considering the statutory requirement, the Omnibus Trade and Competitiveness Act of 1988, the need for a compliance measure, and the arguments presented in the comments, FDA concludes that the most straightforward way to comply with the law, to fulfill the agency's regulatory needs, and to make the label most useful to consumers is to require the serving size to be declared in common household units followed by the equivalent metric quantity in parenthesis as proposed in the 1991 serving size proposal.

Given the conflicting views in comments on the use of the U.S. measure, the agency has decided to make the listing of the equivalent U.S. measure after the metric measure voluntary. Because of consumers' familiarity with U.S. measures, this declaration is likely to help consumers understand the serving size. However, because its use is voluntary, there is no reason to believe that it will create a crowding problem. Manufacturers will only include this information if they have ample label space. Accordingly, FDA is retaining in new § 101.9(b)(7) the requirement that the label serving size be expressed in common household measures, followed by the metric quantity in parentheses.

159. An industry comment stated that the parenthetical listing of the equivalent metric weight of the serving size is unnecessary on those single-serving containers for which the metric weight of the net quantity of contents is provided on the principal display panel. The comment requested that single-serving containers be exempted from this requirement. The comment contended that the parenthetical metric statement unnecessarily uses valuable label space for small single-serving containers.

FDA agrees that the parenthetical listing of the equivalent metric quantity is not necessary on the single-serving containers when the metric quantity of the net quantity of contents is provided on the principal display panel. However, for some products the metric quantity for the serving size and the metric quantity for the net quantity of

contents may differ. For example, the serving size for products packed or canned in liquid that is not customarily consumed (e.g., canned fish, pickles) must be expressed on a drained weight basis. In this case, the metric quantity on the principal display panel, which includes both the solids and the liquid, may differ from the parenthetical metric quantity for the serving size, which is based on the drained solids only. Thus, FDA has concluded that it is reasonable to exempt single-serving containers from the requirement for listing the parenthetical metric measure but only if the metric quantity for the net quantity of contents is the same as the metric quantity for the serving size. Accordingly, FDA has revised § 101.9(b)(7) to reflect this conclusion.

160. An industry comment stated that because individual products that belong to the same category, and thus have the same reference amount, vary in size and shape, the parenthetical metric measure equivalent to the serving size in household measure can vary from brand to brand. For example, g equivalents of 1/4 cup of nuts may vary from 30 g to 40 g. Thus, different metric equivalents can be declared by different brands for the same product. One brand may declare 30 g as the metric equivalent and present the nutrition information based on the 30 g serving, and another brand may declare 40 g as the metric equivalent and present the nutrition information based on the 40 g serving. The comment stated that this result is confusing and invites manipulation of the metric equivalent of the household measure. The comment recommended that FDA standardize the metric quantity of the reference amount for bulk products and have manufacturers declare an approximate household measure that is closest to that reference amount (e.g., about 1/4 cup (30 g)). Several other industry comments stated that there is no standard procedure for determining g equivalents of household measure, and that it is difficult to measure the g weight of a household measure accurately.

FDA recognizes that the parenthetical metric equivalents of the household measure of the same food may differ for different brands due to the differences in the products' size and shape. However, the agency notes that the 1990 amendments provided FDA with the authority to establish the standards to define serving sizes, not specific label serving sizes. Standardizing the parenthetical metric quantity on the reference amount is like using the reference amount (standard) as the label serving size. Therefore, FDA rejects this request.

However, the agency recognizes that the procedure for determining metric equivalents of household measures needs to be standardized, and that there is no well-established standard procedure used by industry or any other organization for doing so. To promote uniformity in label serving sizes in household measures of the same food declared by different manufacturers, the agency is providing Guidelines for Determining the Gram Weight of the Household Measure. The guidelines can be obtained from Division of Nutrition (HFF–260), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

161. An industry comment requested that FDA allow voluntary labeling of the number of pieces in addition to the serving size in oz for products such as chips and nuts.

FDA agrees that oz is an appropriate household measure for chips. The agency points out that new § 101.9(b)(5)(iii) requires an appropriate visual unit of measure when oz is used as the serving size. Therefore, manufacturers must provide a visual unit of measure, such as the number of chips or a fraction of the package (e.g., 1/4 package), that is equivalent to the oz amount declared.

FDA does not agree that oz is the common household measure most appropriate for nuts. The agency believes that cups is the appropriate household measure for most nuts because most nuts are small in size and can be measured with a cup. When cups are used to express the serving size for nuts, the parenthetical statement for the number of nuts is not required. However, the agency does not object to a manufacturer voluntarily providing an additional visual measure such as the number of nuts, which may help consumers better visualize the serving size. For some exceptionally large nuts that are hard to measure with a cup (e.g., unshelled walnuts), the agency believes the number of nuts would be the most appropriate household measure.

162. A trade association expressed concern that the use of several parentheses (e.g., 1 slice (28 g) (1 oz)) would make the serving size statement more difficult to understand. The comment recommended that FDA allow the flexibility to use commas and slashes.

FDA disagrees with the comment. Allowing such flexibility would result in nonuniformity in the declaration of label serving sizes by different manufacturers. For example, the serving size for sliced breads could be expressed in five different ways: 1 slice (28 g) (1 oz) by brand A; 1 slice (28 g, 1 oz) by brand B; 1 slice (28 g/1 oz) by brand C; 1 slice, 28 g, 1 oz by brand D; and 1 slice/28 g/1 oz by Brand E. The use of these various formats for this declaration would be confusing.

After examining all possible combinations of the formats, FDA finds that the most desirable format is to require the presentation of all serving size information other than the mandatory common household measure, in one set of parenthesis with the different serving size statements separated by slashes, i.e., 1 slice (28 g/1 oz). This format requires less space than most of the other formats and separates the household measure from the rest of the information. Therefore, FDA has modified § 101.9(b)(7) to require that all serving size information, other than the mandatory common household measure, be presented in one set of parenthesis with the different serving size information separated by slashes.

163. An industry comment stated that the label statement example given in proposed § 101.9(b)(7) is confusing because there is no indication of the product for which the example applies.

FDA has revised § 101.9(b)(7) to correct this oversight by adding a phrase indicating what product was used for the example.

164. Several comments recommended that FDA allow voluntary listing of nutrient contents per unit for products that come in discrete units (e.g., 1 slice of bread, 1 doughnut, 1 ice cream bar), when the declared serving size of a multiserving package is more than one unit. These comments stated that: (1) Per-unit nutrition information would aid nutrition professionals in providing dietary guidance to their clients, and (2) although two or more units are determined to be the label serving size according to the FDA regulation, these foods are clearly meant to be consumed one unit at a time. The comments said that per-unit nutrition information will thus help consumers to better understand the nutrient content of the food as consumed.

Because many products in discrete units come in small units, and people customarily consume more than one unit per eating occasion, reference amounts of these products are in multiunits (e.g., 2 small doughnuts). However, FDA recognizes that some individuals may consume only one unit at a time. In addition, the serving sizes contained in some dietary guidance or nutrition education documents (e.g., diabetic exchange list) are often expressed in terms of a single unit. In

an attempt to make the nutrition information on these products more useful to those consumers who consume only one unit at a time and to nutrition professionals who provide dietary guidance to their clients, the agency has revised § 101.9(b)(10) to allow voluntary labeling of a second column of nutrition information on a per unit basis. Finally, for individuals who consume multiple units that differ from the label serving size, the per-unit labeling would facilitate calculating the nutrient content for any multiple of a single unit.

However, products in discrete units vary greatly in size. Also, "mini" or "bite" size versions (e.g., "mini" cookies) are gaining popularity in the marketplace. FDA believes that per unit nutrition information on some of these products would be misleading. For example, a "bite" size version of a product could be labeled as containing zero fat or calories because of FDA's round-off rules for nutrient declaration, when in fact, enough units to constitute a serving contain significant amounts of fat and calories. The agency, therefore, considers that per unit labeling of "mini" or "bite" size products is misleading. FDA will consider regulatory action under section 403(a) of the act for any misuse of this allowance.

165. An industry comment recommended that the serving size declaration should conform to the rules for the net quantity of contents in § 101.105.

Most rules in § 101.105 do not apply to the serving size regulation. The applicable portion of the net quantity rule has been incorporated in the Guidelines for Determining the Gram Weight of the Household Measure mentioned in new § 101.9(b)(7).

2. Definition of household measures

FDA proposed in § 101.9(b)(5) to define "common household measure" or "common household unit" to mean cup, tbsp., tsp., piece, slice, fraction (e.g., 1/4 pizza), oz, or other common household equipment used to package food products (e.g., jar, tray).

166. One comment recommended that units other than those listed in proposed § 101.9(b)(5) be allowed to be used for a common household measure, e.g., 1 cake for single-serving cakes, 1 bar for frozen novelties, and 1 sandwich for sandwiches.

FDA advises that new § 101.9(b)(5)(ii) allows the use of 1 cake, 1 bar, 1 sandwich, and similar units for label serving sizes. These units are examples of "piece" measurements for specific products. FDA listed them as a generic term "piece" because it is not possible to name all common household measures appropriate for specific products in discrete units.

167. Because all beverages can be measured with a cup, the proposed definition for the household measure did not include fl oz. Some comments stated that it would be helpful to have fl oz measures for liquids. Although many consumer comments stated that they do not understand oz measures, they stated that fl oz is known and understood. The comments suggested that parts of the public want fl oz as a measure for expressing serving sizes.

FDA notes that fl oz is a common measure used to express the serving sizes of beverages. Therefore, on the basis of the comments, the agency concludes that it is appropriate to include fl oz in the definition of common household measures. Accordingly, FDA has revised § 101.9(b)(5) to include fl oz as a household measure. In addition, § 101.9(b)(5)(i) has been modified to allow beverages to express the primary household measure in fl oz.

3. Rules for declaring household measures

168. FDA proposed in § 101.9(b)(5)(i) through (b)(5)(iv) a set of rules that manufacturers should follow in expressing serving sizes in household measures. Most comments agreed with the proposed rules. One comment, however, stated that some foods would be more precisely measured in 1/3 cup increments rather than 1/4 cup increments and requested that this option be added to the final rule.

FDA proposed to require that cup measurements be declared in 1/4 cup increments to assure as much uniformity as possible in label serving sizes within a product category. Without such a rule, one manufacturer may choose to use 1/3 cup as the serving and another manufacturer may choose to use 1/4 cup for similar quantities of products. To prevent such inconsistencies in serving sizes, the agency proposed to require that cup measures be expressed in 1/4 cup increments. FDA has reexamined this aspect of the proposal. The agency agrees with the comment that some foods can be measured more precisely in 1/3 cup increments. In addition, FDA recognizes that contrary to the agency's intention, 1/4 cup increments may result in a larger discrepancy in label serving sizes of different brands or contribute to the manipulation of serving sizes when the label serving size is on the borderline between two sizes. One manufacturer may declare 1/4 cup and another manufacturer may declare 1/2 cup for similar quantities of a product. Therefore, FDA has concluded that adding 1/3 cup increments to the final rule is desirable. Accordingly, FDA has revised § 101.9(b)(5)(i) to read: "Cups, tablespoons, or teaspoons shall be used wherever possible and appropriate except for beverages. * * * Cups shall be expressed in 1/4 or 1/3 cup increments, * * *."

169. Because common household measures such as cups, tbsp., and pieces may not be appropriate for some foods, FDA proposed in § 101.9(b)(5)(iii) the use of oz as the common household unit for such foods. When oz is used as the common household measure for serving size, FDA proposed that the oz statement should be accompanied by an appropriate visual unit of measure such as a dimension of a piece (e.g., "about 1 inch slice" for unsliced bread). An industry comment objected to the proposed requirement for an appropriate visual unit of measure. The comment stated that oz is a unit of measure that is understood by the public, and that the parenthetical dimensional measurement will only confuse the consumers. The comment did not submit any data to support its claim.

FDA disagrees that oz is a unit of measure well understood by the public. Consumer comments on the 1990 proposal overwhelmingly opposed the oz measure for serving sizes. They stated that they did not understand the oz measurement very well, and that they did not have a scale to measure food. They preferred common household measures such as cups, tbsp., and pieces. Several consumer comments on the 1991 serving size proposal again stated that they did not understand oz measurement. Therefore, FDA rejects the industry comment. Based on the comments, the agency concludes that when the oz measurement is used as the primary unit for serving size, an appropriate visual unit of measure is needed to help consumers visualize the serving size. Accordingly, FDA has retained the requirement for an appropriate visual unit of measure. However, FDA has revised § 101.9(b)(5)(iii) to permit the use of a fraction as a visual unit if it is the appropriate unit.

170. FDA stated in § 101.9(b)(5)(iii) that when oz is used as the common household measure for serving size, the oz measurements must be expressed in 0.5-oz increments most closely approximating the reference amount, with rounding indicated by use of the term "about" (e.g., about 2.5 oz).

A manufacturer recommended that oz measures should be rounded to the nearest 0.1-oz increment. The

manufacturer stated that since an appropriate visual unit of measure is required, there is no need to round the oz measure to the nearest 0.5 oz. The comment contended that when consumers complained about fractional numbers, it is because they have no means of visualizing what quantity the weight represents. Therefore, as long as they have a visual description, consumers would not object to fractions. The comment further stated that under the proposal, products weighing from 22 to 35 g would all be listed as "about 1 oz." In addition, a product with an exact serving size of 64 g would declare "about 2.5 oz" whereas a product with an exact serving size of 63 g would declare "about 2 oz." The manufacturer stated that it would be a disservice to metric education in this country if people thought that a 1 g difference was a 1/2 oz difference. Because listing g quantities will be mandatory, the manufacturer felt that more exact oz measures need to be used, e.g., in increments of 0.1 oz.

FDA advises that the proposed § 101.9(b)(5)(iii) applies to the oz measure when it is used as the primary serving size. It does not apply to the parenthetical oz measure equivalent to the metric measure that is provided voluntarily by the manufacturer (see § 101.9(b)(7)). The nonuniformity in the oz measure described in the comment (i.e., about 2 oz for 63 g and about 2.5 oz for 64 g) would not occur when oz is used as the primary serving size because in determining the reference amounts, FDA made sure that the values would be in 0.5-oz increments. However, in expressing the reference amounts in g, FDA rounded the g quantity to the nearest 5 g for quantities. Therefore, some reference amounts will not convert to exactly 0.5-oz increments. For example, 30 g reference amount would be translated to about 1.1 oz. To prevent the use of odd decimals and unusually accurate fractional numbers for the primary serving size, the agency proposed to require in § 101.9(b)(5)(iii) that oz measures be expressed in 0.5-oz increments. When oz is used as the primary serving size, the main purpose is to be a reference for consumers. Comments from consumers have strongly objected to odd decimals and fractions (55 FR 29517 at 29524, July 19, 1990) (56 FR 60394 at 60411, November 27, 1991). Therefore, the agency concludes that the primary serving size should be expressed in 0.5-oz increments to be meaningful to consumers. Accordingly, FDA has retained the 0.5-oz incremental rule in § 101.9(b)(5)(iii) when oz is used as the primary serving size.

In the 1991 serving size proposal, FDA did not specifically address how to express voluntary parenthetical labeling of the oz measure that is equivalent to the primary household measure. The oz measure in this case can be any decimal quantity (e.g., 1.4 oz, 2.2 oz, 5.1 oz). These oz measures are not the primary serving size required. They represent the equivalent oz quantity that corresponds to the metric quantity declared. For example, the primary measure would be the household measure followed in parentheses by the g equivalent weight. At the manufacturer's discretion, the equivalent oz quantity could also be included. The primary measure is presented in household units or common fractions of household units (1/4 cup) that are familiar and meaningful to consumers. For secondary measures, it is important that the equivalent oz quantity be an accurate reflection of the primary household measure, and it is less important to round to even divisions since the primary measure is "consumer friendly." Therefore, FDA concludes that it is desirable to have a more accurate oz quantity and has modified § 101.9(b)(7) to provide that the oz quantity equivalent to the metric quantity should be expressed in 0.1 oz increments.

For the same reason, it is important that the g-weight equivalent be an accurate reflection of the primary household measure. In the 1991 serving size proposal, the agency did not provide specific guidelines for expressing the parenthetical g-weight equivalent of the household measure. Because the product categories in new § 101.12(b) have been expanded to include spices and herbs that have very small serving sizes (usually less than 1 g), the agency has concluded that it is particularly important to provide guidelines for expressing the g-weight equivalent of the household measure, so that the parenthetical g-weight equivalent would accurately reflect the primary household measure. The agency is providing the following guidelines for expressing the parenthetical g-weight equivalent: For a parenthetical g-weight of 5 g or more, the values should be expressed in the nearest whole number of g. For a parenthetical g-weight of 2 g or more but less than 5 g, the values should be expressed in 0.5-g increments. This incremental rule is consistent with the incremental rule in § 101.9(b)(8) for the number of servings per container for products that contain 2 or more servings but less than 5 servings per container. For a parenthetical g-weight of less than 2 g, the values should be expressed in 0.1-g increments. Accordingly, FDA ha revised § 101.9(b)(7) to read:

> A label statement regarding a serving shall be the serving size expressed in common household measure * * * followed by the equivalent metric quantity in parenthesis * * * The g quantity equivalent to the household measure should be rounded to the nearest whole number except for quantities that are less than 5 g. The g quantity between 2 and 5 g should be rounded to the nearest 0.5 g and the g quantity less than 2 g should be expressed in 0.1 g increments. In addition, serving size may be declared in oz and fl oz * * *.

171. A consumer organization recommended that FDA require manufacturers to round up the label serving size when the reference amount is 0.5 oz. For example, 0.5 oz should be rounded up to 1 oz, 1.5 oz up to 2 oz, and so forth.

FDA disagrees with the comment. Such rounding would introduce large errors in the label serving size, and the label serving sizes would not reflect the amount customarily consumed. For example, rounding 0.5 oz to 1 oz would introduce 100 percent error and rounding 1.5 oz to 2 oz would introduce 33 percent error. Accordingly, FDA has not adopted this recommendation.

172. A manufacturer recommended that the serving size for a single-serving container should be the net weight of the container, and that it should not be rounded to the nearest 0.5 oz. The comment pointed out that if this were not the case, the serving size of a single-serving container having a net weight of 7.2 oz will state 7 oz. The comment said that such a discrepancy would be confusing.

FDA points out that new § 101.9(b)(5) allows manufacturers to use oz as the serving size only if cups, tbsp., tsp., or units such as piece, slice, tray, jar, and fraction cannot be used. The household unit most appropriate for a single-serving container is the description of the container itself (e.g., tray, package, carton, or box), not oz. Therefore, the serving sizes of single-serving containers must be stated in tray, package, carton, or a similar unit appropriate for the specific container. Accordingly, the rounding rule in new § 101.9(b)(5)(iii) does not apply to the single-serving containers.

173. Some consumers requested that FDA standardize abbreviations used on the label.

FDA advises that new § 101.9(b)(7) standardizes abbreviations for units (e.g., g, mL) if a manufacturer elects to use abbreviations.

4. Labeling of "meal-type" products

FDA proposed in § 101.9(b)(3) that the serving size for "meal-type" products, as defined in § 101.13(l) of the nutrient content claims proposal, be the entire content of the package.

174. Several comments requested that the entire content of "meal-type" products that come in multiserving containers (e.g., lasagna, pizza) not be required to be labeled as one serving.

FDA agrees with the comment. Accordingly, the agency is revising § 101.9(b)(3) to exclude multiserving containers. The agency also notes that it has revised § 101.13(l) of the nutrient content claims regulation, published elsewhere in this issue of the **Federal Register**, by dividing these products into two categories, meal products and main dish products, and adopting new definitions for these products. For clarification, FDA advises that the serving size for a multiserving product that has a reference amount in new § 101.12(b) must be determined according to provisions in § 101.9(b), even if these products are classified as a "meal product" or a "main dish product" in new § 101.13(l) and (m). FDA also notes that for products that do not meet the definition of "meal product" or a "main dish product," claims will be evaluated according to the reference amount in new § 101.12(b) applicable to the product.

To reflect the reclassification and new definitions of "meal product" and "main dish product" in new § 101.13(l) and (m), and for clarity, FDA has revised § 101.9(b)(3) to read: "Serving size for meal products and main dish products as defined in § 101.13(l) and (m) of this chapter that come in single-serving containers as defined in paragraph (b)(6) of this section shall be the entire content (edible portion only) of the package. Serving size for meal products and main dish products in multiserving containers shall be based on the reference amount applicable to the product in § 101.12(b) if the product is listed in § 101.12(b). Serving size for meal products and main dish products in multiserving containers that are not listed in § 101.12(b) shall be based on the reference amount according to § 101.12(f)."

175. One comment requested that FDA require dual declaration, per serving and per 100 g, on "meal-type" products to facilitate nutrition comparisons of these products on an equal basis and to ensure "a level playing field."

FDA disagrees with the comment. The agency recognizes, that because many of these products are used interchangeably in the diet, consumers may want to compare nutritional values of these products. "Meal-type" products (reclassified and redefined as "meal product" and "main dish product" in new § 101.13(l) and (m)) encompass a wide variety of products which vary in product characteristics. Therefore, these products differ greatly in amounts customarily consumed. The agency believes that nutrition information per serving derived from the reference amount applicable to each type of these products facilitates nutrition comparisons of these products on an equal basis in terms of the amount used in the diet. In addition, the 1990 amendments do not provide the authority to require nutrition information per 100 g or 100 mL basis. Accordingly, FDA has not adopted the recommended modification. (However, the agency notes that under new § 101.13(l) and (m), the eligibility of such products to bear nutrient claims will be determined on a per 100 g basis.)

176. Several industry comments suggested that frozen entrees packaged in separate pouches that contain more than one distinct food per package (e.g., rice or pasta with sauce or toppings) should be classified as "meal-type" products rather than mixed dishes.

For the purpose of determining the label serving size, the agency considers these "pouch-type" frozen entrees to be "mixed dishes" rather than "meal-type" products. The components of these frozen entrees are packaged separately for technical reasons, such as differences in required cooking times for the different components and better preservation of the texture and flavor during storage. However, the components from all pouches in a package are consumed as one product like other products in the mixed dishes categories. The only difference between the "pouch-type" products and other mixed dishes is that different components of the "pouch-type" products are packaged in separate pouches within the container, while all components of the other type of mixed dishes are packaged in one container. There is no difference in the characteristics, usage, or the manner of consumption between these two types of products.

However, if a "pouch-type" product meets the definition of "meal product" or "main dish product" in new § 101.13(l) and (m) of the final regulation on nutrient content claims, it will be classified as such for the evaluation of whether the product qualifies to bear a nutrient content claim. If a "pouch-type" product does not meet the definition of "meal product" or "main dish product," its qualification for claims will be based on the reference amount of the specific product.

5. Labeling of variety packs

FDA proposed to require in § 101.9(b)(4) that a variety pack, such as a package containing several varieties of single-serving packages or a product having two or more compartments with each compartment containing a different food, provide nutrition information for each variety or food per serving size that is derived from the reference amount applicable to each variety or food.

177. One comment requested that FDA revise the proposed rule on the labeling of variety packs to state that nutrition labeling should be based on the individual serving actually in each inner container rather than serving size derived from the reference amount.

FDA advises that as long as each inner package meets the requirements for the single-serving unit as defined in § 101.9(b)(2)(i), the content of each inner package is one serving. Thus, the nutrition information would be based on the content in each inner package. Many variety packs contain different products that differ in reference amounts. Therefore, to determine whether each inner package qualifies for the single-serving unit, manufacturers must use the reference amount applicable to each product. Accordingly, FDA has not adopted the comment's request. However, for clarity, FDA has revised § 101.9(b)(4) to read: "A variety pack such as a package containing several varieties of single-serving units as defined in paragraph (b)(2)(i) of this section * * * shall provide nutrition information for each variety or food per serving size that is derived from the reference amount in § 101.12(b) applicable for each variety or food and the procedures to convert the reference amount to serving size in paragraph (b)(2) of this section."

6. Labeling of foods for special dietary use

In the preamble to the 1991 serving size proposal (56 FR 60394 at 60408), FDA tentatively concluded that the serving size requirements that applied to foods intended for weight control or weight reduction, available in the marketplace, should also apply to the products sold only to enrollees of a weight control program. The agency also stated that it would not object if products available only as part of a weight-control program provided dual columns of nutrition information based on the reference amount and the serving size prescribed by the program.

178. A consumer organization supported the proposal but recommended that FDA require both the nutrition information and the product's qualification for claims to be based on the reference amount. Industry comments objected to the proposed requirement. A manufacturer of weight-control products requested that FDA allow manufacturers of portion controlled or other products that are part of a weight-control or weight-maintenance plan to base serving sizes on amounts specified under such plans and not necessarily on serving sizes derived from reference amounts in new § 101.12(b). Comments from the providers of weight-control programs requested that FDA allow them to determine serving sizes that are consistent with the meal plans for products that are available only through the weight-control program. The comments asserted that if portion controlled products are required to use the same serving size as for the regular counterpart, it could lead to overconsumption of these foods and defeat the purpose of the program. The comments claimed that the dual labeling proposed by FDA could be confusing. A nutrition professional organization also stated that dual columns of nutrition information on these products may be confusing.

FDA has given careful consideration to all arguments presented in the comments on this issue. To ensure that the labeling is not misleading, the serving sizes for all foods available in the marketplace to the general public, including those intended for weight-control or weight-reductions, must be based on the reference amount in new § 101.12(b). However, the agency also finds that for weight-control products that are available only as part of a weight-control program, the use of a serving size that differs from the serving size for the meal plan may be confusing to the enrollees and may undermine the purpose of the program. Therefore, the agency concludes that, for products that are available only through the weight-control program and are not available at a general retail store, it is in the best interest of the enrollees of the weight-control program to have labeling that is consistent with the meal plan of the program in order to avoid any potential confusion about the serving size. FDA has revised § 101.9(b)(2) to exempt products that are both intended for weight-control and available only through weight-control or weight-maintenance programs. To avoid any confusion with the general retail products, manufacturers are required to label their products as "for sale only through the ———— program" (fill in the blank with the name of the appropriate weight-control program, e.g., Smith's Weight Control), on the principal display panel. If these products are also available at the retail market, the serving size derived from the reference amount must be used. FDA advises that qualification of these products for nutrient content or health claims will be based on the reference amount, not the serving size determined by the provider of the weight-control program.

In addition, FDA advises that the label statements regarding the usefulness of these products in reducing or maintaining body weight are subject to the provisions in new § 105.66 of the nutrient content claims regulation published elsewhere is this issue of the **Federal Register.**

G. Declaration of Number of Servings Per Container

FDA proposed in § 101.9(b)(8) that a manufacturer, in declaring the number of servings per container, may use either of the two options listed in that section, choosing the one most meaningful for a specific product. The options proposed were: (1) Declare serving size as the approximate whole household measure that results in a whole number of servings in the container (e.g., serving size: approximately 1/2 cup; number of servings per container: 10) or (2) declare the serving size in the exact household measure and the approximate number of servings per container (e.g., serving size: 1/2 cup; number of servings per container: approximately 10). In either case, FDA proposed to require that whole numbers of servings be used with the exception of random weight products. For random weight products, FDA proposed to use "varied" for the number of servings per container provided the nutrition information is based on the reference amount expressed in oz.

179. Most comments supported the proposed requirements for the declaration of the number of servings per container. However, several comments objected to rounding the number of servings to the nearest whole number. The comments argued that rounding to the nearest whole number does not accurately account for the actual number of servings in a container and in many cases would significantly distort a container's contents, especially for packages containing between 1.5 to 4.5 servings. Some of the comments acknowledged that many consumers do not like fractional numbers of servings on the label but argued that this dislike results primarily from the use of odd decimal fractions (e.g., 2.7 servings) and from fractional numbers of servings on packages typically consumed in their entirety (e.g., 1.5 servings on a 12 fl oz can of soda). The comments stated that rounding to the nearest 0.5 servings would be understood by virtually all consumers. A few comments suggested that at the very best, FDA should permit rounding to the nearest half-serving for packages containing 4.5 servings or fewer.

FDA acknowledges that consumer objections to the fractional number of servings may be the result of the use of odd fractional numbers of servings and of their use on products typically consumed in their entirety. The agency agrees that, for packages containing 4.5 servings or less, the number of servings in 0.5-increments would reflect more closely the number of servings in the container. For larger containers, the 0.5 serving difference between the next lower or next higher whole number is a smaller relative percentage of the total number of servings in the package and, therefore, reflects an unrealistic and meaningless precision (e.g., 8.5 servings or 28.5 servings) because the number of servings are approximations. For this reason, FDA has revised § 101.9(b)(8) to allow fractional servings on packages containing between 2 and 5 servings. This procedure would reduce the errors in the number of servings per container to a maximum of about 12 percent (2.24 servings rounded to 2 servings) or less.

179a. Several comments addressed the two options proposed in § 101.9(b)(8) for declaring the number of servings per container. A comment from a trade association stated that the two options would provide manufacturers flexibility in deciding the number of servings per container appropriate to their food products and providing the consumer with the most useful serving size information. Other comments from industry, consumers, and consumer organizations expressed concern about providing an option. They stated that allowing the two options would result in different serving sizes (and thus different nutrition information) for different brands of the same food, making nutrition comparisons of different brands difficult. One consumer organization contended that it is more important for consumers, especially those on medically-prescribed diets, to know the exact serving size that is the basis for the nutrition information than the exact number of servings. These latter comments recommended that FDA require manufacturers to list the exact serving size and an approximate number of servings per container.

Although the two options would provide flexibility to manufacturers, FDA recognizes that it would result in nonuniformity in serving sizes of different brands of the same food. The agency also agrees with the latter comments that it is more important to have the exact serving size than the exact number of servings. Many comments on the 1991 serving size proposal stated that the serving size regulation should facilitate nutrition comparisons of different brands. Therefore, FDA has revised § 101.9(b)(8) to require the exact serving size and the approximate number of servings.

180. Most comments approved of permitting the "varied" declaration for the number of servings on random weight products. However, one comment from a consumer organization expressed concern. The comment argued that the "varied" declaration is unnecessary because random weight products, such as cheese, are usually priced per pound, and the retailer or manufacturer must weigh a package of cheese to determine the price. The comment contended that once the weight has been measured, the servings per container can be easily calculated.

FDA agrees that random weight products are usually priced by weight, and that the retailer or manufacturer must weigh the product first to price it. However, because these products vary widely in weight, it would be difficult for retailers and manufacturers to have labels printed with the number of servings per container unless they have automated label machines that print the number of servings as they print the weight. Therefore, it would be unreasonable to require all retailers and manufacturers to include the number of servings on random weight products. Accordingly, FDA is retaining the "varied" declaration for the number of servings on random weight products. However, the agency encourages the retailers and manufacturers to label the number of servings per container if they have automated machines or some means to provide the information.

181. A few comments suggested that FDA permit an optional declaration of "typical number of servings" with the term "varied" on random weight packages. The comments contended that an approximate number of servings per container could help consumers determine the approximate number of servings contained in the package.

FDA agrees with the comment. Accordingly, FDA has revised § 101.9(b)(8) to allow voluntary labeling of the "typical number of servings" when "varied" is used to declare the number of servings per container, e.g., "varied (usually 5 servings)" or "varied (usually 4 to 6 servings)." The agency encourages manufacturers to provide the typical number of servings whenever feasible.

182. Several comments from the pickle industry stated that the size and shape of the vegetables used to make pickles vary widely as a result of numerous factors, including the variety, weather conditions, and maturation when harvested. The comment contended that pickles are random weight products and should be allowed to use "varied" for the number of servings per container.

FDA disagrees with the comments. Products that contain individual units in the container that vary in size, such as pickles, are not random weight products because the net quantity of the container size remains constant. Random weight products are those products that are sold in units whose net quantity of contents is random, e.g., cheese. In the case of random weight cheese, the number of servings is difficult to estimate because the net quantity of content vary widely from package to package of the same product. Because the container size of pickles (and thus the net quantity of contents) is constant, pickle manufacturers, unlike cheese manufacturers, can have a label printed for each size of the container. Therefore, FDA is not allowing a "varied" declaration on pickles.

However, because the serving size for pickles will be based on the drained solids, the net quantity of the drained solids in the same size container may vary somewhat because of the variation in the size and shape of pickles. Consequently, the number of servings per container may vary somewhat for different containers of the same size. Therefore, FDA has revised § 101.9(b)(8) to allow declaration of the typical number of servings per container (e.g., usually 5 servings) for canned products that naturally vary in unit size, and the serving size is required to be expressed on the drained solids basis (e.g., pickles).

183. A few comments from the produce industry requested that FDA clarify in the serving size regulation that raw fruits and vegetables are exempt from declaring the number of servings per container.

FDA advises that raw fruit, vegetables, and fish are exempt from mandatory nutrition labeling requirements under new § 101.9(j)(10) (see document entitled "Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision" published elsewhere in this issue of the **Federal Register**). These foods are subject to the guidelines of the voluntary nutrition labeling program in § 101.45. Section 101.45(b)(3) states that the number of servings per container need not be included in nutrition labeling of raw fruit, vegetables, and fish. Accordingly, there is no need to cover this exemption in new § 101.9(b).

184. A manufacturer requested that FDA confirm in a preamble statement to the final rule that the product of the number of servings multiplied by the parenthetical metric equivalent of the serving size is not expected to precisely equal the net quantity of the product declared on the principal display panel.

FDA concurs with the comment's statement. It is true for two reasons: (1) An oz is defined differently for the net quantity of content regulation than for the serving size regulation, and (2) the number of servings are usually an approximate number. One oz is defined as 28.3452 g for the determination of the net quantity of contents (Ref. 39) and 28 g for the purpose of labeling serving size.

H. Other Related Issues

1. "As packaged" versus "as consumed" as the basis for the nutrition information

In § 101.9(b)(9) of the 1991 serving size proposal, FDA proposed that the declaration of nutrient content information shall be on the basis of food as packaged or purchased with the exception of those products that were specifically excluded. Additionally, FDA encouraged manufacturers to voluntarily provide the nutrient content of their products on an as consumed basis using package directions for preparation (56 FR 60394 at 60413).

185. Several comments supported the proposed rule. A health professional organization strongly opposed nutrition labeling on an as prepared (i.e., as consumed) basis because nutrition information should reflect the content of food in the package that consumers are selecting and purchasing. A consumer comment stated that all nutrition information should be based on food as packaged. Anything beyond that becomes the consumer's responsibility.

Many other comments objected to the proposal for basing the nutrition information of the products that require further preparation before consumption (e.g., dry mixes) on an as packaged basis. The comments requested that FDA require that nutrition information on these products be provided on an as consumed basis. The comments contended that because these products cannot be eaten in the form packaged and often require adding additional

ingredients, nutrition information on an as packaged basis is not meaningful to consumers. Some comments argued that nutrition information on an as packaged basis does not allow consumers to make informed comparisons between similar products in different forms (prepared and dry) and provides no incentive for manufacturers to develop preparation directions in support of current dietary recommendations. A manufacturer argued that the nutrition information on an as packaged basis for products that require the addition of other ingredients often underestimates the nutritional contribution of the product in the total daily diet because it does not include the nutrient contribution of other ingredients added in the preparation for consumption. The comment contended that in these cases, as packaged information violates the 1990 amendments that require the nutrition information to be conveyed in a manner which enables the public to understand its relative significance in the context of a total daily diet.

Some comments from the popcorn industry objected to nutrition labeling on an as packaged basis because: (1) Popcorn is inedible as packaged, and (2) some of the fat that is added to microwave popcorn to facilitate popping sticks to the bag after popping and is therefore not consumed. Nutrition labeling on an "as packaged" basis would, therefore, overstate the fat content as consumed.

Several comments also asserted that the qualification of a product for nutrient content claims should be based on the product "as prepared." Comments stated that nutrient content claims based on the product as packaged could be misleading on those products that, when prepared according to package directions, would not meet the criteria for the claim on an "as prepared" basis.

Other comments suggested that products that require the addition of ingredients, such as dry cake mixes, should list nutrition information on both an "as packaged" and an "as prepared" basis. The comments contended that if they did not, labels that list the fat and sodium contents as "0" (zero) would lead consumers to believe that these products are fat free or sodium free when eaten, even though fat and salt must be added according to the preparation directions.

FDA does not agree with the comments that suggested that FDA should require nutrition information on an "as prepared" basis. The agency has found that it cannot regulate products as effectively on an "as prepared" basis. For example, many products that require further preparation before consumption require the addition of ingredients. The nutrient content of a particular ingredient may vary from brand to brand (e.g., different brands of butter may vary in sodium content; different brands of fats and oils may vary in saturated fatty acid content). In addition, manufacturers often provide multiple directions for preparation (e.g., using different types of fats, several directions for preparing different foods such as pancakes, waffles, and biscuits). There may be no obvious or rational basis for the agency to determine which set of directions should be used to check the accuracy of the nutrition information. Furthermore, a product may be used by consumers in many different ways, and the agency has no control over how a product is used after purchase.

However, FDA recognizes that it would be helpful to make comparisons of foods in their prepared state (e.g., prepared package salad dressing and bottled salad dressing). Therefore, for the benefit of the consumers who follow the package directions in preparing these products, the agency continues to encourage manufacturers to voluntarily provide nutrient information on their products on an as prepared basis, using the package directions in preparing the food, and, in the case of multiple directions, using the directions that represent the major usage of the product. The agency agrees that such voluntary information may provide an incentive for manufacturers to develop methods of preparation that support dietary recommendations.

The agency disagrees with the comment that "as packaged" nutrition information violates the 1990 amendments because the "as packaged" information underestimates the nutritional contribution of the product to the total daily diet. Section 403(q)(1) of the act states that nutrition information is to be provided on "a food intended for human consumption and is offered *for sale* * * *" (emphasis added). Thus, the manufacturer has the responsibility to provide nutrition information on the product as offered for sale. Once the product is purchased and other ingredients are added, the packaged product becomes a different product. Therefore, the contribution of a product to a total daily diet must be evaluated in terms of the nutrient content of the product in the package as sold.

With regard to the comments about the nutrition labeling of unpopped popcorn, the agency notes that popcorn is no different than other foods that require further preparation before consumption (e.g., cake mixes, pancake mixes) and that are required to provide nutrition information on an as packaged basis. Therefore, no special provision is needed for unpopped popcorn. The agency notes, however, that § 101.9(b)(10)(iii) permits a second column on nutrition information on popcorn products in multiserving containers on a per cup popped basis.

As for the fat in microwave popcorn, the agency notes that the amount of fat that is retained with the popcorn may vary depending on the popping conditions and equipment used. Therefore, the agency cannot monitor compliance on an as consumed basis.

In regard to comments that nutrient content claims should be based on the product "as prepared," FDA notes that it did not address this issue in either the 1991 serving size proposal or the proposal entitled "Nutrient Content Claims, General Principles, Petitions, Definition of Terms" (56 FR 60421, November 27, 1991). The agency does not believe that the 1990 amendments contemplated regulation of claims on products as prepared by the consumer. Section 403(r) of the act focuses on claims for nutrients in the food that is offered for sale. Moreover, regulation on an "as prepared" basis would raise significant compliance problems. However, the agency does agree that a nutrient content claim could be misleading if directions for use of the packaged product specify the addition of ingredients that would result in the finished edible product no longer meeting the criteria for the claim. If FDA finds that a problem exists in the marketplace after implementation of these final rules, the agency will consider further rulemaking under section 403(a) of the act.

Likewise, FDA did not propose to require that a product that requires the addition of ingredients declare nutrition information on both an as purchased and an as prepared basis, and, as discussed previously, the agency does not believe that it is appropriate to do so.

186. Some comments stated that for products where water must be added before the product can be consumed (e.g., dry soup or noodle mixes), the nutrition information should be based on the rehydrated product.

FDA advises that water contains some minerals. In its final rule on the declaration of sodium content in nutrition labeling, the agency reviewed and discussed data on the sodium content of the U.S. water supplies (49 FR 15510 at 15524). The data showed that sodium ranged from less than 3 mg to approximately 52 mg per 6 fl oz.

However, to prevent the introduction of error in the analysis of a product for compliance purposes, the agency is denying this request.

187. A health professional organization recommended that for products where choice in the preparation method can markedly alter its nutritional content, nutrition information on the product as prepared should be provided through educational point of purchase materials or in places on the package other than the nutrition label.

FDA has no objections to the placement of nutrition information other than that required in the nutrition label on other places on the label or in labeling (such as point of purchase materials). However, the agency has no authority to require such information. Accordingly, no action is being taken on this comment.

2. Nutrition information on a drained solids basis

Food consumption data showed that the liquid in foods such as canned fish, canned maraschino cherries, pickled fruits, olives, and canned or pickled vegetables is not customarily consumed. Therefore, FDA proposed in § 101.9(b)(9) to require that the declaration of nutrient and food component content of such foods be based on the drained solids.

188. Comments from a food manufacturer and a trade association opposed the proposal for basing nutrition information on a drained solids basis for beans, potatoes, and vegetables canned in liquid. The comments contended that upon cooking starch and other nutrients are released into the packing medium. The comments argued that because the entire contents of the container is frequently consumed, information on a drained weight basis would be misleading. One comment submitted data from a marketing survey showing that a large percentage of people use the liquid.

FDA agrees with the comment that the marketing survey showed that a large percentage of people use the liquid and that the liquid also contains nutrients (Ref. 64). Accordingly, the agency has deleted canned beans, potatoes, and vegetables from the list of foods in new § 101.9(b)(9) that are exempted from the requirement for nutrition information on an "as packaged" basis and has modified footnote 6 for Table 2 in new § 101.12(b) to reflect this change. Canned beans, potatoes, and vegetables will, therefore, be required to provide nutrition information on an "as packaged" basis.

189. An industry comment stated that the liquid that is present in "Alaska" canned salmon is the natural juice that has cooked out of the fish during thermal processing, and no additional liquid is added to "Alaska" canned salmon. The comment, therefore, asserted that nutrition information for canned salmon should be on an "as packaged" basis.

FDA agrees with the comment that nutrition information on canned salmon to which liquid has not been added for canning should be based on an as packaged basis. Accordingly, the agency has revised the footnote to Table 2 in new § 101.12(b) so that canned salmon that is not in a liquid packing medium is required to be labeled on an "as packaged" basis. Canned salmon that is in a liquid packing medium is subject to being labeled on a drained weight basis. The revised footnote reads: "If packed or canned in liquid * * *."

3. Miscellaneous issues

190. A manufacturer requested that FDA install a toll-free telephone number regarding questions on the reference amounts.

FDA advises that budgetary constraints do not allow for the installation of a toll-free telephone number to assist manufacturers in any aspect of the implementation of these final rules. However, agency personnel will respond to the maximum extent possible to all written or telephone requests for assistance. In addition, the agency intends to prepare materials to assist manufacturers in implementing these regulations as well as the educational materials to assist consumers in understanding and using the new nutrition labels.

I. Listing of a Second Column of Values

1. Listing nutrient contents based on 100 g, 100 mL, 1 oz, or 1 fl oz

FDA proposed in § 101.9(b)(10) that another column of figures may be used to declare the nutrient and food component information on the basis of 100 g or 100 mL or of 1 oz or 1 fl oz of the food as packaged or purchased.

191. Most comments on this issue supported voluntary labeling of a second column of values on a uniform basis. These comments reasoned that the second column of values provides nutrition information on a uniform basis, which aids consumers in making nutrition comparisons of different products. Some comments that supported voluntary labeling of a second column of values stated that FDA should not provide two choices for the basis of the second column. Comments that addressed the choice for the basis of the second column preferred 100 g or 100 mL over 1 oz or 1 fl oz. These comments stated that nutrition information per 100 g (or mL): (1) May be useful for persons on a special diet for medical reasons, (2) may assist consumers in understanding the metric system, or (3) is the only presentation of nutrition information internationally understood. One international comment stated that nutrition information per 100 g should be mandatory, and the information per serving should be voluntary. Another international comment stated that nutrition information per 100 g or 100 mL should be allowed on European products. A domestic comment stated that the second column of values per 100 g or 100 mL should be mandatory.

Comments objecting to the use of a second column stated that: (1) The second column of values would be confusing to consumers or is too much information, thus contributing to label clutter, (2) consumers may not understand why this information is on the label or understand how this quantity differs from a typical serving size, (3) consumers may have little need to compare 100 g of mustard with 100 g of a 12 oz frozen dinner, or (4) it is not necessary to add a second column on a per 100 g or 100 mL basis for the reason of international harmonization because every country has its own unique label requirements. Comments argued that because of these vastly different requirements, it is virtually impossible to use U.S. labels internationally.

FDA has given careful consideration to all arguments for and against the second column of values presented in the comments. To facilitate comparison of the nutritional composition of different products, the agency agrees that it would be desirable to have a uniform basis for the second column. However, for consistency with USDA's regulation, the agency has decided to retain the two choices for the basis of the second column as proposed.

FDA disagrees with the comment that stated that the second column of values per 100 g or 100 mL should be mandatory. The 1990 amendments do not mandate such a requirement. Further, nutrition information per 100 g or 100 mL is not meaningful for many foods that are customarily consumed in small quantities (e.g., croutons, crackers, cream and cream substitutes, sugar, butter, margarine, oil, and condiments) and dry mixes (e.g., dry beverage mixes). Therefore, the agency has not adopted this recommendation.

FDA is not persuaded that the declaration of nutrition information in a second column on a per 100 g or 100 mL basis should be prohibited. The provision is voluntary; therefore, manufacturers who do not wish to present the second column of values are not required to provide it. However, the presence of the information could help to facilitate comparisons between types of foods. While one comment stated that there is little need to compare 100 g of foods which would not be used interchangeably (e.g., mustard and frozen dinner), FDA notes that facilitation of nutrition comparisons is intended for different products which are used interchangeably in the diet.

Considering the weight of the comments supporting the second column of values on a uniform basis, FDA believes that voluntary labeling of a second column of values is desirable. This information will enable those who desire the information to benefit from it. Additionally, in response to comments that said a second column would be confusing, FDA intends to follow publication of these final rules with consumer education activities about the new food labeling requirements. This education initiative will assist consumers in understanding the utility of a second column of values based on 100 g, 100 mL, 1 oz, or 1 fl oz and should minimize consumer confusion.

Therefore, FDA has retained § 101.9(b)(10) as proposed and redesignated as § 101.9(b)(10)(i).

2. Mandatory listing of nutrient contents for a use that differs in quantity by two-fold or greater from the use upon which the reference amount was based

FDA proposed in § 101.9(b)(11) that if a product is promoted on the label, labeling, or advertising for a use that differs in quantity by twofold or greater from the use upon which the reference amount was based (e.g., liquid cream substitutes promoted for use with breakfast cereals), the manufacturer must provide a second column of nutrition information based on the amount customarily consumed for the promoted use in addition to the nutrition information per serving derived from the reference amount in § 101.12(b).

192. Two comments from consumer and nutrition professional organizations supported the proposal. One of the comments recommended that FDA also require dual columns of values on foods "that are consumed in two quantities that differ by two-fold or greater, as long as the alternative use occurs at least 25 percent of the time." To illustrate the point, the comment cited the use of liquid cream substitutes in coffee versus on cereal or fruit. On the other hand, a comment from a trade association argued that this approach is not required under the act and could severely hamper traditional marketing techniques and reduce the flow of helpful information to consumers. They further stated that such a requirement is simply unworkable, particularly for nondiscrete bulk products packaged in multiserving containers (e.g., flour, sugar, multipurpose baking mixes). Many manufacturers make recipes available to the consumer through labeling (e.g., recipe booklets) and advertising. Many of these recipes are for the use of modified substitutes in regular recipes, such as lower fat alternatives. Manufacturers may also promote multiple uses of their products, some of which may suggest the use of the quantity of the product by twofold or greater than the reference amount. In such circumstances, the manufacturer could not possibly label the amount customarily consumed for every promoted use. Under such a rule, manufacturers will be less likely to promote several types of legitimate uses for their products. The comment stated that FDA should not discourage the dissemination of information that consumers find useful and informative.

FDA disagrees that in addition to requiring dual columns for promoted uses, FDA should also require dual columns for alternative uses that occur at least 25 percent of the time. Many foods are used for more than one purpose, and it is not always possible for manufacturers to determine which uses constitute 25 percent or more of the total usage of the food and to continually monitor trends in usage with this kind of precision. Consequently, FDA is not requiring dual columns based on percentage of use of the food.

However, FDA does find that this situation must be addressed. Section 403(q) of the act defines a serving size to be an amount customarily consumed. In some cases, such as the example given in proposed § 101.9(b)(11) of cream substitutes, the reference amount for the product category in § 101.12(b) clearly does not represent the customarily consumed amount for the product's promoted use on breakfast cereal. Thus, a separate customarily consumed amount is needed for the promoted use according to the definition of the serving size under the act. In addition, the agency notes that under 403(a) of the act, the nutrition information based on the reference amount (1 tbsp.) for the liquid cream substitute example is misleading for its promoted use with breakfast cereals (1/2 cup). Therefore, FDA believes that it has legal authority under section 403(a) and (q) of the act to require dual columns of values based on the customarily consumed amount for each use.

Finally, FDA agrees with the comment that stated that it is unreasonable to require multiple columns of values for some nondiscrete bulk products that are used primarily as ingredients (e.g., flour, sweeteners, shortenings, oils), traditionally used for multipurposes (e.g., eggs, butter, margarine), and multipurpose baking mixes (e.g., mixes with multiple recipes) because the products are promoted generically and are listed in hundreds of recipes and requiring hundreds of columns would be impractical and impossible.

Accordingly, in regard to dual columns, in new § 101.9(b)(11), FDA has retained the requirement for dual labeling for products that are promoted for a use that differs by twofold or greater from the use upon which the reference amount is based. However, the agency has added a statement that specifically exempts certain foods from this requirement for dual labeling: nondiscrete bulk products used primarily as ingredients (e.g., flour, sweeteners, shortenings, oils) or traditionally used for multipurposes (e.g., eggs, butter, margarine), and multipurpose baking mixes.

193. A trade association objected to the use of advertising to determine whether a second column of nutrition information is required under § 101.9(b)(11).

The agency advises that it views advertising as evidence of how the manufacturer intends the product to be used. If, as discussed in the preceding comment, this use is significantly different than the use on which the reference amount is based, the provisions of new § 101.9(b)(11) are triggered. Accordingly, FDA is not making the suggested change.

J. Use of Serving Size to Evaluate Nutrient Content and Health Claims

FDA proposed in § 101.12(g) to require that the reference amount be used in determining whether a product meets the criteria for nutrient content claims, such as "low calorie," and for health claims. However, the agency noted that label serving sizes often differ from the reference amounts. Thus, products that meet the criteria for a claim on a reference amount basis may not qualify on a serving size basis. For example, a soft drink that contains 30 mg of sodium per reference amount (240

mL) meets the criteria for a "very low sodium" claim (less than or equal to 35 mg per 8 fl oz (240 mL)). A 12-fl oz single-serving container of this soft drink, however, contains 50 mg of sodium and, therefore, would not qualify for the "very low sodium" claim. For these products, FDA proposed that both the reference amount and the label serving size be used to determine whether the product meets FDA criteria for a claim. The agency also discussed another option based solely on the reference amount plus a disclaimer and solicited comments on both options.

194. Many comments supported the proposal to base claims on both the reference amount and the label serving size. However, numerous comments from the food industry, nutrition professionals, Government, and consumers contended that claim evaluations for all products should be based solely on the reference amount. The comments argued that claims should reflect the true characteristics of the product, and that a product that qualifies for a claim should be able to bear the claim on all container sizes. According to these comments, using both the reference amount and the label serving size as criteria will result in a product that would be able to bear a claim for one container size but would not be able to bear the same claim for another. The comment stated that such inconsistency in the use of claims for the same product in different-sized containers would be confusing to consumers and should not be permitted. Some of these comments suggested that FDA's concern about the misleading claims could be alleviated by requiring a statement of the basis for the claim along with the claim on a product that meets the criteria only on the basis of the reference amount, e.g., "very low sodium, 35 mg or less per 8 fl oz."

As discussed in the 1991 serving size proposal (56 FR 60394 at 60412), there are advantages and disadvantages to both options. After careful consideration of the comments received and of the advantages and disadvantages of both options, FDA concludes that the most reasonable solution for this issue is to base claim evaluations on the reference amount and to require a disclaimer with the claim. FDA agrees with the comments that claims should reflect the true characteristics of a product, and those characteristics do not change if the product is packaged in a different size container. Thus, it is appropriate to use the standard established by FDA, the reference amount, as the basis for evaluating claims. However, FDA also recognizes that products packaged in containers that differ from the reference amount may contain an amount of the nutrient significantly different from the amount on which the claim is based (e.g., 50 mg of sodium in a 12-fl oz container that can claim "very low sodium" since it contains only 35 mg sodium per 8 fl oz). In order to not be misleading, FDA agrees with the comments suggesting that a disclaimer that includes a statement of the basis for the claim is appropriate on such products. The agency recognizes that consumers may not readily understand the significance of the disclaimer (i.e., that it is alerting them to the fact that the product does not meet the criteria for the claim on the basis of the label serving size). The agency intends to inform consumers about the meaning of various claims on product labels through nutrition education activities that will follow the publication of the final regulations for food labeling. Accordingly, FDA has revised § 101.12(g) to base the qualification for a claim on the reference amount and to require a disclaimer if the label serving size of a product differs from the reference amount, and the product does not qualify for the claim on the basis of the label serving size.

In presenting the disclaimer, manufacturers must state the reference amount as it appears in new § 101.12(b). The reference amount in metric measure should be followed, in parenthesis, by the equivalent household measure appropriate for the food. Many consumers have complained that they do not understand metric measures. The parenthetical household measure should help consumers to visualize the quantity on which the claim is based. For example, a 12-fl oz soft drink that meets the criteria for "very low sodium" per reference amount, but not per 12 fl oz, would state "very low sodium, 35 mg or less per 240 mL (8 fl oz)." A slice of bread that meets the criteria for "high in fiber" per reference amount, but not per slice, would state "high in fiber, 20 percent or more of the Recommended Daily Intake per 50 g (about 1 1/2 slices)."

Revised § 101.12(g) reads:

The reference amount set forth in paragraphs (b) through (f) of this section shall be used in determining whether a product meets the criteria for nutrient content claims, such as "low calorie," and for health claims. If the serving size declared on the product label differs from the reference amount, and the product meets the criteria for the claim only on the basis of the reference amount, the claim shall be followed by a statement that sets forth the basis on which the claim is made. That statement shall include the reference amount as it appears in § 101.12(b) followed, in parenthesis, by the amount in common household measure if the reference amount is expressed in measures other than common household measures (e.g., for a beverage, "Very low sodium, 35 mg or less per 240 mL (8 fl oz).

195. A few comments recommended that the determination as to whether a food qualifies to bear a nutrient content or health claim should be based only on the label serving size.

FDA disagrees with the comment. Basing claim evaluations only on the label serving size could encourage manipulation of serving sizes to qualify for claims. Therefore, FDA is not adopting this recommendation.

196. Other comments recommended using 1 oz as the basis for the claim evaluation. The comments contended that 1 oz is a simple criterion and provides a "level playing field" for all products making claims.

FDA believes that 1 oz is inappropriate to use for declaring nutrient content or for evaluating claims because it has no relation to the amount of food customarily consumed or a food's contribution to the total daily diet as required by the 1990 amendments and thus will result in misleading or meaningless claims. For example, on a 1 oz basis, foods that may qualify for a "high" claim on a per serving basis (e.g., "high calcium" on yogurt) may not be able to bear the claim, whereas foods that may not qualify for a "low" claim on a per serving basis (e.g., "low calorie" cake) may be able to bear the claim. Therefore, FDA is not adopting this recommendation.

K. Petition Process

FDA proposed in § 101.12(h) a set of requirements for filing a petition to establish or amend a reference amount.

Several comments from nutrition professional organizations and the industry supported the petition process. A major trade association stated that the system is necessary because of the changing consumption patterns of Americans and the everchanging nature of food products. The association further stated that it agrees with the type and amount of information proposed by FDA to be included in the petition. A few comments opposed or expressed a reservation on certain specific aspects of the petition process as described below.

197. FDA proposed in § 101.12(h)(11)(i) to provide that a petition to create a new subcategory of food with its own reference amount must include data that demonstrate that the new subcategory of food will be consumed in amounts that differ enough from the reference amount for the parent category to warrant a separate reference amount. Data must include sample size

and the mean, median, and modal amounts consumed per eating occasion for the petitioned product and for the products in the parent category, excluding the petitioned product.

An industry comment objected to the requirement in proposed § 101.12(h)(11)(i) for data on other products in the category. The comment stated that this information is not necessary, and that the data requirement is so burdensome that a petition for a new subcategory is almost impossible.

FDA disagrees with the comment that the data requirement for other products in the parent category is not necessary. The consumption data for other products in the category are needed to compare with the consumption data for the petitioned product to ensure that the customarily consumed amounts of the two product groups differ enough to warrant a separate reference amount for the petitioned product. The consumption data for other products in the parent category serve as the reference standard against which the consumption data for the petitioned product can be compared. Without a reference standard, it can not be known whether the difference in the customarily consumed amount of the petitioned product and the reference amount for the parent category is real or the result of the methodological or procedural differences in the surveys used. Use of the data on the other products is analogous to using a control or a reference standard in a laboratory experiment to validate the value of a test article.

FDA also disagrees that the data requirement is so burdensome that a petition for a new subcategory is almost impossible. Available national food consumption data bases provide information needed to meet the data requirement in new § 101.12(h)(11)(i). Some comments on the 1991 serving size proposal presented evidence that a relatively inexpensive survey can be conducted to collect food consumption data under actual conditions of use when information is not available from data bases.

However, to avoid an overly stringent data requirement, paragraph (h)(11)(i) has been modified to reduce the amount of information that must be submitted. While the proposed provision required information "* * * for the petitioned product and for all products in the category, excluding the petitioned product * * *," the modified provision seeks only data "* * * for the petitioned product and for other products in the category, excluding the petitioned product * * *." Also, to correct an oversight, the agency has added standard deviation to the data requirement to read "* * * Data must include sample size; and the mean, standard deviation, median, and modal consumed amount * * *."

198. FDA proposed in § 101.12(h)(14) that as part of the petition submission, a statement must be included concerning the feasibility of convening associations, corporations, consumers, and other interested parties to engage in negotiated rulemaking to develop a proposed rule consistent with the Negotiated Rulemaking Act of 1990 (Pub. L. 101–648). A consumer organization opposed the negotiated rulemaking in establishing a reference amount through a petition. The comment contended that the process is resource-intensive and will favor those organizations and companies that have the time and money to devote to such negotiations.

FDA believes that in certain circumstances, negotiated rulemaking may be a useful tool in developing new or amended reference amounts. The feasibility of convening an appropriate group of interested parties would be discussed by the petitioner; however, the decision on whether to convene a discussion session would be at FDA's discretion with full awareness of agency resources. FDA is convinced that it is frequently useful to provide a forum for open discussion of particularly contentious issues. All interested parties, including consumer organizations, would be invited to participate in any such negotiated rulemaking. Therefore, FDA has retained § 101.12(h)(14) as proposed.

199. One industry comment requested that a procedural method be established to modify, add, or expand a category or reference amount. Because of the length of time necessary for issuing and finalizing a proposal as a result of a petition, the comment stated that the proposed petition method is not optimal. The comment recommended that USDA and FDA investigate alternatives to the proposed petition process.

FDA believes that the petition process referred to in § 101.12(h) is the appropriate process to establish or amend a reference amount. Such a process is necessary because the reference amounts adopted by the agency have the force and effect of laws. However, new § 101.12(h) merely incorporates the citizen petition process in § 10.30. This petition process will ensure full participation of all interested parties. FDA recognizes that issuing and finalizing a proposal does take time. Therefore, the agency will do its best to expedite the petition for establishing or amending a reference amount so that the petitioner can properly label and market its product at the earliest date possible.

200. A trade association contended that manufacturers of the products with reference amounts in § 101.12(b) are at a competitive advantage over those manufacturers whose products are not included in § 101.12(b) because they do not have the burden or expense of petitioning for a reference amount. The comment argued that the petition process is unfair, and that it is the government's responsibility to provide a rational basis for determining serving sizes on all products. The comment further contended that in the absence of a meaningful reference amount for a product, a "small" business should be permitted to determine an appropriate reference amount or to delay nutrition labeling until FDA has completed its task.

FDA disagrees with the comment. To comply with the act, the agency has established reference amounts for virtually all foods in the current food supply that are regulated by FDA. The agency notes that the list of reference amounts in new § 101.12(b) is extensive and applicable to all products that belong to the generic description of the product category. Therefore, manufacturers should be able to find reference amounts for practically all products currently in the food supply.

The agency is aware that new products are continuously being introduced into the market. Because the product category description is generic, manufacturers should also be able to find the reference amounts in § 101.12(b) that are applicable to most of these new products. However, some new products may not fit in the product categories in § 101.12(b). Therefore, the agency has installed a petition process to establish or amend reference amounts to encompass new products that do not fit in any of the product categories in § 101.12(b) and any products in the current food supply that were not brought to FDA's attention in this rulemaking process. Although FDA recognizes that there is both time and money involved in the petition process, this process is necessary to keep the reference amounts in § 101.12(b) current.

The agency agrees that it has the authority to establish the reference amount. However, it is not FDA's responsibility to know every new food product that is introduced in the market. The agency points out that it is the manufacturer's responsibility to inform FDA if any products have not been covered by § 101.12(b) and to provide appropriate information to

establish or amend the reference amounts in § 101.12(b).

Lastly, the agency points out that "small" businesses as defined in § 101.9(j)(1) are exempt from nutrition labeling and thus, there is no need for concern about the petition process.

V. Other Affected Rules

The agency proposed to revise 21 CFR 101.8(a) to state that where nutrition information is required, and firms elect to place statements on product labels concerning the number of servings in a package in other locations in addition to the location where nutrition information is placed, such statements must be in the same terms as that used for nutrition information. FDA proposed this revision to prevent consumer confusion over serving size.

FDA received no comments on this provision. However, to correct a typographical error in the 1991 serving size proposal, the agency has modified § 101.8(a) to read: "* * * Such statement shall not be misleading in any particular * * *."

V. Environmental Impact

The agency previously considered the environmental effects of the action being taken in this final rule. As announced in its nutrition labeling proposed rules published in the Federal Register of November 27, 1991 (56 FR 60366 et al.), the agency determined that under 21 CFR 25.24(a)(8) and (a)(11), these actions are of a type that do not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

In its November 1991 nutrition labeling proposed rules, the agency proposed that the final rules for these actions would become effective 6 months following their publication in the Federal Register. Several comments on the nutrition labeling proposed rules suggested that there would be significant adverse environmental effects from the final rules unless the agency allowed more time between the publication of the final rules and their effective dates. The concern in these comments was that, if the agency did not allow firms more time between the publication of the final rules and their effective dates to use up existing label inventories, large stocks of labels and labeled packaging would have to be discarded. These comments questioned whether the agency had sufficiently examined the impact of disposing of obsolete labels and labeled packaging on this country's solid waste disposal capabilities. Two comments estimated the amounts of labeling from their respective industries, i.e., dairy and confectionery, that would need to be discarded following publication of FDA's final rules on several food labeling actions, including this action. However, these comments did not: (1) Provide details on how these estimates were derived, (2) identify what portion of the estimated amounts are attributable to these two actions, or (3) describe what impact the discarded labels and packaging would have on the disposal of solid waste.

Based on its consideration of comments received, the agency has decided to allow additional time for companies to use up their old labels. Thus, the nutrition labeling final rules will not be effective until May 8, 1994. FDA believes there will thus be ample time for food companies to use up most of the existing labeling and packaging stocks and to incorporate labeling language that complies with FDA's regulations into their food labels. Consequently, the comments on the potential for adverse environmental effects do not affect the agency's previous determination that no significant impact on the human environment is expected and that an environmental impact statement is not required.

VI. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the Federal Register of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the Federal Register. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the Federal Register announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

VII. Paperwork Reduction Act

In the Federal Register of February 14, 1992 (57 FR 5398), FDA announced that the agency had submitted to the Office of Management and Budget (OMB) for its review the collection of information requirements contained in the proposed rule (November 27, 1991, 56 FR 60394) that provided, in part, for petitions regarding serving sizes. Also in the February 1992 document, FDA published its estimated annual collection of information burden.

Based on its consideration of the written comments received in response to the aforementioned Federal Register documents and the oral presentations made at the public hearing on food labeling, FDA modified the serving size petition requirements from those that were proposed. Those modifications were discussed in detail earlier in this final rule. Accordingly, FDA has also revised its estimated annual collection of information burden.

This final rule contains collection of information requirements that are subject to review by OMB under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507). Therefore, in accordance with 5 CFR 1320, the title, description, and respondent descriptions of the collection of information requirements are shown below with an estimate of the annual collection of information burden. Included in the estimate is the amount of time for reviewing instructions, searching existing data sources, gathering necessary information, and completion and submission of petitions.

Title: 21 CFR 101.12—Food Labeling: Serving Sizes.

Description: This final rule provides the procedures and format for the submission of petitions to the agency. Section 101.12(h) describes the information needed by FDA to evaluate the need for the change or addition requested in the petition and to

determine the appropriate reference amount for the petitioned food if the change or addition is judged as needed. The information included in these petitions will be reviewed by the agency, and a decision will be made in accordance with the criteria specified in this final rule.

Description of Respondents: Persons and businesses, including small businesses.

Estimated Annual Reporting and Recordkeeping Burden:

Section	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Annual Burden Hours
101.12(h)	10	1	10	60	600
Total					600

FDA has submitted copies of the final rule to OMB for its review of these reporting requirements.

VIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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2. Park, Youngmee K., memo to file, October 30, 1991.
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22. USDA, Nationwide Food Consumption Survey/Individual—Summer Quarter 1977–1978, accession no. PB80–197429/HAE, National Technical Information Service, Springfield, VA, 1980.
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List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.8 is amended by revising paragraph (a) to read as follows:

§ 101.8 Labeling of food with number of servings.

(a) The label of any package of a food that bears a representation as to the number of servings contained in such package shall bear in immediate conjunction with such statement, and in the same size type as is used for such statement, a statement of the net quantity (in terms of weight, measure, or numerical count) of each such serving; however, such statement may be expressed in terms that differ from the terms used in the required statement of net quantity of contents (for example cups, tablespoons) when such differing term is common to cookery and describes a constant quantity. Such statement shall not be misleading in any particular. Where nutrition labeling information is required in accordance with the provisions of § 101.9, however, the statement of the net quantity of each serving shall be consistent with the requirements for serving size expression set forth in that section (e.g., 10 1-cup (240 milliliters) servings). A statement of the number of units in a package is not in itself a statement of the number of servings.

* * * * *

3. Section 101.9 is amended by revising paragraph (b) to read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(b) Except as provided in § 101.9(h)(3), all nutrient and food component quantities shall be declared in relation to a serving as defined in this section.

(1) The term "serving" or "serving size" means an amount of food customarily consumed per eating occasion by persons 4 years of age or older which is expressed in a common household measure that is appropriate to the food. When the food is specially formulated or processed for use by infants or by toddlers, a serving or serving size means an amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively.

(2) Except as provided in paragraphs (b)(3), (b)(4), and (b)(6) of this section and for products that are intended for weight control and are available only through a weight-control or weight-maintenance program, serving size declared on a product label shall be determined from the "Reference Amounts Customarily Consumed Per Eating Occasion" (reference amounts) that appear in § 101.12(b) using the procedures described below. For products that are both intended for weight control and available only through a weight-control program, a manufacturer may determine the serving size that is consistent with the meal plan of the program. Such products must bear a statement, "for sale only through the ——— program" (fill in the blank with the name of the appropriate weight control program, e.g., Smith's Weight Control), on the principal display panel. However, the reference amounts in § 101.12(b) shall be used for purposes of evaluating whether weight-control products that are available only through a weight-control program qualify for nutrient content claims or health claims.

(i) For products in discrete units (e.g., muffins, sliced products such as sliced bread, apples, or individually packaged products within a multiserving package), except for products that naturally vary in size such as maraschino cherries, pickles, shellfish, whole fish, and fillet of fish, serving size shall be the number of whole units that most closely approximates the reference amount for the product category. If a unit weighs 67 percent or more, but less than 200 percent of the reference amount, the serving size shall be one unit. If a unit weighs more than 50 percent but less than 67 percent of the reference amount, the manufacturer may declare one unit as one serving. If a unit weighs 200 percent or more of the reference amount, the manufacturer may declare the whole unit as one serving if the whole unit can reasonably be consumed at a single-eating occasion. Serving size for maraschino cherries shall be expressed as 1 cherry with the parenthetical metric measure equal to the average weight of a medium size cherry. Serving size for other products that naturally vary in size shall be expressed in the amount in oz that most closely approximates the reference amount for the product category. Manufacturers shall adhere to the requirements in paragraph (b)(5) of this section for expressing the serving size in oz.

(ii) For products in large discrete units that are usually divided for consumption (e.g., cake, pie, pizza, melon, cabbage), the serving size shall be the fractional slice of the food (e.g., 1/12 cake, 1/8 pie, 1/4 pizza, 1/4 melon, 1/6 cabbage) that most closely approximates the reference amount for the product category. In expressing the fractional slice, manufacturers shall use 1/2, 1/3, 1/4, 1/5, 1/6, or smaller fractions that can be generated by further division by 2 or 3.

(iii) For nondiscrete bulk products (e.g., breakfast cereal, flour, sugar, dry mixes, concentrates), serving size shall be the amount in household measure that most closely approximates the reference amount for the product category.

(3) The serving size for meal products and main dish products as defined in § 101.13(l) and (m) of this chapter that come in single-serving containers as defined in paragraph (b)(6) of this section shall be the entire content (edible portion only) of the package. Serving size for meal products and main dish products in multiserving containers shall be based on the reference amount applicable to the product in § 101.12(b) if the product is listed in § 101.12(b). Serving size for meal products and main dish products in multiserving containers that are not listed in § 101.12(b) shall be based on the reference amount according to § 101.12(f).

(4) A variety pack such as a package containing several varieties of single-serving units as defined in paragraph (b)(2)(i) of this section, and a product having two or more compartments with each compartment containing a different food, shall provide nutrition information for each variety or food per serving size that is derived from the reference amount in § 101.12(b) applicable for each variety or food and the procedures to convert the reference amount to serving size in paragraph (b)(2) of this section.

(5) For labeling purposes, the term "common household measure" or "common household unit" means cup, tablespoon, teaspoon, piece, slice, fraction (e.g., 1/4 pizza), ounce (oz), fluid ounce (fl oz), or other common household equipment used to package food products (e.g., jar, tray). In expressing serving size in household measures, the following rules shall be used:

(i) Cups, tablespoons, or teaspoons shall be used wherever possible and appropriate except for beverages. For beverages, a manufacturer may use fl oz. Cups shall be expressed in 1/4 or 1/3 cup increments, tablespoons in whole number of tablespoons for quantities less than 1/4 cup but greater than or equal to 1 tablespoon, and teaspoons in whole number of teaspoons for quantities less than 1 tablespoon but greater than or equal to 1 teaspoon and in 1/4 teaspoon increments for quantities less than 1 teaspoon.

(ii) If cups, tablespoons or teaspoons are not applicable, units such as piece, slice, tray, jar, and fraction shall be used.

(iii) If paragraphs (b)(5)(i) and (b)(5)(ii) of this section are not applicable, oz may be used with an appropriate visual unit of measure such as a dimension of a piece, e.g., 1 oz (28 g/about 1/2 pickle). Ounce measurements shall be expressed in 0.5 oz increments most closely approximating the reference amount, with rounding indicated by use of the term "about" (e.g., about 2.5 oz).

(iv) For nutrition labeling purposes, a teaspoon means 5 milliliters (mL); a tablespoon means 15 mL; a cup means 240 mL; 1 fluid ounce (fl oz) means 30 mL; and 1 oz in weight means 28 g.

(v) When a serving size, determined from the reference amount in § 101.12(b) and the procedures described in this section, falls exactly half way between two serving sizes, e.g., 2.5 tbsp, manufacturers shall round the serving size up to the next incremental size.

(6) A product that is packaged and sold individually and that contains less than 200 percent of the applicable reference amount shall be considered to be a single-serving container, and the entire content of the product shall be labeled as one serving except for products that have reference amounts of 100 g (or mL) or larger, manufacturers may decide whether a package that contains more than 150 percent but less than 200 percent of the reference amount is 1 or 2 servings. Packages sold individually that contain 200 percent or more of the applicable reference amount may be labeled as a single-serving if the entire content of the package can reasonably be consumed at a single-eating occasion.

(7) A label statement regarding a serving shall be the serving size expressed in common household measures as set forth in paragraphs (b)(2) through (b)(6) of this section and shall be followed by the equivalent metric quantity in parenthesis (fluids in mL and all other foods in g) except for single-serving containers. For a single-serving container, the parenthetical metric quantity, which will be presented as part of the net weight statement on the principal display panel, is not required except where nutrition information is required on a drained weight basis according to § 101.9(b)(9). The g quantity equivalent to the household measure should be rounded to the nearest whole number except for quantities that are less than 5 g. The g quantity between 2 and 5 g should be rounded to the nearest 0.5 g and the g quantity less than 2 g should be expressed in 0.1-g increments. In addition, serving size may be declared in oz and fl oz, in parenthesis, following the metric measure separated by a slash where other common household measures are used as the primary unit for serving size, e.g., 1 slice (28 g/1 oz) for sliced bread. The oz quantity equivalent to the metric quantity should be expressed in 0.1 oz increments. If a manufacturer elects to use abbreviations for units, the following abbreviations shall be used: tbsp for tablespoon, tsp for teaspoon, g for gram, mL for milliliter, oz for ounce, and fl oz for fluid ounce. To promote uniformity in label serving sizes in household measures declared by different manufacturers, FDA has provided Guidelines for Determining the Gram Weight of the Household Measure. The guidelines can be obtained from Division of Nutrition (HFF-260), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

(8) Determination of the number of servings per container shall be based on the serving size of the product determined by following the procedures described in this section. The number of servings shall be rounded to the nearest whole number except for the number of servings between 2 and 5 servings and random weight products. The number of servings between 2 and 5 servings shall be rounded to the nearest 0.5 serving. Rounding should be indicated by the use of the term "about" (e.g., about 2 servings, about 3.5 servings). When the serving size is required to be expressed on a drained solids basis and the number of servings vary because of a natural variation in unit size (e.g., maraschino cherries, pickles), the manufacturer may state the typical number of servings per container (e.g., usually 5 servings). For random weight products, a manufacturer may declare "varied" for the number of servings per container provided the nutrition information is based on the reference amount expressed in oz. The manufacturer may provide the typical number of servings in parenthesis following the "varied" statement.

(9) The declaration of nutrient and food component content shall be on the basis of food as packaged or purchased with the exception of raw fish covered under § 101.42 (see § 101.44), packaged

single-ingredient products that consist of fish or game meat as provided for in paragraph (j)(11) of this section, and of foods that are packed or canned in water, brine, or oil but whose liquid packing medium is not customarily consumed (e.g., canned fish, maraschino cherries, pickled fruits, and pickled vegetables). Declaration of nutrient and food component content of raw fish shall follow the provisions in § 101.45. Declaration of nutrient and food component content of foods that are packed in liquid but the liquid packing medium is not customarily consumed, shall be based on the drained solids.

(10) Another column of figures may be used to declare the nutrient and food component information,

(i) Per 100 g or 100 mL or per 1 oz or 1 fl oz of the food as packaged or purchased.

(ii) Per one unit if the serving size of a product in discrete units in a multiserving container is more than one unit.

(iii) Per cup popped for popcorn in a multiserving container.

(11) If a product is promoted on the label, labeling, or advertising for a use that differs in quantity by twofold or greater from the use upon which the reference amount in § 101.12(b) was based (e.g., liquid cream substitutes promoted for use with breakfast cereals), the manufacturer shall provide a second column of nutrition information based on the amount customarily consumed in the promoted use, in addition to the nutrition information per serving derived from the reference amount in § 101.12(b), except that nondiscrete bulk products that are used primarily as ingredients (e.g., flour, sweeteners, shortenings, oils), or traditionally used for multipurposes (e.g., eggs, butter, margarine), and multipurpose baking mixes are exempt from this requirement.

* * * * *

4. Section 101.12 is added to subpart A to read as follows:

§ 101.12 Reference amounts customarily consumed per eating occasion.

(a) The general principles and factors that the Food and Drug Administration (FDA) considered in arriving at the reference amounts customarily consumed per eating occasion (reference amounts) which are set forth in paragraph (b) of this section, are that:

(1) FDA calculated the reference amounts for persons 4 years of age or older to reflect the amount of food customarily consumed per eating occasion by persons in this population group. These reference amounts are based on data set forth in appropriate national food consumption surveys.

(2) FDA calculated the reference amounts for an infant or child under 4 years of age to reflect the amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively. These reference amounts are based on data set forth in appropriate national food consumption surveys. Such reference amounts are to be used only when the food is specially formulated or processed for use by an infant or by a child under 4 years of age.

(3) An appropriate national food consumption survey includes a large sample size representative of the demographic and socioeconomic characteristics of the relevant population group and must be based on consumption data under actual conditions of use.

(4) To determine the amount of food customarily consumed per eating occasion, FDA considered the mean, median, and mode of the consumed amount per eating occasion.

(5) When survey data were insufficient, FDA took various other sources of information on serving sizes of food into consideration. These other sources of information included:

(i) Serving sizes used in dietary guidance recommendations or recommended by other authoritative systems or organizations;

(ii) Serving sizes recommended in comments;

(iii) Serving sizes used by manufacturers and grocers; and

(iv) Serving sizes used by other countries.

(6) Because they reflect the amount customarily consumed, the reference amount and, in turn, the serving size declared on the product label are based on only the edible portion of food, and not bone, seed, shell, or other inedible components.

(7) The reference amount is based on the major intended use of the food (e.g., milk as a beverage and not as an addition to cereal).

(8) The reference amounts for products that are consumed as an ingredient of other foods, but that may also be consumed in the form in which they are purchased (e.g., butter), are based on use in the form purchased.

(9) FDA sought to ensure that foods that have similar dietary usage, product characteristics, and customarily consumed amounts have a uniform reference amount.

(b) The following reference amounts shall be used as the basis for determining serving sizes for specific products:

TABLE 1

REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: INFANT AND TODDLER FOODS[1, 2, 3, 4]

Product category	Reference amount	Label statement[5]
Cereals, dry instant	15 g	1/3 cup (13 g)
Cereals, prepared, ready-to-serve	110 g	——— cup(s) (——— g)
Other cereal and grain products, dry ready-to-eat, e.g., ready-to-eat cereals, cookies, teething biscuits, and toasts.	7 g for infants and 20 g for toddlers for ready-to-eat cereals; 7 g for all others.	——— cup(s) (——— g) for ready-to-eat cereals; ——— piece(s) (——— g) for others
Dinners, desserts, fruits, vegetables or soups, dry mix	15 g	——— tbsp(s) (——— g) or ——— cup(s) (——— g)
Dinners, desserts, fruits, vegetables or soups, ready-to-serve, junior type.	110 g	——— cup(s) (——— g)
Dinners, desserts, fruits, vegetables or soups, ready-to-serve, strained type.	60 g	——— cup(s) (——— g)
Dinners, stews or soups for toddlers, ready-to-serve	170 g	——— cup(s) (——— g)
Fruits for toddlers, ready-to-serve	125 g	——— cup(s) (——— g)
Vegetables for toddlers, ready-to- serve	70 g	——— cup(s) (——— g)
Eggs/egg yolks, ready-to-serve	55 g	——— cup(s) (——— g)
Juices, all varieties	120 mL	4 fl oz (120 mL)

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–1978 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.
[2] Unless otherwise noted in the Reference amount column, the reference amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e., heat and serve, brown and serve). If not listed separately, the reference amount for the unprepared form (e.g., dry cereal) is the amount required to make one reference amount of the prepared form. Prepared means prepared for consumption (e.g., cooked).
[3] Manufacturers are required to convert the reference amount to the label serving size in a household measure most appropriate to their specific product using the procedures in 21 CFR 101.9(b).
[4] Copies of the list of products for each product category are available from the Division of Nutrition (HFF–260), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.
[5] The label statements are meant to provide guidance to manufacturers on the presentation of serving size information on the label, but they are not required. The term "piece" is used as a generic description of a discrete unit. Manufacturers should use the description of a unit that is most appropriate for the specific product (e.g., sandwich for sandwiches, cookie for cookies, and bar for frozen novelties).

TABLE 2

REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY[1, 2, 3, 4]

Product category	Reference amount	Label statement[5]
Bakery Products:		
Biscuits, croissants, bagels, tortillas, soft bread sticks, soft pretzels, corn bread, hush puppies.	55 g	——— piece(s) (——— g)
Breads (excluding sweet quick type), rolls	50 g	——— piece(s) (——— g) for sliced bread and distinct pieces (e.g., rolls); 2 oz (56 g/——— inch slice) for unsliced bread
Bread sticks—see crackers		
Toaster pastries—see coffee cakes		
Brownies	40 g	——— piece(s) (——— g) for distinct pieces; fractional slice (——— g) for bulk
Cakes, heavy weight (cheese cake; pineapple upside-down cake; fruit, nut, and vegetable cakes with more than or equal to 35 percent of the finished weight as fruit, nuts, or vegetables)[6].	125 g	——— piece(s) (——— g) for distinct pieces (e.g., sliced or individually packaged products); ——— fractional slice (——— g) for large discrete units
Cakes, medium weight (chemically leavened cake with or without icing or filling except those classified as light weight cake; fruit, nut, and vegetable cake with less than 35 percent of the finished weight as fruit, nuts, or vegetables; light weight cake with icing; Boston cream pie; cupcake; eclair; cream puff)[7].	80 g	——— piece(s) (——— g) for distinct pieces (e.g., cupcake); ——— fractional slice (——— g) for large discrete units
Cakes, light weight (angel food, chiffon, or sponge cake without icing or filling)[8].	55 g	——— piece(s) (——— g) for distinct pieces (e.g., sliced or individually packaged products); ——— fractional slice (——— g) for large discrete units
Coffee cakes, crumb cakes, doughnuts, Danish, sweet rolls, sweet quick type breads, muffins, toaster pastries.	55 g	——— piece(s) (——— g) for sliced bread and distinct pieces (e.g., doughnut); 2 oz (56 g/visual unit of measure) for bulk products (e.g., unsliced bread)
Cookies	30 g	——— piece(s) (——— g)
Crackers that are usually not used as snack, melba toast, hard bread sticks, ice cream cones[9].	15 g	——— piece(s) (——— g)
Crackers that are usually used as snacks	30 g	——— piece(s) (——— g)
Croutons	7 g	——— tbsp(s) (——— g) or ——— cup(s) (——— g); ——— piece(s) (——— g) for large pieces
French toast, pancakes, variety mixes	110 g prepared for french toast and pancakes; 40 g dry mix for variety mixes.	——— piece(s) (——— g); ——— cup(s) (——— g) for dry mix
Grain-based bars with or without filling or coating, e.g., breakfast bars, granola bars, rice cereal bars.	40 g	——— piece(s) (——— g)

Ice cream cones—see crackers		
Pies, cobblers, fruit crisps, turnovers, other pastries	125 g	——— piece(s) (———g) for distinct pieces; ——— fractional slice (——— g) for large discrete units
Pie crust	1/6 of 8 inch crust; 1/8 of 9 inch crust	1/6 of 8 inch crust (——— g); 1/8 of 9 inch crust (——— g)
Pizza crust	55 g	——— fractional slice (——— g)
Taco shells, hard	30 g	——— shell(s) (——— g)
Waffles	85 g	——— piece(s) (——— g)
Beverages:		
Carbonated and noncarbonated beverages, wine coolers, water	240 mL	8 fl oz (240 mL)
Coffee or tea, flavored and sweetened	240 mL prepared	8 fl oz (240 mL)
Cereals and Other Grain Products:		
Breakfast cereals (hot cereal type), hominy grits	1 cup prepared; 40 g plain dry cereal; 55 g flavored, sweetened cereal	——— cup(s) (——— g)
Breakfast cereals, ready-to-eat, weighing less than 20 g per cup, e.g., plain puffed cereal grains.	15 g	——— cup(s) (——— g)
Breakfast cereals, ready-to-eat weighing 20 g or more but less than 43 g per cup; high fiber cereals containing 28 g or more of fiber per 100 g.	30 g	——— cup(s) (——— g)
Breakfast cereals, ready-to-eat, weighing 43 g or more per cup; biscuit types.	55 g	——— piece(s) (——— g) for large distinct pieces (e.g., biscuit type);——— cup(s) (——— g) for all others
Bran or wheat germ	15 g	——— tbsp(s) (——— g) or ——— cup(s) (——— g)
Flours or cornmeal	30 g	——— tbsp(s) (——— g) or ——— cup(s) (——— g)
Grains, e.g., rice, barley, plain	140 g prepared; 45 g dry	——— cup(s) (——— g)
Pastas, plain	140 g prepared; 55 g dry	——— cup(s) (——— g); ——— piece(s) (——— g) for large pieces (e.g., large shell) or 2 oz (56 g/visual unit of measure) for dry bulk products (e.g., lasagna or spaghetti noodles)
Pastas, dry, ready-to-eat, e.g., fried canned chow mein noodles	25 g	——— cup(s) (——— g)
Starches, e.g., cornstarch, potato starch, tapioca, etc.	10 g	1 tbsp (8 g) for cornstarch; 1 tbsp (10 g) for tapioca; 1 tbsp (——— g) for others
Stuffing	100 g	——— cup(s) (——— g)
Dairy Products and Substitutes:		
Cheese, cottage	110 g	1/2 cup (105 g) for small curd; 1/2 cup (113 g) for large curd, low fat, or with fruit added; 1/2 cup (——— g) for others
Cheese used primarily as ingredients, e.g., dry cottage cheese, ricotta cheese.	55 g	1/3 cup (48 g) for dry curd cottage cheese; 1/4 cup (62 g) for ricotta cheese
Cheese, grated hard, e.g., Parmesan, Romano	5 g	1 tbsp(s) (5 g)
Cheese, all others except those listed as separate categories—includes cream cheese and cheese spread.	30 g	——— piece(s) (——— g) for distinct pieces;——— tbsp(s) (——— g) for cream cheese and cheese spread; 1 oz (28 g/visual unit of measure) for bulk
Cheese sauce—see sauce category		
Cream or cream substitutes, fluid	15 mL	1 tbsp (15 mL)
Cream or cream substitutes, powder	2 g	1 tsp (2 g)
Cream, half & half	30 mL	2 tbsp (30 mL)
Eggnog	120 mL	1/2 cup (120 mL) or 4 fl oz (120 mL)
Milk, condensed, undiluted	30 mL	2 tbsp (30 mL)
Milk, evaporated, undiluted	30 mL	2 tbsp (30 mL)
Milk, milk-based drinks, e.g., instant breakfast, meal replacement, cocoa.	240 mL	1 cup (240 mL) or 8 fl oz (240 mL)
Shakes or shake substitutes, e.g., dairy shake mixes, fruit frost mixes	240 mL	1 cup (240 mL) or 8 fl oz (240 mL)
Sour cream	30 g	2 tbsp (30 g)
Yogurt	225 g	1 cup (——— g)
Desserts:		
Ice cream, ice milk, frozen yogurt, sherbet: all types, bulk and novelties (e.g., bars, sandwiches, cones).	1/2 cup-includes the volume for coatings and wafers for the novelty type varieties.	——— piece(s) (——— g) for individually wrapped or packaged products; 1/2 cup (——— g) for others
Frozen flavored and sweetened ice and pops, frozen fruit juices: all types, bulk and novelties (e.g., bars, cups).	85 g	——— piece(s) (——— g) for individually wrapped or packaged products; ——— cup(s) (——— g) for others
Sundae	1 cup	1 cup (——— g)
Custards, gelatin or pudding	1/2 cup	——— piece(s) (——— g) for distinct unit (e.g., individually packaged products); 1/2 cup (——— g) for bulk
Dessert Toppings and Fillings:		
Cake frostings or icings	35 g	——— tbsp(s) (——— g)
Other dessert toppings, e.g., fruits, syrups, spreads, marshmallow cream, nuts, dairy and nondairy whipped toppings.	2 tbsp	2 tbsp (——— g)
Pie fillings	85 g	——— cup(s) (——— g)
Egg and Egg Substitutes:		
Egg mixtures, e.g., egg foo young, scrambled eggs, omelets	110 g	——— piece(s) (——— g) for discrete pieces;——— cup(s) (——— g)

TABLE 2—Continued

REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY[1, 2, 3, 4]

Product category	Reference amount	Label statement[5]
Eggs (all sizes)[9]	50 g	1 large, medium, etc. (——— g)
Egg substitutes	An amount to make 1 large (50 g) egg	——— cup(s) (——— g)
Fats and Oils:		
Butter, margarine, oil, shortening	1 tbsp	1 tbsp (14 g) for butter, margarine, or oil; 1 tbsp (9 g) for whipped butter or margarine; 1 tbsp (13 g) for shortening
Butter replacement, powder	2 g	——— tsp(s) (——— g)
Dressings for salads	30 g	2 tbsp (——— g)
Mayonnaise, sandwich spreads, mayonnaise-type dressings	15 g	1 tbsp (14 g) for mayonnaise; 1 tbsp (15 g) for imitation mayonnaise, mayonnaise-type dressings or sandwich spread
Spray types	0.25 g	About ——— seconds spray (——— g)
Fish, Shellfish, Game Meats[10], and Meat or Poultry Substitutes:		
Bacon substitutes, canned anchovies,[11] anchovy pastes, caviar	15 g	——— piece(s) (——— g) for discrete pieces; ——— tbsp(s) (——— g) for others
Dried, e.g., jerky	30 g	——— piece(s) (——— g)
Entrees with sauce, e.g., fish with cream sauce, shrimp with lobster sauce.	140 g cooked	——— cup(s) (——— g); 5 oz (140 g/visual unit of measure) if not measurable by cup
Entrees without sauce, e.g., plain or fried fish and shellfish, fish and shellfish cake.	85 g cooked; 110 g uncooked[12]	——— piece(s) (——— g) for discrete pieces; ——— cup(s) (——— g); ——— oz (——— g/visual unit of measure) if not measurable by cup[13]
Fish, shellfish or game meat[10], canned[11]	55 g	——— piece(s) (——— g) for discrete pieces; ——— cup(s) (——— g)
Substitute for luncheon meat, meat spreads, Canadian bacon, sausages and frankfurters.	55 g	——— piece(s) (——— g) for distinct pieces (e.g., slices, links); ——— cup(s) (——— g); 2 oz (56 g/visual unit of measure) for nondiscrete bulk product
Smoked or pickled[11] fish, shellfish, or game meat[10]; fish or shellfish spread.	55 g	——— piece(s) (——— g) for distinct pieces (e.g., slices, links) or ——— cup(s) (——— g); 2 oz (56 g/visual unit of measure) for nondiscrete bulk product
Substitutes for bacon bits—see miscellaneous category		
Fruits and Fruit Juices:.		
Candied or pickled[11]	30 g	——— piece(s) (——— g)
Dehydrated fruits—see snacks category		
Dried	40 g	——— piece(s) (——— g) for large pieces (e.g., dates, figs, prunes); ——— cup(s) (——— g) for small pieces (e.g., raisins)
Fruits for garnish or flavor, e.g., maraschino cherries[11]	4 g	1 cherry (——— g)
Fruit relishes, e.g., cranberry sauce, cranberry relish	70 g	——— cup(s) (——— g)
Fruits used primarily as ingredients, avocado	30 g	See footnote 13
Fruits used primarily as ingredients, others (cranberries, lemon, lime)	55 g	——— piece(s) (——— g) for large fruits; ——— cup(s) (——— g) for small fruits measurable by cup[13]
Watermelon	280 g	See footnote 13
All other fruits (except those listed as separate categories), fresh, canned, or frozen.	140 g	——— piece(s) (——— g) for large pieces (e.g., strawberries, prunes, apricots, etc.); ——— cup(s) (——— g) for small pieces (e.g., blueberries, raspberries, etc.)[13]
Juices, nectars, fruit drinks	240 mL	8 fl oz (240 mL)
Juices used as ingredients, e.g., lemon juice, lime juice	5 mL	1 tsp (5 mL)
Legumes:		
Bean cake (tofu)[11], tempeh	85 g	——— piece(s) (——— g) for discrete pieces; 3 oz (84 g/visual unit of measure) for bulk products
Beans, plain or in sauce	130 g for beans in sauce or canned in liquid; 90 g for others	1/2 cup (——— g)
Miscellaneous category:		
Baking powder, baking soda, pectin	1 g	1/4 tsp (——— g)
Baking decorations, e.g., colored sugars and sprinkles for cookies, cake decorations.	1/4 tsp or 4 g if not measurable by teaspoon	——— piece(s) (——— g) for discrete pieces;1/4 tsp (——— g)
Batter mixes, bread crumbs	30 g	——— tbsp(s) (——— g) or——— cup(s) (——— g)
Cooking wine	30 mL	2 tbsp (30 mL)
Drink mixers (without alcohol)	Amount to make 240 mL drink (without ice)	——— fl oz (——— mL)
Chewing gum[9]	3 g	——— piece(s) (——— g)
Meat, poultry and fish coating mixes, dry; seasoning mixes, dry, e.g., chili seasoning mixes, pasta salad seasoning mixes.	Amount to make one reference amount of final dish	——— tsp(s) (——— g) or ——— tbsp(s) (——— g)
Salad and potato toppers, e.g., salad crunchies, salad crispins, substitutes for bacon bits.	7 g	——— tbsp(s) (——— g)

Salt, salt substitutes, seasoning salts (e.g., garlic salt)	1 g	——— tsp(s) (——— g);——— piece(s) (——— g) for discrete pieces (e.g., individually packaged products)
Spices, herbs (other than dietary supplements)	1/4 tsp or 0.5 g if not measurable by teaspoon	1/4 tsp (——— g); ——— piece(s) (——— g) if not measurable by teaspoons (e.g., bay leaf)
Mixed Dishes:		
Measurable with cup, e.g., casseroles, hash, macaroni and cheese, pot pies, spaghetti with sauce, stews, etc..	1 cup.	1 cup (——— g)
Not measurable with cup, e.g., burritos, egg rolls, enchiladas, pizza, pizza rolls, quiche, all types of sandwiches.	140 g, add 55 g for products with gravy or sauce topping, e.g., enchilada with cheese sauce, crepe with white sauce[14].	——— piece(s) (——— g) for discrete pieces; ——— fractional slice (——— g) for large discrete units
Nuts and Seeds:		
Nuts, seeds, and mixtures, all types: sliced, chopped, slivered, and whole.	30 g	——— piece(s) (——— g) for large pieces (e.g., unshelled nuts);——— tbsp(s) (——— g) or——— cup(s) (——— g) for small pieces (e.g., peanuts, sunflower seeds)
Nut and seed butters, pastes, or creams	2 tbsp	2 tbsp (——— g)
Coconut, nut and seed flours	15 g	——— tbsp(s) (——— g)
Potatoes and Sweet Potatoes/Yams:		
French fries, hash browns, skins, or pancakes	70 g prepared; 85 g for frozen unprepared french fries	——— piece(s) (——— g) for large distinct pieces (e.g., patties, skins); 2.5 oz (70 g/——— pieces) for prepared fries; 3 oz (84 g/——— pieces) for unprepared fries
Mashed, candied, stuffed, or with sauce	140 g	——— piece(s) (——— g) for discrete pieces (e.g., stuffed potato); ——— cup(s) (——— g)
Plain, fresh, canned, or frozen	110 g for fresh or frozen; 160 g for canned in liquid	——— piece(s) (——— g) for discrete pieces;——— cup(s) (——— g) for sliced or chopped products
Salads:		
Gelatin Salad	120 g	1/2 cup (120 g)
Pasta or potato salad	140 g	——— cup(s) (——— g)
All other salads, e.g., egg, fish, shellfish, bean, fruit, or vegetable salads.	100 g	——— cup(s) (——— g)
Sauces, Dips, Gravies and Condiments:		
Barbecue sauce, hollandaise sauce, tartar sauce, other sauces for dipping (e.g., mustard sauce, sweet and sour sauce), all dips (e.g., bean dips, dairy-based dips, salsa).	2 tbsp	2 tbsp (——— g)
Major main entree sauces, e.g., spaghetti sauce	125 g	1/2 cup (——— g)
Minor main entree sauces (e.g., pizza sauce, pesto sauce), other sauces used as toppings (e.g., gravy, white sauce, cheese sauce), cocktail sauce.	1/4 cup	1/4 cup (——— g)
Major condiments, e.g., catsup, steak sauce, soy sauce, vinegar, teriyaki sauce, marinades.	1 tbsp	1 tbsp (——— g)
Minor condiments, e.g., horseradish, hot sauces, mustards, worcestershire sauce.	1 tsp	1 tsp (——— g)
Snacks:		
All varieties, chips, pretzels, popcorns, extruded snacks, fruit- based snacks (e.g., fruit chips,) grain-based snack mixes.	30 g	——— cup(s) (——— g) for small pieces (e.g., popcorn) ——— piece(s) (——— g) for large pieces (e.g., large pretzels; pressed dried fruit sheet); 1 oz (28 g/visual unit of measure) for bulk products (e.g., potato chips)
Soups:		
All varieties	245 g	1 cup (——— g)
Sugars and Sweets:		
Baking candies (e.g., chips)	15 g	——— piece(s) (——— g) for large pieces; ——— tbsp(s) (——— g) for small pieces; 1/2 oz (14 g/visual unit of measure) for bulk products
Hard candies, breath mints	2 g	——— piece(s) (——— g)
Hard candies, roll-type, mini-size in dispenser packages	5 g	——— piece(s) (——— g)
Hard candies, others	15 g	——— piece(s) (——— g) for large pieces;——— tbsp(s) (——— g) for "mini-size" candies measurable by tablespoon; 1/2 oz (14 g/visual unit of measure) for bulk products
All other candies	40 g	——— piece(s) (——— g); 1 1/2 oz (42 g/visual unit of measure) for bulk products
Confectioner's sugar	30 g	1/4 cup (30 g)
Honey, jams, jellies, fruit butter, molasses	1 tbsp	1 tbsp (——— g)
Marshmallows	30 g	——— cup(s) (——— g) for small pieces or ——— piece(s) (——— g) for large pieces
Sugar	4 g	1 tsp (——— g); ——— piece(s) (——— g) for discrete pieces (e.g., sugar cubes, individually packaged product)

TABLE 2—Continued

REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY[1, 2, 3, 4]

Product category	Reference amount	Label statement[5]
Sugar substitutes	An amount equivalent to one reference amount for sugar in sweetness	——— tsp(s) (——— g) for solids; ——— drop(s) (——— g) for liquid; ——— piece(s) (——— g) (e.g., individually packaged products)
Syrups	30 mL for syrups used primarily as an ingredient (e.g., light or dark corn syrup); 60 mL for all others.	2 tbsp (30 mL) for syrups used primarily as an ingredient; 1/4 cup (60 mL) for all others
Vegetables:		
Vegetables primarily used for garnish or flavor, e.g., pimento, parsley	15 g	——— piece(s) (——— g); ——— tbsp(s) (——— g) for chopped products
Chili pepper, green onion	30 g	——— piece(s) (——— g)[13]; ——— tbsp(s) (——— g) or ——— cup(s) (——— g) for sliced or chopped products
All other vegetables without sauce: fresh, canned, or frozen	85 g for fresh or frozen; 95 g for vacuum canned; 130 g for canned in liquid, cream-style corn, canned or stewed tomatoes, pumpkin, or winter squash.	——— piece(s) (——— g) for large pieces (e.g., brussel sprouts); ——— cup(s) (——— g) for small pieces (e.g., cut corn, green peas); 3 oz (84 g/visual unit of measure) if not measurable by cup[13]
All other vegetables with sauce: fresh, canned, or frozen	110 g	——— piece(s) (——— g) for large pieces (e.g., brussel sprouts); ——— cup(s) (——— g) for small pieces (e.g., cut corn, green peas); 4 oz (112 g/visual unit of measure) if not measurable by cup
Vegetable juice	240 mL	8 fl oz (240 mL)
Olives[11]	15 g	——— piece(s) (——— g); ——— tbsp(s) (——— g) for sliced products
Pickles, all types[11]	30 g	1 oz (28 g/visual unit of measure)
Pickle relishes	15 g	1 tbsp (15 g)
Vegetable pastes, e.g., tomato paste	30 g	2 tbsp (33 g) for tomato paste; 2 tbsp (——— g) for all others
Vegetable sauces or purees, e.g, tomato sauce, tomato puree	60 g	1/4 cup (61 g) for tomato sauce; 1/4 cup (63 g) for tomato puree; 1/4 cup (——— g) for all others

[1] These values represent the amount (edible portion) of food customarily consumed per eating occasion and were primarily derived from the 1977–1978 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the USDA.

[2] Unless otherwise noted in the Reference Amount column, the reference amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e., heat and serve, brown and serve). If not listed separately, the reference amount for the unprepared form (e.g., dry mixes; concentrates; dough; batter; dry, fresh, and frozen pasta) is the amount required to make one reference amount of the prepared form. Prepared means prepared for consumption (e.g., cooked).

[3] Manufacturers are required to convert the reference amount to the label serving size in a household measure most appropriate to their specific product using the procedures in 21 CFR 101.9(b).

[4] Copies of the list of products for each product category are available from the Division of Nutrition (HFF–260), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

[5] The label statements are meant to provide guidance to manufacturers on the presentation of serving size information on the label, but they are not required. The term "piece" is used as a generic description of a discrete unit. Manufacturers should use the description of a unit that is most appropriate for the specific product (e.g., sandwich for sandwiches, cookie for cookies, and bar for frozen novelties).

[6] Includes cakes that weigh 10 g or more per cubic inch.

[7] Includes cakes that weigh 4 g or more per cubic inch but less than 10 g per cubic inch.

[8] Includes cakes that weigh less than 4 g per cubic inch.

[9] Label serving size for ice cream cones and eggs of all sizes will be one unit. Label serving size of all chewing gums that weigh more than the reference amount that can reasonably be consumed at a single-eating occasion will be one unit.

[10] Animal products not covered under the Federal Meat Inspection Act or the Poultry Products Inspection Act, such as flesh products from deer, bison, rabbit, quail, wild turkey, geese, ostrich, etc.

[11] If packed or canned in liquid, the reference amount is for the drained solids, except for products in which both the solids and liquids are customarily consumed (e.g., canned chopped clam in juice).

[12] The reference amount for the uncooked form does not apply to raw fish in § 101.45 or to single-ingredient products that consist of fish or game meat as provided for in § 101.9(b)(j)(11).

[13] For raw fruit, vegetables, and fish, manufacturers should follow the label statement for the serving size specified in Appendices A and B to the regulation entitled "Food Labeling; Guidelines for Voluntary Nutrition Labeling; and Identification of the 20 Most Frequently Consumed Raw Fruits, Vegetables, and Fish; Definition of Substantial Compliance; Correction" (56 FR 60880 as amended 57 FR 8174, March 6, 1992).

[14] Pizza sauce is part of the pizza and is not considered to be sauce topping.

(c) The reference amount of a product that requires cooking or the addition of water or other ingredients shall be the amount required to prepare one reference amount of the final product as established in paragraph (b) of this section.

(d) The reference amount for an imitation or substitute food or altered food such, as a "low calorie" version, shall be the same as for the food for which it is offered as a substitute.

(e) If a food is modified by incorporating air (aerated), and thereby the density of the food is lowered by 25 percent or more in weight than that of an appropriate reference regular food as described in § 101.13(j)(1)(ii)(A), and the reference amount of the regular food is in g, the manufacturer may determine the reference amount of the aerated food by adjusting for the difference in density of the aerated food relative to the density of the appropriate reference food provided that the manufacturer will show FDA detailed protocol and records of all data that were used to determine the density-adjusted reference amount for the aerated food. The reference amount for the aerated food shall be rounded to the nearest 5 g increment. Such products shall bear a descriptive term indicating that extra air has been incorporated (e.g., whipped, aerated). The density-adjusted reference amounts described above may not be used for cakes except for cheese cake. The differences in the densities of different types of cakes having different degrees of air incorporation have already been taken into consideration in determining the reference amounts for cakes in § 101.12(b). In determining the difference in density of the aerated and the regular food, the manufacturer shall adhere to the following:

(1) The regular and the aerated product must be the same in size, shape, and volume. To compare the densities of products having nonsmooth surfaces (e.g., waffles), manufacturers shall use a device or method that ensures that the volumes of the regular and the aerated products are the same.

(2) Sample selections for the density measurements shall be done in accordance with the provisions in § 101.9(e).

(3) Density measurements of the regular and the aerated products shall be conducted by the same trained operator using the same methodology (e.g., the same equipment, procedures, and techniques) under the same conditions.

(4) Density measurements shall be replicated a sufficient number of times to ensure that the average of the measurements is representative of the true differences in the densities of the regular and the "aerated" products.

(f) The reference amount for products that represent two or more foods packaged and presented to be consumed together (e.g., peanut butter and jelly, cracker and cheese pack, pancakes and syrup) shall be the sum of the reference amounts for individual foods in the package if the reference amount for the product is not listed in paragraph (b) of this section.

(g) The reference amount set forth in paragraphs (b) through (f) of this section shall be used in determining whether a product meets the criteria for nutrient content claims, such as "low calorie," and for health claims. If the serving size declared on the product label differs from the reference amount, and the product meets the criteria for the claim only on the basis of the reference amount, the claim shall be followed by a statement that sets forth the basis on which the claim is made. That statement shall include the reference amount as it appears in § 101.12(b) followed, in parenthesis, by the amount in common household measure if the reference amount is expressed in measures other than common household measures (e.g., for a beverage, "Very low sodium, 35 mg or less per 240 mL (8 fl oz)").

(h) The Commissioner of Food and Drugs, either on his or her own initiative or in response to a petition submitted pursuant to part 10 of this chapter, may issue a proposal to establish or amend a reference amount in § 101.12(b). A petition to establish or amend a reference amount shall include:

(1) Objective of the petition;

(2) A description of the product;

(3) A complete sample product label including nutrition label, using the format established by regulation;

(4) A description of the form (e.g., dry mix, frozen dough) in which the product will be marketed;

(5) The intended dietary uses of the product with the major use identified (e.g., milk as a beverage and chips as a snack);

(6) If the intended use is primarily as an ingredient in other foods, list of foods or food categories in which the product will be used as an ingredient with information on the prioritization of the use;

(7) The population group for which the product will be offered for use (e.g., infants, children under 4 years of age);

(8) The names of the most closely-related products (or in the case of foods for special dietary use and imitation or substitute foods, the names of the products for which they are offered as substitutes);

(9) The suggested reference amount (the amount of edible portion of food as consumed, excluding bone, seed, shell, or other inedible components) for the population group for which the product is intended with full description of the methodology and procedures that were used to determine the suggested reference amount. In determining the reference amount, general principles and factors in paragraph (a) of this section should be followed.

(10) The suggested reference amount shall be expressed in metric units. Reference amounts for fluids shall be expressed in milliliters (mL). Reference amounts for other foods shall be expressed in grams (g) except when common household units such as cups, tablespoons, and teaspoons, are more appropriate or are more likely to promote uniformity in serving sizes declared on product labels. For example, common household measures would be more appropriate if products within the same category differ substantially in density such as frozen desserts.

(i) In expressing the reference amounts in mL, the following rules shall be followed:

(A) For volumes greater than 30 mL, the volume shall be expressed in multiples of 30 mL.

(B) For volumes less than 30 mL, the volume shall be expressed in mL equivalent to a whole number of teaspoons or one tablespoon, i.e., 5, 10, or 15 mL.

(ii) In expressing the reference amounts in g, the following general rules shall be followed:

(A) For quantities greater than 10 g, the quantity shall be expressed in nearest 5 g increment.

(B) For quantities less than 10 g, exact g weights shall be used.

(11) A petition to create a new subcategory of food with its own reference amount shall include the following additional information:

(i) Data that demonstrate that the new subcategory of food will be consumed in amounts that differ enough from the reference amount for the parent category to warrant a separate reference amount. Data must include sample size; and the mean, standard deviation, median, and modal consumed amount per eating occasion for the petitioned product and for other products in the category, excluding the petitioned product. All data must be derived from the same survey data.

(ii) Documentation supporting the difference in dietary usage and product characteristics that affect the consumption size that distinguishes the

petitioned product from the rest of the products in the category.

(12) A claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter; and

(13) In conducting research to collect or process food consumption data in support of the petition, the following general guidelines should be followed.

(i) Sampled population selected should be representative of the demographic and socioeconomic characteristics of the target population group for which the food is intended.

(ii) Sample size (i.e., number of eaters) should be large enough to give reliable estimates for customarily consumed amounts.

(iii) The study protocol should identify potential biases and describe how potential biases are controlled for or, if not possible to control, how they affect interpretation of results.

(iv) The methodology used to collect or process data including study design, sampling procedures, materials used (e.g., questionnaire, interviewer's manual), procedures used to collect or process data, methods or procedures used to control for unbiased estimates, and procedures used to correct for nonresponse, should be fully documented.

(14) A statement concerning the feasibility of convening associations, corporations, consumers, and other interested parties to engage in negotiated rulemaking to develop a proposed rule consistent with the Negotiated Rulemaking Act (Pub. L. 101–648).

Dated: October 27, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

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Department of Health and Human Services

Food and Drug Administration

21 CFR Part 1, et al.

Food Labeling; General Provisions; Nutrition Labeling; Label Format; Nutrient content Claims; Health Claims; Ingredient Labeling; State and Local Requirements; and Exemptions; Final Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 5 and 101

[Docket Nos. 91N-0384 and 84N-0153]

RIN 0905-AD08 and 0905-AB68

Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its food labeling regulations to: (1) Provide definitions for specific nutrient content claims using the terms "free," "low," "lean," "extra lean," "good source," "high," "reduced," "light" or "lite," "less," "fewer," and "more" and provide for their use on the food label; (2) provide for the use of implied nutrient content claims; (3) define and provide for the use of the term "fresh;" and (4) address the use of the terms "natural" and "organic." This action is part of the food labeling initiative of the Secretary of Health and Human Services (the Secretary) and in response to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments).

EFFECTIVE DATE: February 14, 1994, except §§ 101.10 and 101.13(q)(5) concerning restaurant firms consisting of 10 or less individual restaurant establishments for whom these sections will become effective on February 14, 1995.

FOR FURTHER INFORMATION CONTACT: Elizabeth J. Campbell, Center for Food Safety and Applied Nutrition (HFF-312), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5229.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Background

In the **Federal Register** of November 27, 1991 (56 FR 60421), FDA published a proposed rule (entitled "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms" hereinafter referred to as the general principles proposal) to: (1) Define nutrient content claims (also known as descriptors) and to provide for their use on foods labels; (2) define specific nutrient content claims that include the terms "free," "low," "source," "reduced," "light" or "lite," and "high"; (3) provide for comparative claims using the terms "less," "fewer," and "more"; (4) set forth specific requirements for sodium and calorie claims; (5) establish procedures for the submission and review of petitions regarding the use of nutrient content claims; (6) revise § 105.66 (21 CFR 105.66), to solely cover foods for special dietary use in reducing or maintaining body weight; (7) establish criteria for the appropriate use of the term "fresh;" and (8) address the use of the term "natural." A document correcting various editorial errors in that proposed rule was published in the **Federal Register** of March 6, 1992 (57 FR 8189).

In the same issue of the **Federal Register** (56 FR 60478), FDA also published a proposed rule (entitled "Food Labeling: Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food" hereinafter referred to as the fat/cholesterol proposal) to define and provide for the proper use of the nutrient content claims "fat free," "low fat," "reduced fat," "low in saturated fat," "reduced saturated fat," "cholesterol free," "low cholesterol," and "reduced cholesterol." A document correcting various editorial errors in the fat/cholesterol proposal was also published in the **Federal Register** of March 6, 1992 (57 FR 8177). The agency published the fat/cholesterol proposal as a separate document from the general principles proposal, even though it had based the two documents on the same statutory provisions, because it had published a tentative final rule on cholesterol content claims in the **Federal Register** of July 19, 1990 (55 FR 29456). FDA included proposed definitions for fat and fatty acid content claims in the fat/cholesterol proposal because of the interrelationship among these nutrients and cholesterol in the etiology of cardiovascular disease.

Also in the same issue of the **Federal Register** (56 FR 60507), FDA published a proposed rule (entitled "Food Labeling: 'Cholesterol Free,' 'Low Cholesterol,' and '——— Percent Fat Free' Claims") to define "cholesterol free" and "low cholesterol" and to provide for the proper use of these terms and the term "——— percent fat free." The proposed rule was intended to ensure on an interim basis that these terms are not used in a manner that is misleading to consumers.

The general principles proposal (56 FR 60421) and the fat/cholesterol proposal (56 FR 60478) were issued as part of the agency's food label reform initiative and in response to the 1990 amendments (Pub. L. 101-535). The food label reform began in 1989 when FDA published an advance notice of proposed rulemaking (ANPRM) that announced a major initiative concerning the use of food labeling as a means for promoting sound nutrition. The following year (November 8, 1990), the President signed the 1990 amendments into law. This legislation clarified and strengthened FDA's legal authority to require nutrition labeling on foods and to establish those circumstances whereby claims can be made about nutrients in foods. Now as FDA prepares to implement the new regulations, the agency reiterates that the 1990 amendments have three basic objectives. They are: (1) To make available nutrition information that can assist consumers in selecting foods that can lead to healthier diets, (2) to eliminate consumer confusion by establishing definitions for nutrient content claims that are consistent with the terms defined by the Secretary, and (3) to encourage product innovation through the development and marketing of nutritionally improved foods. With these goals in mind, the agency believes that the new regulations will reestablish the credibility of the food label.

With respect to nutrient content claims, the 1990 amendments amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 403(r)(1)(A) of the act (21 U.S.C. 343(r)(1)(A)) which states that a food is misbranded if it bears a claim in its label or labeling that either expressly or implicitly characterizes the level of any nutrient of the type required to be declared as part of the nutrition labeling, unless such claim is made in accordance with section 403(r)(2).

The agency received over 1,800 comments in response to the general principles proposal, and 500 comments in response to the fat/cholesterol proposal. Each comment addressed one or more of the provisions in these proposals. The comments were from a variety of sources including consumers, health care professionals, trade organizations, manufacturers, consumer advocacy organizations, foreign governments, and State and local governments. Many of the comments generally agreed with one or more provisions of the proposal, without providing other grounds for support other than those provided by FDA in the preamble to the proposal. Several comments addressed issues covered by other proposals that are a part of this overall food labeling initiative and will be addressed in those final documents, while other comments addressed issues

outside the scope of the proposal and will not be discussed here.

A number of comments to the general principles and fat/cholesterol proposals suggested modifications in, or were opposed to, various provisions of the proposals. Because the general principles governing both documents are identical, and because the issues raised in comments responding to the two proposals are similar, FDA has chosen to address the comments on, and to establish regulations based on, both proposals in this single document. The agency will summarize the issues raised in the comments and address them in this document.

The agency also notes that it received about 125 comments on the tentative final rule on cholesterol content claims after the closing date for comments of August 20, 1990. These comments were not addressed in the fat/cholesterol proposal. However, the agency has reviewed these comments and is also responding to them in this final rule.

As for the third proposal on cholesterol claims and "——— percent fat free," FDA has concluded that this final rule will provide adequate assurance to consumers that these terms are not used in a misleading manner. Therefore, the agency is announcing that it is withdrawing this proposal. Comments that were submitted on this proposal (Docket No. 84N–153A) have been considered in the development of this final rule. They will be addressed with the other comments on the general principles proposal and the fat/cholesterol proposal in this final rule.

B. Foods for Special Dietary Use

In 1978, FDA promulgated regulations in § 105.66 pertaining to the use of the terms "low calorie" and "reduced calorie" on foods represented as or purporting to be for special dietary use in the maintenance or reduction of caloric intake or body weight. Under the 1990 amendments, FDA is defining the terms "low" and "reduced" as nutrient content claims that identify the level of a nutrient in a food intended for consumption by the general population and is adopting specific definitions for the terms "low calorie" and "reduced calorie." To reflect these actions, the agency is revising § 105.66 to delete the provisions that define "low calorie" and "reduced calorie." Because § 105.66 was adopted under the authority of section 403(j) of the act, these revisions must be made in accordance with the formal rulemaking procedures in section 701(e) of the act (21 U.S.C. 371(e)). Under these procedures, there is an opportunity to object to a final rule and to request a public hearing based upon such objection. Such an opportunity is not provided as part of the notice-and-comment rulemaking procedures that are appropriate for most of the rest of the rulemaking that FDA is doing in response to the 1990 amendments. Therefore, for administrative convenience, FDA is publishing the final rule amending § 105.66 elsewhere in this issue of the **Federal Register**.

II. General Principles for Nutrient Content Claims

A. Legal Basis

FDA has the authority to issue this final rule regarding nutrient content claims under sections 201(n) (21 U.S.C. 321(n)), 403(a), 403(r), and 701(a) of the act. These sections authorize the agency to adopt regulations that prohibit labeling that: (1) Is false or misleading in that it fails to reveal facts that are material in light of the representations that are made with respect to consequences that may result from use of the food, or (2) uses terms to characterize the level of any nutrient in a food that has not been defined by regulation by FDA.

B. Scope

Section 403(r)(1)(A) of the act provides that claims, either expressed or implied, that characterize the level of a nutrient which is of a type required to be declared in nutrition labeling may not be made on the label or in labeling of any food intended for human consumption that is offered for sale unless the claim is made in accordance with section 403(r)(2). In the general principles proposal, the agency proposed to incorporate this general statutory requirement into proposed § 101.13(a) and (b) and to establish a new § 101.13 and the applicable regulations in part 101, subpart D (21 CFR part 101) as the provisions governing nutrient content claims.

1. One comment stated that the claims that are subject to the proposed regulations, which implement section 403(r)(1)(A) of the act, are appropriately called "nutrient descriptors," not "nutrient content" claims as proposed by FDA. The comment pointed out that the statutory language of the 1990 amendments does not include the phrase "nutrient content" claim. It stated that the words in section 403(r)(1)(A) of the act refer to a covered claim as a claim that "characterizes the level of any nutrient * * *." The comment's purpose in contrasting the wording of the proposal and that of the statute is to limit the applicability of the regulation to claims about the level of a nutrient and to exclude statements about amounts of nutrients. The comment stated that simple factual information about the nutrient content of a food, for which no characterizing claims are made, is explicitly excluded from regulation under section 403(r)(1)(A) of the act. It said that the last sentence in section 403(r)(1) of the act provides that a statement of the type contained in nutrition labeling—for example, that a food contains 25 calories per serving, or 10 percent of the U.S. Recommended Daily Allowance (U.S. RDA) for vitamin C, or 50 milligrams (mg) of sodium—is not a claim characterizing the level of the nutrient. The comment requested that to assure that the regulations for section 403(r)(1)(A) of the act claims are not misunderstood to extend to nutrient statements that do not "characterize the level of a nutrient," all references to "nutrient content" claims be redesignated to "nutrient descriptors" or "nutrient descriptor claims."

The agency advises that while it can agree that the terms "nutrient descriptor" and "nutrient descriptor claims" may be used to describe the claims subject to section 403(r)(1)(A) of the act and these regulations, it does not agree that the scope of the statute and the regulations excludes statements of the amount of a nutrient in a food. The distribution the comment draws between "nutrient descriptors" and "nutrient content" claims is unpersuasive. In fact, one of the sponsors of the 1990 amendments in the Senate specifically used the term "nutrition content claim" to refer to claims covered under section 403(r)(1)(A) (136 Cong. Rec. S16608 (October 24, 1990)). Moreover, the statement in section 403(r)(1) of the act referred to by the comment as excluding from coverage statements of the type contained in nutrition labeling, in fact excludes "a statement of the type required by paragraph (q) that appears as part of the nutrition information required or permitted by such paragraph * * *." FDA stated in the general principles proposal (56 FR 60421 at 60424), that the legislative history of this provision specifically states that the identical information will be subject to the descriptor requirements if it is included in a statement in another portion of the label (136 Congressional Record H5841 (July 30, 1990)). In addition, section 403(r)(2)(E) of the act specifically exempts from the limitations on claims established in section 403(r)(2)(A)(i) through (r)(2)(A)(v), "a statement in the label or labeling of food which describes the percentage of vitamins and minerals in

the food which describes the percentage of such vitamins and minerals recommended for daily consumption by the Secretary." If such declarations as "10 percent of the U.S. RDA for vitamin C" were not within the scope of section 403(r)(1)(A) of the act, there would have been no need for Congress to provide a specific exemption for such claims. Furthermore, section 3(b)(1)(A)(iv) of the 1990 amendments provides that the mandated regulations "shall permit statements describing the amount and percentage of nutrients in food which * * * are consistent with the terms defined in section 403(r)(2)(A)(i) of such Act." Again, if statements of the amount and percentage of nutrients were not subject to section 403(r)(1)(A) of the act, there presumably would have been no need for Congress to express its desire that such claims be permitted by the regulations. Accordingly, FDA concludes that section 403(r)(1)(A) of the act and therefore these final regulations apply to statements of the amount of a nutrient in food as well as to statements of the level of a nutrient in food. Thus, FDA's use of the term "nutrient content claims" is fully consistent with the act.

2. In proposed § 101.13(b)(3), FDA stated that no nutrient content claims could be made on foods specifically intended for infants and children less than 2 years of age.[1] A few comments stated that the prohibition was inconsistent with the overall intent of the 1990 amendments, which is to avoid consumer confusion by providing relevant and useful information to consumers by which they can make informed food choices. The comments said that such a prohibition would unfairly restrict nutrient content claims on foods primarily intended for infants and children less than two years of age while allowing such claims on products that, though aimed primarily at adults and older children, are actively promoted either on the label or in the advertising as being for use by infants or children less than 2 years of age. Although the comments recognized the validity of this prohibition with respect to certain nutrients, they requested that the agency provide an exception from this general prohibition for claims about other nutrients. Specifically, the comments requested changes that would, among other things, allow "no salt added" and "no sugar added" claims, permit "high protein cereal" to be so labeled, allow the percentage of the Reference Daily Intake (RDI) of a vitamin or mineral to be stated on the principle display panel (PDP), allow claims about fortification of the product with vitamins and minerals, and allow products to be labeled with a statement of identity that includes an ingredient that is a standardized food whose name includes a claim (e.g., "juice with low fat yogurt") without the normal referral statements required for nutrient content claims. The comments maintained that these exceptions would place infant foods on a par with foods intended for the general population that are promoted for infants and children less than 2 years of age and would allow continuation of the long standing practice of providing information relevant to the perceived special nutritional needs of this group.

The comments added that permitting "no sugar added" and "no salt added" claims on these foods is consistent with recent research that shows that sugar and salt are not necessary for a baby's palate, and that feeding sweetened or salted foods to infants can enhance their preference for such foods which is carried into adult eating patterns. Such "no salt added" and "no sugar added" claims, the comments said, would also allow manufacturers to highlight products that are consistent with dietary recommendations for infants and children less than 2 years of age provided over the past 11 years by health authorities, including the American Academy of Pediatrics, the U.S. Surgeon General, and U.S. Department of Agriculture (USDA)/FDA Dietary Guidelines.

In response to the comments, FDA has reconsidered the propriety of nutrient content claims on foods specifically intended for infants and children less than 2 years of age. The agency now believes that the complete prohibition of nutrient content claims on foods for infants and children less than 2 years of age may have been overly broad. Although current dietary recommendations for Americans do not include infants and children less than 2 years of age, there is no basis in the 1990 amendments to limit nutrient content claims to only foods intended for the population over the age of 2. In addition, the agency cannot discount the possibility that information may be developed that will allow the agency to define specific claims on the level of a nutrient in the food that are appropriate for foods for infants and children less than 2 years of age. Such claims are subject to the requirements of section 403(r) of the act.

Accordingly, the agency has revised new § 101.13(b)(3) to state that no nutrient content claims may be made on foods for infants and children less than 2 years of age unless a regulation specifically authorizing such a claim has been established in part 101, subpart D, among certain other parts of the regulations. Interested persons may submit a petition under new § 101.69 with appropriate information that would provide a basis on which the agency could determine that a specific nutrient content claim would be appropriate for foods for infants and children less than 2 years of age.

The agency also notes that it can permit, by regulation under section 403(j) of the act, claims that are made because of the special dietary usefulness of the food. The agency intends to use its authority under section 403(j) and (r) of the act to regulate foods for infants and children less than 2 years of age. In evaluating a petition for the use of a claim, it will determine under which authority of the act the claim is appropriately regulated. Accordingly, the agency is including in new § 101.13(b)(3) a reference to regulations in part 105 among those regulations that permit claims on foods for infants and children less than 2 years of age. In addition, in the general principles proposal, FDA stated that the regulations in part 107, issued under the authority of section 412 of the act (21 U.S.C. 350), permit certain nutrient content claims on infant formulas. For clarity, FDA has also included part 107 among the regulations permitting claims in new § 101.13(b)(3).

The comments that requested permission to make certain claims did not provide, nor has the agency developed, a sufficient basis on which to conclude that any of the nutrient content claims that FDA is defining, or any other claims, are appropriate for food specifically intended for infants and children less than 2 years of age. Although the agency is not prohibiting the statement of identity, "juice with low fat yogurt" because low fat yogurt is a standardized food and the statement of identity accurately characterizes the product, the agency notes that the other statements about the fat content of a product would be inappropriate on a food intended for infants and children less than 2 years of age. Such a food would be inconsistent with the guidance provided by various health authorities, which was noted in the general principles proposal and

[1] The agency notes that in the comments on the mandatory nutrition labeling proposal, one comment stated that the term "toddler" was improperly used. In the final rule for mandatory nutrition labeling, the agency agrees with this comment and is replacing the term "toddler" with the phrase "children less than 2 years of age". The term "toddler" was also used throughout the nutrient content claims proposal. Therefore, for clarity and consistency, the agency is using the phrase "children less than two years of age" in lieu of the term "toddler" in this final rule.

published in a report by the National Heart, Lung, and Blood Institute, National Cholesterol Education Program (NCEP) (Ref. 1), that fat and cholesterol should not be restricted in the diets of infants.

The agency has also considered the request to authorize the use of "no sugar added" and "no salt added" claims on foods specifically intended for infants and children less than 2 years of age. The terms "no sugar added" and "no salt added" have been defined as nutrient content claims for adult foods in §§ 101.60(c)(2) and 101.61(c)(2) and imply that the food is either "low" or "reduced" in calories or sodium, respectively. However, because dietary guidelines urging Americans to moderate their intake of sodium and salt are specifically for adults and children over 2 years of age, claims on foods intended specifically for infants and children less than 2 years of age are not appropriate. Therefore, the agency is not granting this request.

However, terms "unsweetened" and "unsalted" can be viewed differently. In the general principles proposal (56 FR 60421 at 60437), the agency cited the September 22, 1978, final rule on label statements for special dietary foods (43 FR 43238). In that final rule, FDA concluded that the term "unsweetened" was a factual statement about an organoleptic property of a food. The general principles proposal stated that the agency was not aware of any reason to change this view. Although the agency did not propose in the general principles proposal to define the terms "unsweetened" for foods intended specifically for infants and children less than 2 years of age the agency considers that this statement on baby food, as on adult food, is not intended as a nutrient content claim but as a taste claim. As such it is consistent with the recommendations of the American Academy of Pediatrics (Ref. 33) and the Surgeon General's report (Ref. 4) that sugar should be added sparingly, if at all, to foods prepared for normal infants. Consequently, the agency believes that highlighting that a food is unsweetened may provide useful information about the organoleptic properties of the food. Accordingly, the agency is adding foods intended specifically for infants and children less than 2 years of age to the exceptions provided in § 101.60(c)(3) for the term "unsweetened" as a factual statement.

Similarly, the agency believes that a statement that the food is "unsalted" on foods for infants and children less than 2 years of age can also be viewed as a statement about the organoleptic properties of the food. This term is also consistent with the recommendation from the same health authorities, noted in the comments, that, similar to sweetness, a salty taste is not necessary for an infant's palate. The agency recognizes that although the word "sweet" is used exclusively to identify a taste, the word "salt" may be associated with the level of a nutrient or with the taste of a food. However, consistent with the use of the word "unsweetened" as a statement of taste, the agency is permitting the term "unsalted" to be used on foods intended exclusively for infants and children less than 2 years of age. The agency is providing in § 101.61(c)(3) that "unsalted" may be used on these foods provided that it refers only to the taste of the food and is not otherwise false and misleading.

Finally, in keeping with section 403(r)(2)(E) of the act as amended, which permits, without further definition, label statements that describe the percentage of vitamins and minerals in the food relative to the RDI, the agency concludes that it is appropriate to permit statements of this type on foods intended specifically for infants and children less than 2 years of age. Elsewhere in this issue of the **Federal Register**, FDA is listing values that may be used as RDI's specifically for infants and for children under 4 years of age. These reference amounts provide an appropriate basis for label statements on foods intended specifically for infants and children less than 2 years of age that describe the percentage of vitamins and minerals relative to the RDI. Accordingly, the agency is clarifying its intentions by amending new § 101.13(q)(3) to specifically include foods for infants and children less than 2 years of age among those that may bear a percent RDI statement.

The agency has not prohibited claims on foods that are promoted for infants and children under the age of 2 but that are intended primarily for adults and older children. However, the agency cautions that any nutrient content claims made on such products in association with a statement about use of the food for infants and children under the age of 2 would be misleading under section 403(r) of the act unless such claim has specifically been permitted for such a population by regulation.

C. Labeling Mechanics

The 1990 amendments do not include specific limits on the prominence of nutrient content claims. However, FDA did propose certain requirements on how claims are to be presented. In the general principles proposal (56 FR 60421 at 60424), FDA proposed to require in § 101.13(f) that a nutrient content claim be, in type size and style, no larger than the statement of identity. The agency stated that this proposed requirement would ensure that descriptors are not given undue prominence. The agency proposed this requirement under section 403(f) of the act and under its general authority under section 403(r). Section 403(f) of the act states that a food is misbranded if any statement required by or under the authority of the act is not placed on the label with such conspicuousness, as compared to other words, statements, designs, or devices, as to render it likely to be understood by the ordinary consumer.

Section 403(r)(2)(B) of the act states that if a nutrient content claim is made, the label or labeling of the food shall contain, prominently and in immediate proximity to such claim, a statement referring the consumer to the nutrition label (i.e., "See ———— for nutrition information"). FDA proposed to incorporate this requirement in § 101.13(g).

Section 403(r)(2)(B) of the act requires that the referral statement appear prominently, but it does not contain specific requirements such as to type size or style. However, section 403(r)(2)(A)(iii) through (r)(2)(A)(v) of the act require that statements that disclose the level of fat, saturated fat, or cholesterol, which must be presented in conjunction with certain nutrient content claims, "have appropriate prominence which shall be no less than one-half the size of the claim." For consistency and because the referral statement and the statement disclosing the level of another nutrient must both be in immediate proximity to the claim, and therefore adjacent to one another, the agency tentatively concluded that these statements should be of the same type size. Therefore, the agency proposed in § 101.13(g)(1) that the referral statement be in type one-half that of the claim, but in no case less than one-sixteenth of an inch, consistent with other minimum type size requirements for mandatory label information.

3. Many comments stated that no type size requirements for either nutrient content claims or referral statements (other than those specifically included in section 403(r)(2)(A)(iii) through (r)(2)(A)(iv)) are mandated by the 1990 amendments, and that the agency should not impose requirements beyond those included in these amendments.

While the 1990 amendments do not specify type size requirements for nutrient content claims or for the

referral statement, the act must be read as a whole. Section 403(f) of the act requires that information required under the act be placed on the label with such conspicuousness as to render it likely to be read. FDA has, therefore, included those prominence requirements in these regulations that it finds necessary to ensure that this requirement is satisfied with respect to the information required under the 1990 amendments.

1. Relationship of size of nutrient content claim to statement of identity

4. Some comments suggested that the type size for claims be limited to a size no larger than the most prominent type size on the PDP. Some comments suggested that the type size should not exceed either the size of, or one-half the size of, the largest type or brand name. Some of these comments stated that these alternatives will allow manufacturers more flexibility and be more in line with the Executive Order 12291. Several comments stated that there is no reason to connect type size of the nutrient content claim to that of the statement of identity because if the nutrient content claim is disproportionately large, the statement of identity as well as other mandatory information on the PDP, such as net quantity of contents, will be so obscured or small as to violate existing section 403(f) of the act.

The agency rejects these comments. The nutrient content claim and the statement of identity are two of the most important pieces of information on the PDP. Given the limited amount of space on the PDP, the agency finds that it is necessary to link the size of the two pieces of information, so that manufacturers, can, and will, give appropriate prominence to each of them in planning their labels. The options suggested by the comments to unlink the size of the nutrient content claim from the statement of identity could result in a claim being unduly prominent. It would not be consistent with the goal of adopting regulations for the efficient enforcement of the act if the agency's regulations created a situation in which violations of the act were likely to develop. Thus, the agency rejects those options. However, the agency does agree that more flexibility with respect to the size of the nutrient content claim is appropriate.

5. Several comments stated that claims should have maximum prominence and be permitted to be of a type size greater than the statement of identity, especially when the claim is included in a brand name, since claims both provide important information to the consumer and serve to draw consumer attention to a specific product among other similar products. Several comments stated that the claim should not be more than twice the size of the statement of identity to provide for flexibility in communicating the claim effectively. Some comments stated that this alternative will allow manufacturers more flexibility and be more in line with the Executive Order 12291.

FDA recognizes the concerns expressed in these comments. FDA has reconsidered the proposed limit on type size for nutrient content claims and concludes that the proposed limit may unduly restrict the effectiveness of claims. FDA is concerned that, as a result, the incentives for manufacturers to innovate and improve their food products may be reduced. As some comments pointed out, style and format play important roles in effective marketing which is important not only in selling the product but in bringing the healthful attributes of the product to consumers' attention. The alternative presented in the comments of limiting the claim to not more than twice the size of the statement of identity provides for the flexibility requested to further the effectiveness of claims, while ensuring a certain proportionality of these two important pieces of information on the PDP. Therefore, the agency is revising new § 101.13(f) to require that the claim be no larger than two times the statement of identity.

2. Referral statements

6. Several comments stated that referral statements are redundant if the claim appears on the information panel with complete nutrition information. Other comments stated that these statements contribute to label clutter and cause the PDP to look like an information panel.

In response to the first group of comments, the agency points out that under proposed § 101.13(g)(2), a referral statement is not required when a claim appears on the information panel. More importantly, the requirement for a referral statement when a claim is made is statutory. Section 403(r)(2)(B) of the act specifically provides that the label contain this statement prominently and in immediate proximity to the nutrient content claim. Although the referral statement does add to the information in the PDP, this statement is necessary to ensure that consumers fully understand the nutrient content claim that is being made.

7. Several comments stated that referral statements, if required at all, should be one-half the size of the claim. Other comments stated that if a minimum type size requirement is necessary for the referral statement, FDA should specify only a minimum type size of one-sixteenth of an inch, which is the minimum type size prescribed for most mandatory information on a food label. Other comments suggested that referral statements if required at all, should be a minimum of one-sixteenth of an inch, or be of a minimum type size consistent with that required for the net quantity of contents statement in § 101.105(i) (which varies from one-sixteenth of an inch to one-quarter of an inch depending upon the area of the PDP), because this standard would assure a proportionality to the other printed material on the label.

The agency has considered these comments on the minimum type size of the referral statement. FDA agrees that it is not necessary to link the type size of the referral statement to that of the claim (as the proposal does). Such a requirement could contribute to label clutter. However, FDA does not agree that specifying only a minimum type size of one-sixteenth of an inch for the referral statement will assure adequate prominence for that statement, particularly on packages where the area of the PDP is large, and the claim is in large letters. Rather, FDA agrees that the requirements of section 403(f) and (r)(2)(b) of the act will be satisfied if the referral statement is presented in a type size consistent with the minimum type size requirements for the net quantity of contents declaration, which are linked to the area of the PDP. The proportionality between the size of the referral statement and the size of the label will ensure that the referral statement is presented with appropriate prominence.

However, FDA does not wish to inadvertently establish minimum type sizes for nutrient content claims. When the claim is less than twice what the minimum size of the referral statement would be given the size of the label and § 101.105(i), FDA believes that the type size of the referral statement may be less than that required under § 101.105 for net quantity of contents. In such circumstances, the referral statement is of appropriate prominence if it is at least one-half the size of the claim and not less than one-sixteenth of an inch. The agency believes that this approach to the type size requirement for the referral statement provides additional flexibility to firms in utilizing label space but still ensures adequate prominence for this statement.

Therefore, FDA is revising the referral statement requirement in new § 101.13(g)(1) to provide that the type

size of the referral statement be no less than that required by § 101.105(i) for net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the referral statement shall be no less than one-half the size of the claim but no smaller than one-sixteenth of an inch.

8. Several comments requested that FDA provide that the referral statement on labels bearing a nutrient content claim become optional after 2 years. The comments argued that after 2 years, consumers will have learned that information supporting the claim is elsewhere on the label.

Section 403(r)(2)(B) of the act does not provide any authority for the agency to make such a modification to the requirement for the referral statement. Therefore, the agency rejects this request.

D. Disclosure Statements

Section 403(r)(2)(B)(ii) of the act states that if a food that bears a nutrient content claim "contains a nutrient at a level which increases to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food in the total daily diet, the required referral statement shall also identify such nutrient," i.e., a disclosure referral statement. FDA referred to this level as the "disclosure level" in the general principles proposal (56 FR 60425). In proposed § 101.13(h), FDA defined such levels for fat, saturated fat, cholesterol, and sodium, based upon an approach that considered dietary recommendations for these nutrients, the number of servings of food in a day, and available information on food composition. The proposed provision set out the required contents of the referral statement that would result (56 FR 60421 at 60425).

9. Several comments supported the disclosure level concept. However, others expressed the view that the concept places emphasis upon a single food rather than on the total diet, with the result that a food is perceived by consumers as being "good food" or "bad food," based upon the presence or absence of a disclosure referral statement.

The disclosure statement is required under section 403(r)(2)(B)(ii) of the act, and the disclosure provision in this final rule is consistent with that requirement. However, FDA disagrees with the assertion that the presence of a disclosure statement on a food label will lead consumers to perceive that the labeled food is "bad," or that the absence of a disclosure statement on a food label will be perceived as "good." The disclosure statement specifically directs the consumer to the information panel for information about other nutrients in the food in addition to the nutrient for which disclosure is triggered, e.g., "See side panel for information about fats and other nutrients." Thus, consumers' attention will be directed to the nutrition label, and they will be able to utilize the information therein, not just the disclosure statement, as a basis for making a purchase decision about the food. The disclosure statement is not intended to serve as a primary basis for making a purchase decision. However, if a nutrient content claim is made, the label must provide the consumer with the facts that bear on the advantages asserted by the claim and with sufficient information to understand how the product fits into a total dietary regime.

10. Several comments noted that in the preamble of the general principles proposal (56 FR 60421 at 60425), the agency stated that "there are no generally recognized levels at which food components such as fat, saturated fat, cholesterol, or sodium in an individual food will pose an increased risk of disease," and that a similar statement appears in the preamble of the November 27, 1991, proposed rule entitled "Labeling; General Requirements for Health Claims for Food" (56 FR 60537 at 60543). Based on these statements, the comments reasoned, the agency would not be able to make the analysis required in section 403(r)(2)(B)(ii) of the act for including a disclosure statement in the referral statement.

The agency disagrees with the comments. Although the agency stated in the proposal that "there are no generally recognized levels at which nutrients such as fat, saturated fat, cholesterol, or sodium in an individual food will pose an increased risk of disease," and thus "if FDA were to attempt to set these (disclosure) levels on an individual food basis, it would not be possible to do so," the agency also specifically noted that the act directs the agency to take into account the significance of the food in the total daily diet when making its analysis for when a disclosure statement is required.

The analysis that the agency performed in arriving at the circumstances where a disclosure statement is required was based upon dietary guidelines, taking into account the significance of the food in the total daily diet. The analysis utilized the agency's proposed Daily Reference Value's (DRV's) for total fat, saturated fat, cholesterol, and sodium and estimates of the amounts of these nutrients in foods and the number of servings of food consumed in a day. Therefore, although the disclosure levels are applied to individual foods, the basis of their derivation is the total dietary intake of nutrients that may pose an increased risk of diet-related disease, and the difficulty in maintaining healthy dietary practice that is created if these nutrients are consumed in particular foods at levels that exceed those established as disclosure levels. Thus, the agency concludes that its statements in the proposal did not preclude it from performing this analysis, and that it performed its analysis in a manner consistent with the statute's guidance.

11. Some comments asserted that consumers should be warned if the level of certain nutrients poses an increased risk of disease, irrespective of whether a nutrient content claim is made.

The agency disagrees with these comments. Although section 403(r)(2)(B)(ii) of the act mandates that the agency require that referral statements identify particular nutrients in certain circumstances where health or nutrient claims are made, the act does not direct the agency to require the identification of such nutrients in instances where a claim is not made.

Under sections 201(n), 403(a), and 701(a) of the act, the agency could require the identification of nutrients that are present at levels that increase the risk of a disease or health-related condition in the absence of a claim. However, in the absence of a nutrient content claim, there would be no basis to conclude that consumption of the food would receive any particular emphasis as part of the total daily diet, and thus there would be no particular basis for concern, and hence for a warning, about the levels of fat, saturated fat, cholesterol, or sodium in the food. Only when the significance of the food in the total daily diet is highlighted, as it is when a nutrient content claim is made, does the level of these other nutrients become material not only for purposes of section 403(r)(2)(B)(ii) of the act but also for sections 201(n) and 403(a) of the act.

12. One comment expressed concern that the agency's establishment of disclosure levels will be an open invitation for product liability suits for all products exceeding the threshold amounts.

As stated above, the agency believes that "there are no generally recognized levels at which nutrients such as fat, saturated fat, cholesterol, or sodium in an individual food will pose an increased risk of disease." The

disclosure levels are not tied to concerns about consuming the individual food but to concerns that claims can mislead consumers about the significance of the food in the total daily diet, and that rather than facilitating compliance with dietary guidelines (see H. Rept. 101–538, 101st Cong., 2d sess. (October 1990)), such claims could make compliance with such guidelines more difficult if certain relevant information is not brought to the consumer's attention. The disclosure levels should be understood in this way. The agency wishes to make clear, however, as stated in the final rule on health claims, published elsewhere in this issue of the **Federal Register**, that foods that contain nutrients at levels that exceed the disclosure level are not unsafe, will not cause a diet related disease, and are not dangerous or "bad" foods.

13. Several comments suggested that levels other than 15 percent of the DRV should be used as the threshold level for disclosure statements. Some comments stated that a 20 percent level should be used because it is consistent with the definitions of "more" and "high" and supportable on the basis of estimates of food consumption. Another comment suggested a 7 1/2 percent level specifically for fat and saturated fat, believing that 15 percent is too high for these nutrients. Similar comments pertaining to a disqualifying level for a nutrient for a health claim in response to the November 27, 1991, proposal on "Labeling; General Requirements for Health Claims for Food," were received by the agency.

The statutory language defining a disclosure level for a nutrient in conjunction with a nutrient content claim is the same as that for a disqualifying level for the nutrient for a health claim. The agency is, therefore, adopting the same levels for the individual nutrients for both types of claims. The agency is modifying the disclosure levels in new § 101.13(h)(1) and the disqualifying levels in new § 101.14(a)(5) to 20 percent of the DRV. The rationale for increasing these levels to 20 percent of the DRV is given in the final rule on general requirements for health claims for food, which is published elsewhere in this issue of the **Federal Register**, and is incorporated herein. Therefore, the disclosure levels in new § 101.13(h) are being revised to 13.0 grams (g) of fat, 4.0 g of saturated fat, 60 mg of cholesterol and 480 mg of sodium per reference amount customarily consumed (hereinafter referred to as "reference amount"), per labeled serving size or for foods with reference amounts of 30 g or less or 2 tablespoons or less, per 50 g (for dehydrated foods that must have water added to them prior to typical consumption, the 50 g criterion applies to the "as prepared" form) (see also discussion in section III.A.1.b. of this document).

14. Several comments opposed the proposed requirement of § 101.13(h) that if a food contains more than the specified amounts of fat, saturated fat, cholesterol, or sodium per reference amount, per labeled serving size, or per 100 g, then the referral statement must include a disclosure statement. The comments stated that "per 100 g" unfairly discriminates against foods with standard serving sizes of less than 100 g, e.g., cheese, crackers, cookies, margarine, and butter. The comments further stated that the 100-g criterion makes little sense and should be eliminated.

The agency considered these comments and continues to believe that a weight-based criterion, in addition to the per reference amount and per labeled serving size criteria, is needed as a criterion for disclosure levels to ensure that if a claim is made for a food that is dense in fat, saturated fat, cholesterol, or sodium, the claim will not be misleading in light of the levels of fat, saturated fat, cholesterol, or sodium in the food. Therefore, the agency is retaining a weight-based criterion for disclosure levels in the final rule.

However, the agency agrees that the 100-g criterion is too restrictive and is modifying the criterion applied to disclosure levels in new § 101.13(h) and disqualifying levels in new § 101.14 to a weight-based criterion of 50 g that is applicable only to foods with reference amounts of 30 g or less or 2 tablespoons or less (see also discussion in section III.A.1. of this document). The rationale for this modification is fully set forth in the final rule on general requirements for health claims for food, published elsewhere in this issue of the **Federal Register** and is incorporated herein.

15. One comment contended that there is not an appropriate scientific basis for establishing a disclosure level for sodium.

The agency rejects the comment's assertion that the scientific evidence is not sufficient to support the establishment of a disclosure level for sodium. In the general requirements for health claims for food document and in the sodium/hypertension health claims document published elsewhere in this issue of the **Federal Register**, FDA responds to comments that assert that identifying sodium as a disqualifying nutrient for health claims is inappropriate and to comments that the scientific evidence relating sodium to hypertension is insufficient. Those responses are incorporated herein. The agency notes that the evidence from clinical trials supports that high sodium intake is related to high blood pressure, that the evidence from human observational studies is generally consistent and supportive, that the long-term prospective study data are sometimes inconclusive and sometimes supportive, and that there is significant scientific agreement among experts that this relationship exists. The agency concludes that the scientific basis is sufficient, and that sodium reduction is likely to benefit a significant portion of the general population.

However, as explained in the general requirements for health claims in food document published elsewhere in this issue of the **Federal Register**, in response to comments FDA is increasing the disqualifying/disclosure level to 20 percent of the DRV, as compared to 15 percent as proposed, and thus the level will be 480 mg per serving as compared with the proposed level of 360 mg.

E. Amount and Percentage of Nutrient Content Claims

In the general principles proposal (56 FR 60421 at 60426), FDA proposed to regulate the use of statements of amount (e.g., contains 2 g of fat) or that use a percentage (e.g., less than 1 percent fat) to describe the level of a nutrient in a food. The agency proposed in § 101.13(i) that foods bearing statements about the amount or percentage of a nutrient in food must meet the definition for "low" in the case of fat, saturated fat, sodium, and calories and "high" for fiber, vitamins, minerals, and other nutrients for which the term is defined.

16. Some comments expressed the view that statements regarding the amount and percentage of nutrients in food are confusing, deceptive, and misleading to most consumers and should not be permitted. One comment suggested that studies are needed to ascertain consumer perceptions in this area, and that amount or percentage labeling statements are not necessary on foods.

The agency is not persuaded that studies are needed to ascertain how these statements are understood by the consumer, or that it is necessary to ban these statements. The agency believes that statements concerning the amount and percentage of nutrients in food can provide useful information to consumers and flexibility to the food manufacturer in stating the nutritional attributes of a food. However, FDA recognizes that these statements can be

misleading. Therefore, FDA has carefully prescribed the circumstances in which such statements may be used in new § 101.13(i).

17. One comment stated that the 1990 amendments do not require FDA to limit amount or percentage statements about nutrient claims in the manner that the agency has proposed.

The 1990 amendments provide, in section 3(b)(1)(A)(iv), that FDA shall permit statements describing the amount and percentage of nutrients in food if they are not misleading, and if they are consistent with the terms defined by the agency. As discussed in the general principles proposal (56 FR 60421 at 60426), the legislative history of the 1990 amendments contemplates that the agency would define the circumstances by regulation "under which statements disclosing the amount and percentage of nutrients in food will be permitted" (136 Congressional Record, H5841–2 (July 30, 1990)). This portion of the legislative history states that "amount and percentage statements must be consistent with the terms that the Secretary has defined under section 403(r)(2)(A)(i) of the act [definition of descriptive terms] and they may not be misleading under section 403(a) in the current law." Thus, the agency believes that regulations to ensure that these statements will not be used in a misleading manner are consistent with the 1990 amendments. Therefore, the agency concludes that, consistent with the intent of the 1990 amendments, regulations controlling the use of label statements that state the amount or percentage of a nutrient in a food are appropriate.

18. Several comments suggested that amount and percentage disclosure statements should be permitted without restriction if the statement is accompanied by appropriate explanatory information, and as long as the statements are not misleading. Additionally, the comments implied that the agency should not prohibit or restrict the use of claims that convey the amount and percentage of nutrients in food because this information can direct consumers to the favorable characteristics of a food and allow consumers to compare food products within the same product line.

Other comments stated that foods should not be required to comply with such strict requirements before they can use amount and percentage statements. These comments contended that the agency has ample authority to regulate amount and percentage statements under section 403(a) of the act.

FDA finds that some restrictions on amount and percent claims are necessary. FDA advises that numerous consumer complaints, comments on a 1989 ANPRM on food labeling (54 FR 32610, August 8, 1989), and comments on the general principles and fat/cholesterol proposals about misuse of label statements such as "—— percent fat free" have persuaded the agency that, in many cases, statements regarding the amount and percentage of nutrients in food have been misleading. Moreover, section 3(b)(1)(A)(iv) of the 1990 amendments prescribes specific conditions in which such claims may be made. Therefore, FDA believes that it is necessary to limit the use of such statements in a manner that ensures that they will not mislead consumers, and that, if they implicitly characterize the level of a nutrient, they are consistent with the terms defined under section 403(r)(2)(A)(i) of the act. If amount and percentage statements are to be limited in this manner, the circumstances in which they can be used must be specifically presented. Thus, the agency concludes that, consistent with the 1990 amendments, it is necessary to limit by regulation the use of label statements that state the amount or percentage of a nutrient in a food. Therefore, as discussed in response to the next comment, the final regulation will include a provision in new § 101.13(i) limiting the use of such statements.

19. Many comments requested that FDA consider revisions in the provisions for amount and percent statements in the final rule. Some comments stated that the agency should not prohibit the use of amount and percentage statements on foods that do not meet the definition for "low" or "high" for a particular nutrient. One comment argued that, as proposed, this regulation would deprive consumers of useful information, hinder consumers from making informed food choices, and prohibit consumers from quickly differentiating between similar foods within the same product category. A similar comment suggested that FDA should permit the use of amount and percentage statements on foods where the value in the factual statement does not exceed the proposed nutrient claim disclosure level for single foods.

A few comments asserted that amount and percentage labeling statements should be permitted on foods that qualify for a "source" claim. Another comment suggested that FDA should permit the use of amount and percentage statements on foods that qualify for a "reduced" claim.

Some comments suggested that FDA should permit the use of amount and percentage statements to convey information regarding the calorie content per serving of food, consistent with the number of calories that appear on the nutrition panel. Other comments suggested that it is customary for consumers to refer to calorie information when selecting foods, and, therefore, the use of amount and percentage statements to describe this information should be permitted in the final regulation.

A few comments suggested that amount and percentage statements about the sodium content of a food provides factual information to consumers and should be permitted. Another comment stated that very few foods could convey amount and percentage statements for sodium under the proposed provisions.

These comments have convinced the agency to reconsider the proposed provisions for statements concerning the amount and percentage of nutrients in foods. The agency believes that statements relating the amount and percentage of nutrients in foods are generally useful to consumers for such purposes as pointing out the level of a nutrient in the food and facilitating comparisons between foods. The proposed provisions for amount and percentage statements would have limited the use of these statements to only foods that are "low" or "high" in the particular nutrient. FDA believes that the provisions in the proposal were too restrictive because they would deny consumers the use of such statements to evaluate many foods. FDA has considered how to permit statements of amount and percent that implicitly characterize the level of a nutrient (e.g., "less than 10 grams of fat") in a manner that benefits consumers and also satisfies the requirements of the statute. FDA believes that these conditions are met when such amount and percentage statements about a nutrient are made on foods that meet the criteria for any nutrient content claim, including relative claims, for the nutrient. Such amount and percentage statements are useful in helping consumers identify foods that facilitate conformance to current dietary guidelines. This includes foods that are a "good source of" or foods "low" or "high" in a nutrient as well as, foods that are alternatives to other reference foods (e.g., foods that are "reduced" in a nutrient.

Thus the final rule has been revised in new § 101.13(i)(1) to provide that a statement of percent and amount may be contained on the label or in the labeling of a food that meets the definition for a claim (as defined in part 101, subpart D) for the nutrient that the label addresses.

The agency also believes that a statement about the amount and percentage of nutrients that implicitly characterize the level of the nutrient can provide useful information to consumers even if the food does not meet the criteria for a claim, provided the statement does not misleadingly imply that a food contains a small or large amount of a nutrient and makes clear whether the food meets one of the nutrient content claims that the agency is defining. In circumstances in which a food does not meet the criteria for a claim, an amount or percentage statement that implicitly characterizes the level of a nutrient, appearing by itself might be misinterpreted. Thus, the statement must be accompanied by a disclaimer such as "less than 10 grams of fat, not a low fat food" or "only 200 mg of sodium per serving, not a low sodium food." The disclaimer will not only make the claim not misleading, as required by section 3(b)(1)(A)(iv) of the 1990 amendments, it will also provide the means by which the amount or percentage can be declared consistently with section 403(r)(2)(A)(i) of the act by affirmatively stating that the amount does not meet the relevant definition.

To provide for statements about the amount or percentage of a nutrient in a food that implicitly characterize the level of the nutrient under these circumstances, FDA is adding new § 101.13(i)(2) to allow for the use of amount and percentage statements when the level of the nutrient does not meet the definition for a claim if a disclaimer accompanies the claim.

This revision also includes provisions for the location and type size of the disclaimer statement that require that the disclaimer be in easily legible print or type and in a size no less than required by § 101.105(i) for net quantity of contents except where the size of the claim is less than two times the size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than one-sixteenth inch. This approach has been fully discussed in response to comment 7 of this document.

Because these revisions permit the use of amount and percentage statements where a food qualifies for all relative claims, and not just "high" or "low," the agency is deleting from new § 101.13(i) the phrase that refers to these statements as implying that a food is "high or low" in a nutrient and is inserting language that states that these statements imply that the food "contains a large or small amount" of that nutrient.

In addition, based on the comments and its review of the 1990 amendments, FDA finds that there are some circumstances in which an amount claim cannot be considered to characterize in any way the level of a nutrient in a food. For example, the statement "100 calories" or "5 grams of fat" on the principal display panel of a food would be a simple statement of amount that, by itself, conveys no implied characterization of the level of the nutrient. As long as such a statement is not false or misleading, it can appropriately be included in food labeling. Therefore, FDA is providing in new § 101.13(i)(3) that an absolute statement of amount may be made without a disclaimer if "[t]he statement does not in any way implicitly characterize the level of the nutrient in the food, and it is not false, or misleading in any respect."

Finally, the agency is advising in new § 101.13(i)(4), for clarification, that amount and percentage statements made on labels or in labeling as "—— percent fat free" are not subject to the provisions of that paragraph. These statements are regulated separately under new § 101.62(b)(6). The agency believes this clarification is necessary because the preamble discussion in the general principles proposal supporting § 101.13(i) cited "—— percent fat free" as an example of a claim subject to section 3(b)(1)(A)(iv) of the 1990 amendments. While this example is appropriate, the agency is making it clear that the actual regulations governing "—— percent fat free" statements are provided in new § 101.62(b)(6) because those provisions differ from those of new § 101.13(i). The provisions for "—— percent fat free" statements are discussed below in the preamble section III.B.c.vi. [on Percent Fat Free] of this document.

F. Nutrition Labeling Required When a Nutrient Content Claim is Made

In the general principles proposal, the agency proposed (56 FR 60421 at 60426) in § 101.13(m) (redesignated as § 101.13(n) in this final rule) that a nutrient content claim may be used on the label or in labeling of a food, provided that the food bears nutrition labeling that complies with the requirements in proposed § 101.9 or, if applicable, proposed § 101.36.

20. The majority of comments addressing this issue favored the proposed requirement. One comment was concerned that requiring nutrition labeling on all foods bearing a claim will confuse consumers rather than empower them to make informed dietary selections.

The agency disagrees with the latter comment. Nutrition labeling is necessary when a claim is made to ensure that other important nutritional aspects of the food are presented along with that aspect highlighted by the claim. This fact is recognized in section 403(r)(2)(B) of the act, which requires that any nutrient content claim be accompanied by a statement referring the consumer to the nutrition label. Thus, nutrition labeling in the labeling of a food that bears a claim will assist consumers in making informed dietary selections because it provides them with additional important information about a food.

However, the Dietary Supplement Act of 1992 imposed a moratorium on the implementation of the 1990 amendments with respect to dietary supplements. Therefore, FDA is not adopting § 101.36 and has modified § 101.13(n) to reflect this fact. The agency has also added a reference to § 101.10 to cover the situation in which a nutrient content claim is made for restaurant food (see section IV. of this document).

G. Analytical Methodology

In the general principles proposal (56 FR 60421 at 60428), the agency proposed in § 101.13(n) (redesignated as new § 101.13(o) in this final rule) to determine compliance with the requirements for nutrient content claims using the analytical methodology prescribed for determining compliance with nutrition labeling in proposed § 101.9.

21. A comment expressed the view that specifying methods such as official Association of Official Analytical Chemists (AOAC International) methods for the verification of nutrient claims is a barrier to innovation. The comment suggested that FDA should specify that appropriate valid methods may be used for determining nutrient content. The comment noted that if the manufacturer uses a nonofficial method, the manufacturer should have the burden of substantiating the validity of the method that is used.

FDA notes that new § 101.9(g), as amended by the mandatory nutrition labeling document published elsewhere in this issue of the **Federal Register**, states that, unless otherwise specified, compliance with nutrition labeling will be determined using methods validated by AOAC International. That regulation also states that if no "official" analytical method is available or appropriate, other reliable and appropriate analytical procedures may be used.

An AOAC International Task Force on Nutrient Labeling Methods has

considered the adequacy of AOAC International methods to meet nutritional labeling needs. The task force judged adequacy on the basis of a survey of nutrient method users and on the basis of the collaboratively validated and officially approved status of methods in the AOAC International Official Methods of Analysis. The methods judged to be adequate relative to the regulations and to reflect current analytical definitions are listed in *The Referee* 16:7–12 (1992) (Ref. 2).

Section 101.9(g) sets out the methods that the agency will use for compliance determinations. Manufacturers may use nonofficial methods of analysis to establish nutrient content label values, but in doing so, they should ensure the validity of their methods with respect to applicability, specificity, sensitivity, accuracy, precision, and detectability. If they fail to do so, and their methods produce significantly different results than the official method, their label may subject them to regulatory action. Reliable and appropriate alternative analytical methods may be submitted to FDA for a review of their acceptability.

Thus, by referencing new § 101.9, new § 101.13(o) does not preclude a manufacturer from using alternative analytical methods for determining nutrient content label values. No amendment of the regulation is necessary to comply with the comment's suggestion.

Analytical methodology is more extensively discussed in the final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**.

H. Exemptions

This section addresses provisions in the general principles proposal for certain exemptions from the requirements for nutrient content claims: (1) Claims in a brand name; (2) "diet" soft drinks; (3) certain infant formulas; and (4) standards of identity. Other exemption provisions are addressed in the sections of this document pertaining to scope, restaurant foods, sugar free, and petitions. FDA advises that the exemption provisions proposed as § 101.13(o) have been redesignated as new § 101.13(q) in this final rule.

1. Claims in a brand name

Under section 403(r)(2)(C) of the act, manufacturers may continue to use brand names that include nutrient content claims that have not been defined by regulation, as long as those claims appeared as part of a brand name before October 25, 1989, and are not false or misleading under section 403(a). Section 403(r)(2)(B) of the act, which requires the nutrition information referral statement, does apply to foods whose brand name includes such claims. Consequently, the labeling of products whose brand name includes such terms will have to bear an appropriate referral statement.

To implement this provision of the act, the agency proposed § 101.13(o)(1) (redesignated as § 101.13(q)(1)), which states that nutrient content claims not defined by regulation, appearing as part of a brand name that was in use prior to October 25, 1989, may be used on the label or in labeling of a food, provided that they are not false or misleading under section 403(a) of the act.

22. Several comments stated that allowing some products to continue to use a nutrient content claim in a brand name while precluding others on the basis of a date (October 25, 1989) is not justified, even if it is legally sustainable. Further, some comments contended that some nonexempt products could have an equivalent or superior nutritional profile. Other comments stated that the agency should broaden the exemption to include some claims in brand names appearing after October 25, 1989, without requiring a petition or other administrative process.

The agency advises that section 403(r)(2)(C) of the act grants the agency authority to exempt only those claims in the brand names of products bearing such claims before October 25, 1989, unless the brand name contains a term defined by the Secretary under section 403(r)(2)(A)(i) or is false or misleading. While some nonexempt foods may have an equivalent or superior nutrition profile, such foods are not recognized by the statute as exempt from the section 403(r)(2)(A) of the act. Thus, the agency is obligated by the statute's language to subject nonexempt foods to the general requirements of section 403(r)(2)(A) of the act that claims contained in a brand name be defined by regulation or by an approved brand name petition submission.

23. Several comments stated that claims in brand names should be restricted to terms that have been defined by FDA, so that claims appearing before October 25, 1989, will be consistent with claims in brand names appearing after that date. The comments stated that requiring claims to be consistent will facilitate the education of the public, while allowing some claims to be exempt will create multiple meanings for the same term depending on whether it appeared on a label before or after October 25, 1989. The comments stated further that such an exemption would likely lead to nonuniformity in the marketplace and consequent consumer confusion. One of these comments stated that FDA lacked the resources necessary to provide exemptions for some products while enforcing regulations on others.

A clarification of the 1990 amendments' provisions concerning exemptions is necessary. For a claim in a brand name to remain exempt from the act's requirements, that claim would have to be, of necessity, one that has not been defined by the agency by regulation. Thus, after the effective date of section 403(r)(1)(A) of the act, that claim could not be used on food products that were not on the market before October 25, 1989. Therefore, while an undefined term may have inconsistent meanings in brand names of food products that were on the market before October 25, 1989, it will not have multiple meanings depending on whether it appeared on a food label before or after October 25, 1989, as the comment stated. Until the claim is defined, it can not be used at all on post-October 25, 1989, products or anywhere but in the brand name of pre-October 25, 1989, products. Once it is defined, it can only be used in accordance with that definition.

The agency agrees that the establishment of definitions that state clear and consistent meanings for nutrient content claims will facilitate consumer understanding of those claims. Toward this end, the agency has endeavored in this final rule to establish definitions for both expressed and implied claims that will govern as many of the types of claims that frequently appear in brand names as is possible.

However, the agency notes that because numerous types of claims appear as part of brand names, this final rule will not likely define all of the claims that may be expressed or implied as part of a brand name. The agency expects that some of these claims will continue to be used under the exemption granted in section 403(r)(2)(C) of the act. In this regard, after these regulations become effective, FDA will monitor claims used in brand names that remain exempt, and if there is evidence that use of undefined claims could result in consumer confusion or misleading labeling, the agency will consider defining terms for such claims on its own initiative.

FDA believes that defining such claims will further the statute's goal of providing consistent nutrition information on food labels and will encourage competition in the marketplace by making the terms available for products not eligible for the exemption. The agency does not

agree with the comment that stated that FDA lacks the resources necessary to enforce a regime in which some products are subject to exemptions while others are not. The agency does not expect a significant added burden to be placed upon its resources if some claims in a brand name remain exempt, since exempt status does not flow from agency action or approval but is granted by the statute if the claim appeared in a brand name of a food product before October 25, 1989.

24. Some of the comments requested that FDA either define terms that are implied nutrient content claims used in brand names by regulation, to provide for their use under section 403(r)(2)(A) of the act, or regulate their use on a case by case basis under the general misbranding provisions of the act.

The agency agrees in principle with this comment's suggestion that it should define terms used as part of a brand name that may express or imply a nutrient content claim. As noted in the response to the previous comment, the agency has endeavored in this final rule to establish definitions for both expressed and implied claims that will permit, to the extent feasible at this time, as many as possible of the types of claims that frequently appear in brand names.

However, as also noted above, the provisions in this final rule will not likely define all claims made as part of a brand name. With regard to any claim not defined by the agency, the alternatives provided by the statute are that either the claim is exempt, or it must be the subject of a brand name petition that is granted by the agency. There is no provision in the statute for nondefined terms used in claims to be evaluated under the broad misbranding provisions of the act, other than that which states that exempt claims in brand names (i.e., claims that are contained in the brand name of a specific food product that was the brand name in use on such food before October 25, 1989; see discussion in comment 25 of this document) must not be misleading under section 403(a) of the act. Therefore the agency rejects the suggestion that it either define all the terms or regulate their use on a case by case basis under the provisions of the act that prohibit false or misleading labeling.

25. Several comments stated that proposed § 101.13(o)(1) should be revised to clearly state that the exemption applies only to terms used in brand names used on specific and discrete food products before October 25, 1989, and not to products introduced after that date. These comments stated that the statutory exemption in section 403(r)(2)(C) of the act is triggered on a product-by-product basis, i.e., "such brand name" must have been in use on "such food" before October 25, 1989, for the exemption to apply. Some of these comments stated that an across-the-board exemption to a particular brand name would give an unfair competitive advantage to manufacturers who happened, before October 25, 1989, to have used an expressed or implied nutrient content claim in a brand name.

Other comments disagreed, arguing that product line extensions of qualifying brand names should also be exempted from the requirements for nutrient content claims because it would be unfair to exclude new products from bearing the same claim in the brand name until a petition for the use of the claim in the brand name is approved. Some comments stated that the 1990 amendments are ambiguous regarding whether the exemption provision for brand names applies to specific products bearing the brand name or to the brand name itself. These comments stated that this provision should be interpreted broadly because: (1) Laws afford special protection from government interference to trademark brand names; (2) a broad interpretation would be in accordance with Executive Order 12630, which directs that agency actions for the protection of public health and safety should be designed to advance significantly the health and safety purpose and be no greater in scope than is necessary to achieve that purpose and (3) a broad interpretation would be consistent with the President's "Memorandum For Certain Department and Agency Heads" on reducing the burden of government regulation (Ref. 3).

The agency does not believe the 1990 amendments are ambiguous on this issue because the statutory language, specifically the requirement that "* * * such brand name was in use on such food," limits the scope of the exemption to specific foods bearing the claim in the brand name. Thus, the agency does not agree with the comments that asserted that the agency should apply the exemption to line extension products.

The agency agrees with the comment that the final rule should be revised to clarify the scope of the exemption for brand names, and therefore it is revising the first sentence of new § 101.13(q)(1) to read:

Nutrient content claims that have not been defined by regulation and that are contained in the brand name of a specific food product that was the brand name in use on such food before October 25, 1989, may continue to be used as part of that brand name for such product, provided that they are not false or misleading under section 403(a) of the Federal Food, Drug, and Cosmetic Act (the act).

26. One comment requested clarification as to whether the exemption for claims in brand names in use before October 25, 1989, applies to the type size of the claim on the label as well as to the claim itself. Several comments stated that referral statements should not be required for claims that are made as part of a brand name. Several comments stated that brand name claims should be required to bear referral statements, particularly if accompanied by a claim that uses a defined term.

Section 403(r)(2)(C) of the act exempts certain claims contained in a brand name from the requirements of section 403(r)(2)(A). This exemption covers all the requirements in section 403(r)(2)(A) of the act , including the disclosure requirements in section 403(r)(2)(A)(iii) through (r)(2)(A)(iv) as well as the accompanying type size requirements. Claims in brand names are not exempted however from section 403(r)(2)(B) or (f). Therefore, such claims are not exempt from the type size requirement in new § 101.13(f) or from the referral statement requirements in new § 101.13(g) and (h). FDA is adding a sentence to new § 101.13(q)(1) to make this clear.

27. Several comments requested that FDA adopt a policy whereby enforcement action will not be taken against products bearing an expressed or implied claim in a brand name that is the subject of a petition until the agency has ruled on the use of the claim.

The agency disagrees with these comments. The statute establishes a petition process for new nutrient content claims, including use of an implied claim in a brand name. See section 403(r)(4)(A) of the act. The latter type of petition is deemed to be granted if the agency does not act on it in 100 days (section 403(r)(4)(A)(iii) of the act). It would make little sense for Congress to have included a petition process with such tight timeframes if it intended that a claim could appear while the petition for such claim is under agency review. Therefore, the agency denies this request.

28. Several comments stated that no nutrient content claim used before October 25, 1989, in a brand name should be permitted regardless of whether or not it has been defined, but provided no supporting rationale for this position.

Because these comments are inconsistent with section 403(r)(2)(C) of

the act, and in the absence of any information to support the position they advance, FDA is rejecting them.

29. Several comments stated that the agency should allow the use of undefined claims in a brand name that were not in use before October 25, 1989 if the claim is accompanied by clarifying information.

The agency disagrees with these comments. The course of action advocated by these comments would nullify the explicit provisions of the statute that require that any claim in a brand name that is not exempt under section 403(r)(2)(C) of the act be used only in accordance with a definition established by the agency, or after the agency has granted a petition for the claim (section 403(r)(1)(A) and (r)(2)(A)). While such information may cure a misbranding under section 403(a) of the act, it would not be consistent with section 403(r). Therefore the agency denies the comment's request that it allow the use of undefined nonexempt claims in a brand name if accompanied by qualifying information.

2. "Diet" soft drinks

Section 403(r)(2)(D) of the act exempts use of the term "diet" on soft drinks from the requirement that a term may be used only in accordance with the definitions established by FDA, provided that its use meets certain conditions: (1) The claim must be contained in the brand name of such soft drink; (2) the brand name must have been in use on the soft drink before October 25, 1989; and (3) the use of the term "diet" must have been in conformity with § 105.66. In accordance with these conditions, the agency proposed in § 101.13(o)(2) that if the claim of "diet" was used in the brand name of a soft drink before October 25, 1989, in compliance with the existing § 105.66, the claim may continue to be used. Any other uses of the term "diet" must be in compliance with amended § 105.66.

30. Several comments requested clarification that the exemption for a claim that uses the term "diet" in the brand name of a soft drink does not preclude line extensions, e.g., new flavors for the brand after October 25, 1989.

For the reason discussed in comment 25 of this document, the statutory exemption for claims using the term "diet" in the brand name of a soft drink does not extend beyond discrete products that were available before October 25, 1989. However, the agency is continuing to define the term "diet" in its regulations, specifically in § 105.66, as discussed in the general principles proposal (56 FR 60421 at 60457). Thus, if the use of the term "diet" in the brand name of a soft drink is in conformity with § 105.66, it may be used on a soft drink product whether or not that product was available before October 25, 1989. The agency is unaware of any instances whereby line extensions for "diet" soft drinks would not be in conformity with § 105.66, and no such instances were presented in the comments. For clarity, the agency is specifying in new § 101.13(q)(2) that soft drinks marked after October 25, 1989, may use the word "diet" provided they are in compliance with current § 105.66.

31. Several comments requested clarification that claims that use the term "diet" in the brand name of a soft drink are exempt from the requirement in section 403(r)(2)(B) of the act that nutrient content claims be accompanied by the referral statement. These comments further stated that the exemption applies to all of the requirements imposed by section 403(r)(2) of the act.

The agency agrees with the comments that section 403(r)(2)(D) of the act exempts a soft drink bearing the term "diet" as part of the brand name from all provisions of section 403(r)(2), including the requirement that a referral statement accompany the claim.

3. Infant formulas and medical foods

Section 403(r)(5)(A) of the act states that section 403(r) does not apply to infant formulas subject to section 412(h) of the act or to medical foods as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee(b)). Section 412(h) of the act applies to any infant formula that is represented and labeled for use by an infant who has an inborn error of metabolism or a low birth weight or who otherwise has an unusual medical or dietary problem. Section 5(b)(3) of the Orphan Drug Act defines the term "medical food" as a food that is formulated to be consumed or administered enterally under the supervision of a physician and that is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. FDA presented its views on what constitutes a medical food in its supplementary proposal on mandatory nutrition labeling (56 FR 60366 at 60377). Accordingly, the agency proposed in § 101.13(o)(4) to reflect these provisions of the act.

32. Several comments pointed to the fact that the agency already permits, under § 107.10(b)(4) (21 CFR 107.10(b)(4)) which was issued under authority of sections 412 and 403 of the act, the labels of certain infant formula products to bear statements such as "with added iron" (see 56 FR 60366 at 60378). These comments requested that the agency revise proposed § 101.13(o)(4) to state explicitly that claims permitted by part 107 (21 CFR part 107) can continue to be made without respect to the requirements of part 101 for infant formulas for normal full term infants, as long as the claims comply with the requirements of part 107. One comment stated that the infant formula regulations ensure FDA oversight for these foods, making additional restrictions unnecessary. These comments stated that such a revision would make it clear that claims permitted under part 107 are not subject to the regulations established under the 1990 amendments.

Under section 403(r)(5)(A) of the act, section 403(r) applies to all infant formulas except infant formula that are exempt under section 412(h) of the act. Under section 403(r)(2)(A)(i) of the act, a claim that characterizes the level of a nutrient in a food may be made only if it uses terms that are defined by regulation by the Secretary (and FDA, by delegation). Thus, while the terms used on infant formula are subject to a nutrient content claims regime, claims made on infant formula in accordance with part 107 are in compliance with that regime because they use terms defined in the regulations of the agency. To reflect this fact, FDA has added references to part 107 in new § 101.13(b) and (b)(3).

33. One comment requested that nutrition information in the form of publications and promotional materials provided to pediatricians concerning infant formula products for normal full-term infants be exempt from the labeling requirements of this final rule.

The agency advises that to the extent that nutrition information in any form, including publications and promotional materials of the type described, is labeling, it must comply with all applicable requirements of the act and their implementing regulations in this final rule. Further, FDA does not have authority to exempt any food labels or labeling from the requirements of the act. Labeling on infant formula products for normal full-term infants is not exempted by the 1990 amendments from the act's requirements for nutrient content claims. Therefore, the labeling for these foods must comply with the requirements in this final rule.

4. Standards of identity

Section 403(r)(5)(C) of the act states that nutrient content claims that are

made with respect to a food because the claim is required by a standard of identity issued under section 401 of the act (21 U.S.C. 341) shall not be subject to section 403(r)(2)(A)(i) or (r)(2)(B). Thus, a nutrient content claim that is part of the common or usual name of a standardized food may continue to be used even if the use of the term in the standardized name is not consistent with the definition for the term that FDA adopts, or if FDA has not defined the term. Moreover, the label of the standardized food would not need to bear a statement referring consumers to the nutrition label. However, in the general principles proposal (56 FR 60421 at 60429), FDA reviewed the legislative history of this provision, which makes clear that Congress did not intend section 403(r)(5)(C) of the act to imply, in any way, that new standards issued under the act would be exempt from the provisions for nutrient content claims in part 101. Rather, Congress intended that this exemption would apply only to nutrient content claims made in the names of existing standards of identity (see H. Rept. 101–538, 101st Cong., 2d sess. 22 (1990)).

Accordingly, the agency proposed in § 101.13(o)(6) that nutrient content claims that are part of the name of a food that was subject to a standard of identity on November 8, 1990, the date of enactment of the 1990 amendments, are not subject to the requirements of proposed § 101.13(b),(g), and (h) or to the definitions of part 101, subpart D.

34. Several comments disagreed that nutrient content claims that are part of the common or usual name of a food that was subject to a standard of identity on November 8, 1990, should be exempt from having to comply with the definitions for such claims established by the agency. These comments stated that consumers may be confused by inconsistent meanings of the same term in standardized versus nonstandardized foods because many consumers do not know the difference between standardized and nonstandardized foods. Additionally, these comments stated that it was unfair to exempt standardized foods from the general requirements for nutrient content claims.

Section 403(r)(5)(C) of the act specifically exempts nutrient content claims that were part of the common or usual name of a food subject to a standard of identity on November 8, 1990, from the requirement that terms used to make claims comply with definitions established by regulation. Because this exemption is statutory, the agency must make it available to foods that meet the criteria for the exemption. Therefore FDA is retaining new § 101.13(q)(6) as proposed. The agency more fully discusses this exemption in the document addressing labeling requirements for foods named by use of a nutrient content claim and a standardized term published elsewhere in this issue of the **Federal Register**.

5. Other

35. The agency determined in the final regulation on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**, that bottled water is not exempt from nutrition labeling unless it contains insignificant amounts of nutrients. Similarly, label statements on bottled water that make claims about nutrients of the type required to be declared in nutrition labeling are nutrient content claims requiring definition under section 403(r) of the act. In this regard, the proposal asked for comment as to how to decide what constitutes a nutrient content claim (56 FR 60421 at 60424). Comments on this issue have led FDA to conclude that fluoride is a special nutrient that warrants different labeling requirements than other nutrients.

Many public drinking water systems add fluoride to drinking water to help reduce dental caries. In addition, the Surgeon General has supported this practice (Ref. 4). However, there are concerns that fluoride levels in drinking water not be too high. The Environmental Protection Agency has established primary and secondary drinking water standards for fluoride (51 FR 11396, April 2, 1986) and FDA has proposed to revise its quality standard for fluoride in bottled water accordingly (53 FR 36036, September 16, 1988). Therefore, FDA believes that while the presence of fluoride in bottled water is of interest to consumers and its declaration should not be prohibited, the agency does not wish to encourage unnecessary addition of fluoride to bottled water. The agency is concerned that if terms like "good source of fluoride" or "high in fluoride" were permitted, they might encourage such additions.

Consequently, the agency has not defined a nutrient content claim for fluoride. Instead, it has provided that a statement indicating the presence of added fluoride may be used, but the claim may not include a description of the level of fluoride present. FDA has provided in new § 101.13(q)(8) that bottled water containing added fluoride may state that fact on the label or in labeling using the term "fluoridated," "fluoride added," or "with added fluoride."

III. Definition of Terms

A. General Approach

1. Criteria for definitions of terms

a. Serving size to evaluate nutrient content claims

In a proposal addressing food labeling and serving sizes that was published in the **Federal Register** on November 27, 1991 (56 FR 60394), FDA proposed among other things to: (1) Define serving and portion size on the basis of the amount of food customarily consumed per eating occasion, (2) establish reference amounts (reference amounts customarily consumed) per eating occasion for 131 food product categories, and (3) provide criteria for determining labeled serving sizes from reference amounts. In § 101.12(g), FDA proposed that if the serving size declared on the product label differs from the reference amount listed in proposed § 101.12(b), then both the reference amount and the serving size declared on the product label are to be used in determining whether the product meets the criteria for a nutrient content claim.

The agency also discussed this requirement in the general principles proposal (56 FR 60421 at 60430), stating that it believed it would be misleading to make a claim on a product that met the criteria for a claim on a reference amount basis but that did not qualify for the claim on the basis of the labeled serving size, i.e., the entire container. The agency noted, however, that this approach created situations in which a product in one size container would be eligible to bear a claim, while the same product in a different size container would not be eligible. In the serving size proposal (56 FR 60394 at 60413), FDA discussed another approach to eligibility for a claim based solely on the reference amount plus a disclaimer on the label and solicited comments on both options.

36. Most comments addressing this issue, including several industry comments, supported FDA's proposal for basing claims on both the reference amount and the labeled serving size. However, several comments from industry, trade associations, and a few professionals objected to requiring both the reference amount and the labeled serving size. These comments stated that claim evaluations should be based solely on the reference amount. The comments argued that claims should reflect true characteristics of the product, and that a product that qualifies for the claim should be able to bear the claim on all container sizes. They argued that inconsistency from

container to container in the use of claims on the same product in different sized containers would be confusing to consumers.

These comments and FDA's responses are fully discussed in the final rule on serving sizes, elsewhere in this issue of the Federal Register. As explained in that document, the agency has been persuaded to reconsider its proposal and has concluded in that final rule to base eligibility for a claim solely on the reference amount and to require a disclaimer when the amount of the nutrient contained in the labeled serving size does not meet the maximum or minimum amount criterion in the definition for the nutrient content claim for that nutrient. The disclaimer that follows the claim will inform consumers of the basis on which the product qualifies for the claim. Therefore, the possibility of misleading the consumer is reduced. The agency believes that this approach resolves the objections raised in the comments. Further, under this approach the claim would reflect true characteristics of the product, not the container size, and may be less confusing to consumers.

Accordingly, in the final rule FDA is revising all of the provisions for specific nutrient content claims that, as proposed, would have required foods bearing claims to meet both a per reference amount criterion and a per labeled serving size criterion. These sections, as revised, now require that the food only meet a per reference amount criterion.

FDA is also codifying the requirements for the disclaimer in the final rule in new § 101.13(p). New § 101.13(p)(1) states:

> The reference amount set forth in § 101.12(b) through (f) shall be used in determining whether a product meets the criteria for a nutrient content claim. If the serving size declared on the product label differs from the reference amount, and the amount of the nutrient contained in the label serving size does not meet the maximum or minimum amount criterion in the definition for the descriptor for that nutrient, the claim shall be followed by the criteria for the claim as required by § 101.12(g) (e.g., "very low sodium, 35 mg or less per 240 mL (8 fl oz)").

Further, new § 101.13(p)(2) provides that the criteria for the claim must appear immediately adjacent to the most prominent claim in easily legible print or type and in a size no less than that required by § 101.15(i) for net quantity of contents except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer statement should be no less than one-half the size of the claim but not smaller than one-sixteenth inch. This provision ensures that the disclaimer will have appropriate placement on the label and that its prominence will be consistent with other required supporting statements (e.g., referral statements).

b. Criterion based on a designated weight

In the general principles and fat/cholesterol proposals, FDA proposed in §§ 101.60, 101.61, and 101.62 that the definition of certain terms (e.g., "low" for calories, fat, sodium, and cholesterol and "very low" for sodium) be based on the following criteria: (1) The amount of nutrient per reference amount (reference amount), (2) the amount of nutrient per labeled serving size, and (3) the amount of nutrient per 100 g of food. The weight-based criterion (i.e., per 100 g of food) required that the maximum amount of the nutrient allowed per serving also be the maximum amount of the nutrient contained in 100 g of the food (e.g., for "low fat," 3 g or less of fat per serving and 3 g or less of fat per 100 g).

In the general principles proposal (56 FR 60421 at 60430), FDA stated that without the weight-based criterion, "low" claims would be allowed on certain foods that are dense in a nutrient on a weight basis yet still qualify for a "low" claim because of their small serving size. For example, without the weight-based criterion, butter and some margarines could make "low sodium" claims, although they contain as much as 900 mg sodium per 100 g of food. In addition to stating the misleading nature of such claims, FDA expressed concern that nutrient dense foods with small serving sizes may be consumed frequently throughout the day and ultimately make substantial contributions to the diet despite their "low" claims. Thus, FDA proposed the weight-based criterion to prevent misleading "low" claims on certain nutrient dense foods. FDA further stated that such claims may be counterproductive relative to educating consumers about the nutrient quality of foods.

37. Many comments requested that the agency delete the weight-based criterion from the final rule. The comments cited various reasons for this request. One of these comments stated that the weight-based criterion would eliminate important foods from the diet of persons advised by medical personnel to "watch" a particular nutrient and suggested that such persons might not eat particular foods if such foods were not labeled as "low" in that nutrient. The comment maintained that foods that do not meet the agency's proposed criteria for "low" can still be included in a healthy diet.

The agency realizes that some foods that do not meet its criteria for "low" can be included in a diet that meets current guidelines. The agency notes that the proposed definition of "low" is designed to allow a consumer to meet current dietary recommendations while selecting a variety of foods, including some that are "low" in a nutrient such as fat, and some that are not "low." Thus, FDA disagrees with the essential point of this comment, that it should not include a weight-based criterion for "low" claims because some foods that do not meet the criteria for "low" can be included in a diet that meets current guidelines. The agency believes that a weight-based criterion is a necessary criterion for the definition of "low" to prevent misleading claims on certain nutrient dense foods.

38. Some comments argued that the need for the criterion was eliminated or diminished by FDA regulations that would require serving sizes to reflect amounts customarily consumed and would require the listing of both serving size and nutrient content on the nutrition label. One of these comments further stated that if there were still problems with certain nutrient dense foods qualifying for "low" claims, then the reference amount might be adjusted to solve these problems.

FDA considered the comments suggesting that the weight-based criterion could be deleted because serving sizes will be based on amounts customarily consumed. However, the agency rejects this suggestion because basing eligibility for a claim on serving size alone would mean that certain foods with small serving sizes that have a substantial amount of a particular nutrient on a per weight basis could make "low" claims. For example, the agency conducted an analysis to assess the effect of deleting the weight-based criterion using food composition data of USDA (Ref. 5) in conjunction with the reference amounts in FDA's final rule on serving sizes. The analysis showed that without a weight-based criterion, products such as sugar, grated parmesan cheese, and 25 percent fat cream could be labeled as "low calorie;" evaporated whole milk, nondairy creamer, green and ripe olives, and whipped dessert toppings as "low fat;" salted peanuts, butter, margarine, mayonnaise, ripe olives and mustard as "low sodium;" and grated parmesan cheese and regular mayonnaise as "low cholesterol" (Ref. 6). "Low" claims on these foods are contrary to recommendations made in the "Nutrition and Your Health: Dietary

Guidelines for Americans," issued jointly by the U.S. Department of Health and Human Services and USDA (Ref. 7) and would mislead and confuse the consumer.

Furthermore, "low" claims may promote increased consumption of such foods and thus, result in dietary practices even more inconsistent with dietary guidelines. For example, "low calorie" claims could appear on the labels of granulated sugar and brown sugar, although the guidelines state that sugars and the many foods that contain them in large amounts should be used in moderation by most healthy people and used sparingly by people with low calorie needs. A "low fat" claim could be made on evaporated whole milk, although the guidelines promote the consumption of skim or low fat milk to help obtain a diet low in fat. In addition, "low sodium" claims could be made on ripe olives, mayonnaise, and mustard, although the guidelines identify olives, salad dressing, and condiments such as mustard as foods that contain considerable amount of sodium. Further, "low sodium" claims could be made on some salted snacks, although the guidelines recommend that salted snacks be consumed sparingly. Consumer confidence in the validity of nutrient content claims would likely be undermined by "low" claims on foods that are clearly not "low" in certain nutrients but could make a claim because the established serving size is so small. For these reasons, FDA has concluded that the weight-based criterion should not be eliminated.

Furthermore, the agency rejects the suggestion made in one comment to adjust reference amounts (serving size) to prevent claims on nutrient dense foods. The agency does not have the authority to do so. Section 403(q)(1)(A)(i) of the act states that the serving size is an amount that is customarily consumed. Therefore, FDA concludes that a weight-based criterion is the best way to address the problem that it has identified.

39. Several comments stated that the weight-based criterion should be deleted because: (1) The 100 g amount is not based on amounts of foods customarily consumed; (2) consumers do not make food choices based on 100 g of food; (3) some foods now labeled as "low sodium" may no longer be permitted to use that term; and (4) not all food products with similar amounts of a nutrient per serving would be permitted to bear "low" claims.

As discussed in the general principles proposal (56 FR 60421), the 100-g criterion is a criterion that reflects nutrient density. As such, it is not intended to reflect an amount of food customarily consumed. FDA finds no reason to conclude that this criterion will confuse consumers because it is not disclosed to the consumer. Additionally, the agency is not persuaded that consumers will be confused if some products currently using terms such as "low sodium" no longer qualify because of the additional criterion. Rather, the agency believes that consumers expect changes in claims on products to result from the implementation of the 1990 amendments.

Further, FDA does not believe that consumers will be confused if all food products with similar amounts of nutrients per serving did not bear "low" claims because consumers will likely recognize certain foods as being nutrient dense and others as not being nutrient dense. On the contrary, consumer confusion is likely to result if "low" claims appear on foods that are generally known to contain considerable amounts of the subject nutrient on a weight basis.

40. Several comments opposed to the weight-based criterion also disagreed with the statement in the general principles proposal (56 FR 60421 at 60431) that some nutrient dense foods with small serving sizes may be consumed frequently throughout the day. These comments said there was no evidence that these foods are overconsumed, nor was there evidence that they are consumed more than food products with larger serving sizes. A few of these comments stated that consumer education efforts could address any problems with these foods including their possible overconsumption.

FDA has reconsidered whether nutrient dense foods with small serving sizes will be frequently consumed, and the importance of this issue in justifying a weight-based criterion. The agency acknowledges the difficulty in providing persuasive evidence that many nutrient dense products may be frequently consumed, in part because of certain limitations in the available food consumption estimates. However, the agency believes that "low" claims on certain nutrient dense foods with small serving sizes, such as those cited in comment 38 of this document, may promote increased consumption of these foods, and when considered in the context of the total diet, such consumption would be inconsistent with current dietary recommendations. Therefore, the agency believes that "low" claims on these foods will be misleading to consumers.

Further, it would be inappropriate for the agency to use consumer education to promote the acceptance of labeling claims that it regards as misleading because such an approach would undermine the provision of the act that directs the agency to establish regulations to prevent false and misleading label declarations. Therefore, the agency rejects the suggestion that it abandon the weight-based criterion in favor of efforts to educate consumers about "low" claims for nutrient dense foods.

41. Other comments opposed to the proposed weight-based criterion asserted that it will act as a disincentive to manufacturers to produce healthier food products if they could not use claims such as "low" on the label. One of these comments said that manufacturers will have difficulty reformulating some products to meet the weight-based criterion, while another said that the inability to advertise a healthier product could lead to a manufacturer's shifting the emphasis from reducing fat or salt to adding fat or salt for better taste.

FDA examined the extent to which a weight-based criterion would be a disincentive to manufacturers to produce healthier products. The agency acknowledges that an overly restrictive weight-based criterion would limit the number of products that could be reformulated to qualify for "low" claims. However, the agency disagrees that manufacturers are likely to resort to adding fat or salt if they are unable to make "low" claims, because the manufacturer would still have available comparative claims such as "less" to publicize nutritional improvements in products. Therefore, FDA rejects these comments.

42. Several comments were opposed to the weight-based criterion because of the number and type of food products that would be precluded from bearing claims by this criterion. Some of the food products cited by the comments included certain dry food products (e.g., dry hot cereals and dehydrated soups); some types of bread, pasta, crackers, and other cereal grain products; snack products and cookies; lower fat cheeses and other dairy products; lower fat salad dressings; spice blends and seasoning blends; and sauces, margarine, butter, and oils. One comment said that it would make it almost impossible for products whose reference amount was less than 100 g to qualify for certain nutrient content claims, while other comments said that the criterion discriminates against food with small serving sizes and nutrient-dense foods. Other comments said that this criterion

diminished the distinction between the terms "low" and "free" and was unfair to low moisture foods.

FDA considered the comments that said that the weight-based criterion should be deleted because of the number and types of food products that would be precluded from bearing claims. The agency disagrees with the comment that the proposed criterion would make it almost impossible for products with a reference amount of less than 100 g to qualify for certain content claims. Many products with reference amounts under 100 g would qualify for "low" claims under FDA's proposed criterion (e.g., many vegetable products, dried fruit, legumes, some gravies and sauces, some fish products, several cereal grain and pasta products, and a number of breakfast cereals could make "low fat" claims) (Ref. 8).

FDA also considered the comments that said that the proposed weight-based criterion discriminates against foods with small serving sizes and nutrient dense foods, but concluded that a weight-based criterion is needed to prevent nutrient dense foods with small serving sizes from making misleading claims. Further, the agency disagrees that the revised weight-based criterion would diminish the distinction between "low" and "free" claims. The agency has provided clearly distinctive definitions for these two nutrient content claims.

43. At least two comments suggested alternative criteria that would incorporate the frequency of consumption of a food. One comment suggested that nutrient dense foods with small serving sizes should be prevented from making "low" claims only if they are consumed many times during the day. Another comment proposed that foods be required to meet the criteria for "low" claims based both on levels per reference amount and per total daily intake (i.e., reference amount times average number of servings per consumer per day). The daily number of servings would be derived from national food consumption surveys. This comment acknowledged that a major disadvantage to this approach would be the complexity of determining the figures.

The agency agrees that an approach that considers frequency of consumption would be complex. FDA rejects this approach principally because it does not adequately address the agency's concerns with regard to nutrient dense foods with small serving sizes. The agency believes that the suggested approach would not effectively control misleading claims on nutrient dense foods with small serving sizes because it does not provide any means of dealing with the likely effect of the appearance of the claim on the food. In other words, it would make little sense for the agency to allow a claim based on current consumption levels, but then to move to withdraw the authorization for the claim as soon as new consumption information appears showing that there is increased consumption of the food in response to the claim, and that consumption is inconsistent with dietary guidelines. A weight-based criterion will ensure that increased consumption of the food will still be consistent with dietary guidelines.

44. One comment suggested, as an alternative to the weight-based criterion, that food products that may have significantly different serving sizes because of different uses be required to meet the "low" level based on all of the respective reference amounts. The comment stated that one-third of all nondairy creamers are consumed with cereal in place of milk, and thus the reference amount used as a basis for claims should reflect this use. This comment also suggested as an alternative to the weight-based criterion that food products that have small serving sizes be required to meet a lower nutrient level per serving to make a claim. For example, for foods with a one ounce reference amount or less, fat content could not exceed 2 g per reference amount.

The agency rejects these suggestions because the first has only limited application, and the second is not an effective alternative in preventing misleading claims. With regard to the first suggestion, most nutrient dense foods with small serving sizes (e.g., butter) would be subject to only one reference amount. The second suggested alternative would not prevent "low fat" claims on foods such as grated parmesan cheese and whipped dessert toppings (Ref. 9), and, as discussed in comment 38 of this document, such claims would be misleading.

45. Some comments suggested applying a weight-based criterion only to foods with small serving sizes. One comment suggested that the agency develop a provision to cover foods that weigh 40 g or less per serving and contain more than 5 calories per g. Another comment suggested that the proposed weight-based criterion only be applied to foods with reference amounts 15 g or less or 2 tablespoons or less and that are consumed frequently throughout the day. Other comments suggested that certain nutrient content claims be prohibited on specific categories of foods with very small serving sizes or prohibited on foods with less than a minimum serving size that contained more than a certain amount of fat on a dry weight basis. One comment suggested that a minimal serving size for specific nutrient content claims be established such as one tablespoon.

The agency has carefully considered the suggestions raised in the comments that a weight-based criterion apply only to foods with small serving sizes. Because the intent of the agency is to prevent misleading claims on nutrient dense foods that have small serving sizes, the agency has concluded that narrowing the scope of the provision such that it only applies to foods with small serving sizes adequately addresses its concern of misleading claims on nutrient dense foods with small servings. Moreover, the agency has concluded that with appropriate provisions applicable only to foods with small serving sizes, misleading claims on nutrient dense foods can be prevented. However, the alternatives suggested in the comments were not the most effective options in preventing such claims. For example, with the first alternative suggested by the comments, green olives with about 13 g of fat per 100 g could qualify as "low fat" and 25 percent fat cream with about 240 calories per 100 g as "low calorie" (Ref. 10). With the second suggested alternative, salted peanuts with about 430 mg sodium per 100 g could qualify as "low sodium" (Ref. 10).

The agency considered, however, that if the second suggested alternative was modified to apply to foods with reference amounts of 30 g or less or 2 tablespoon or less, and the concept of frequency of consumption was deleted, then the proposed weight-based criterion applied to such foods would prevent inappropriate claims (Ref. 6). In addition, this criterion would permit more foods that are promoted in dietary guidelines to make "low" claims than FDA's proposed criterion. For example, breads and pastas that qualified on a per serving basis could make "low" claims. Accordingly, in the final rule, the agency is including a weight-based criterion for "low" claims only for those foods that have reference amounts of 30 g or less or 2 tablespoons or less. As discussed below, in comment 48 of this document, the agency is also persuaded to adopt a less restrictive weight-based criterion.

46. At least two comments suggested as an alternative that foods with small serving sizes be required to have a qualifying statement such as "low fat per one tablespoon" or "low fat when consumed in a 1-ounce serving." One

comment suggested that this qualifying statement only be required for foods that exceeded FDA's proposed per 100-g criterion. These comments said that the disclosure would alert people to the possibility that the product would no longer be "low fat" if a larger serving were consumed and would educate consumers who did not know that nutrient content claims are dependent on serving sizes.

This alternative would permit claims on all foods meeting the per serving criterion and would provide additional clarification of the claim to the consumer. However, the agency is not persuaded to adopt this alternative because the agency believes that even with the additional disclosure, such claims may confuse the consumer if the food product contains considerable amounts of the nutrient on a weight basis.

47. A few comments suggested as an alternative that all food products that meet the per serving criterion for a claim also be required to meet a caloric density criterion. Reasons cited in support of a caloric density criterion were that it would prevent nutrient dense foods with small serving sizes from making misleading claims, would allow products of widely differing serving sizes and calorie levels to be assessed fairly, and would eliminate inequities of the proposed 100-g criterion that favored hydrated products. One comment recommended that "low fat" foods not contain more than 15 g of fat per 100 g on a dry weight basis, which is equivalent to about 30 percent of calories from fat. Another comment recommended that instead of a weight-based criterion, a criterion of less than 45 percent of calories from fat should be applied to the "low fat" definition.

Disadvantages to a caloric density approach were also cited in comments. They included the potential for: (1) Manufacturer misuse such as increasing the fat/calorie content of a product to obtain a lower level of a particular nutrient (e.g., a lower sodium or cholesterol level) on a per calorie basis, and (2) manufacturer disincentive to produce "lower calorie" foods because, with the caloric density approach, the levels of problem nutrients would be higher compared to the higher calorie version of the product.

Other comments suggested that a weight-based criterion be based on nutrient levels per 100 calories or nutrient levels per 117.5 calories. The latter caloric level was derived by dividing the agency's proposed reference daily caloric intake of 2,350 calories by the agency's estimate of 20 servings of food being consumed in a day. The comment stated that this caloric level would be tied to average daily consumption, whereas 100 g has no relation to daily food consumption.

The agency has considered the appropriateness of applying a caloric density criterion for "low" claims for fat, cholesterol, and sodium. The agency acknowledges that it proposed this type of approach for a weight-based criterion for saturated fat in order to provide "low" claims for saturated fat on certain fats and oils (e.g., canola oil) because all fats and oils would exceed a weight-based criterion based on 100 g.

The agency is concerned, however, that the caloric density approach would permit misleading "low" claims for cholesterol and sodium. For example, if the criterion was that a food could have no more than proposed nutrient levels per 117.5 calories, then butter with about 800 mg of sodium per 100 g could qualify for a "low sodium" claim and grated parmesan cheese with about 80 mg of cholesterol per 100 g for a "low cholesterol" claim (Ref. 11). The agency also agrees with comments that the caloric density approach could encourage the development of higher fat, higher calorie products in order to make "low sodium" and "low cholesterol" claims. Thus, this approach would be inconsistent with national dietary goals of lowering fat intake (Refs. 4, 7, and 12).

The agency also considered whether this type of criterion might be applied to fat but not to sodium and cholesterol. However, if a criterion such as less than 30 percent calories from fat were used, then low calorie, high moisture products such as ready-to-serve gazpacho soup may not qualify for a "low fat" claim (Ref. 11), even though a serving of a cup might contain only 2 g of fat and be consistent with foods promoted in dietary guidelines. In addition, the agency does not believe that there is a sufficient basis to justify a higher level such as no more than 45 percent calories from fat, as suggested by one of the comments. Furthermore, national goals that target nutrient intake as a percentage of calories focus on the total diet, not on the percentage of calories in individual foods (Refs. 4, 7, and 12). Accordingly, the agency rejects a criterion based on caloric density for claims for nutrients other than saturated fat.

48. Several comments suggested as an alternative that FDA use a less restrictive weight-based criterion. Variants of this alternative were to use: (1) The disclosure/disqualifying levels per 100 g, (2) proposed levels per 30 g (one ounce), or (3) proposed levels per 50 g. One of these comments further stated that the use of the proposed levels per 30 g would be more closely tied to reference amounts and would allow truthful nutrient claims on the majority of foods, while preventing claims on nutrient dense foods with small serving sizes. This comment cited as a disadvantage, however, that this approach would still be arbitrary and not related to how consumers actually eat foods.

Another comment supported the use of proposed levels per 50 g because it would allow more grain products to qualify as "low fat." In addition, the comment stated that a per 50-g criterion would prevent higher fat crackers and cookies and other high fat foods with small serving sizes from making "low fat" claims. This comment further stated that the per 50-g criterion would allow more products to qualify for "low sodium" and "low cholesterol" claims and would result in more flexibility for manufacturers and more choices for consumers.

FDA considered the options presented in the comments for a less restrictive weight-based criterion. Upon reconsideration, the agency acknowledges that the level it proposed, per 100 g, is too restrictive. While the proposed criterion would have prevented "low" claims on certain nutrient dense foods, it also would have prevented some breads and other cereal grain products for which increased consumption is recommended in national dietary guidance from qualifying for "low" claims (Ref. 7). FDA has thus rejected maintaining the weight-based criterion as proposed.

The agency disagrees that a main reason for selecting a weight-based criterion should be the relationship of per 100 g, per 50 g, or per 30 g to the amounts of foods consumers actually eat. The criterion serves only as a measure of nutrient density. The reference amount reflects what consumers actually eat. However, FDA notes that a criterion based on proposed levels per 50 g or per 30 g would be more compatible with consumption amounts than per 100 g for individual foods, although 50 g or 30 g amounts would still be substantially greater than the reference amounts for some food products such as minor condiments.

While the agency acknowledges that the proposed criterion of 100 g is too restrictive, FDA is concerned that the alternative suggestions of applying the proposed disqualifying levels per 100 g (e.g., 11.5 g per 100 g for fat) or proposed levels per 30 g (e.g., 3 g per 30 g for fat, which is about 10 g per 100 g) could still result in misleading claims

even if the weight-based criterion is applied only to foods that have reference amounts of 30 g or less or 2 tablespoons or less. For example, with either of these criteria, evaporated whole milk and liquid nondairy creamers could still make "low fat" claims, and regular cream cheese could still make a "low sodium" claim (Ref. 6). In addition, the use of the per 30-g criterion when applied to foods with these reference amounts (i.e., 30 g or less or 2 tablespoons or less) could result in misleading "low calorie" claims on products such as half-and-half, olives, and maraschino cherries. Accordingly, FDA has not adopted these alternatives.

The agency also considered the alternative suggested in the comment of using proposed levels per 50 g. If a 50-g criterion was applied only to foods that have reference amounts of 30 g or less or 2 tablespoons or less, then all of the products cited above as inappropriate for "low" claims would be prevented from making misleading "low" claims (Ref. 6). In addition, compared with FDA's proposed per 100-g criterion, the per 50-g criterion would permit more foods for which increased consumption is recommended in current dietary guidelines to make "low" claims. For example, more breakfast cereals and snacks such as pretzels and air popped popcorn could make "low fat" claims.

The agency concludes that the use of a per 50-g criterion when applied to foods with reference amounts of 30 g or less or 2 tablespoons or less minimizes confusing or misleading claims while maximizing appropriate "low" claims consistent with dietary guidance. Accordingly, the agency is revising relevant paragraphs of new §§ 101.60, 101.61, and 101.62 to provide for a weight-based criterion for these foods be based on nutrient levels per 50 g of food for "low" claims. The agency is also revising new § 101.61(b)(2) to require that the per 50-g criterion apply to "very low sodium" claims.

49. One comment stated that a weight-based density criterion would be unduly restrictive to dry products such as dehydrated soups and dry hot cereals that require water to be added and that would qualify based on an "as prepared" form but not on the "as purchased" form. This comment suggested that a criterion based on the hydrated product would be more equitable for foods that must have water added to them before typical consumption.

The agency points out that the weight-based criterion in the final rule does not apply to dehydrated soups or dry hot cereals because their reference amounts exceed the specified reference amounts to which the weight-based criterion applies. However, the agency agrees with the comment that the weight-based criterion should be applicable to the "as prepared" form when the product purchased is dehydrated, because the reference amount of the product, as well as any accompanying nutritional information, is based on the hydrated form of the food. Thus, the agency concludes that it would be inconsistent to require that a weight-based criterion be based on the dehydrated form when all other accompanying information is based on the "as prepared" or hydrated form. Thus, the agency supports this recommendation for its limited application to dehydrated products with reference amounts of 30 g or less or 2 tablespoons or less. Accordingly, FDA is also revising the above cited sections by inserting "For dehydrated foods that are typically consumed when rehydrated with only water, the per 50-g criterion refers to the as prepared form," to allow products that must have water added to them before typical consumption to make a claim if the "as prepared" hydrated form meets the per 50-g criterion.

2. Need for consistency of terms and limited number of terms

As discussed in the general principles proposal (56 FR 60431), the agency's approach to developing a system of nutrient content claims emphasizes three objectives: (1) Consistency among definitions, (2) claims that are in keeping with public health goals, and (3) claims that can be used by consumers to maintain healthy dietary practices.

The agency also noted that it has followed an approach that will limit the number of defined terms. This approach is consistent with that advocated in the Report of the "Fourth Workshop on Nutritional Quality and Labeling in Food Standards and Guidelines," Committee on the Nutritional Aspects of Food Standards, International Union of Nutritional Sciences (IUNS) (Ref. 13), which states that caution should be exercised to constrain the number of descriptors that are considered desirable. The IUNS Committee questioned the wisdom of more detailed descriptors because of the difficulties of consumer understanding of a plethora of such terms.

Alternatively, the agency noted that some have argued that establishing flexible provisions for the use of terms will facilitate consumer understanding by better attracting attention to the message being delivered about the food. In addition, the agency noted that some have suggested that defining more terms or providing greater flexibility for the use of various terms to convey nutritional information encourages competition among products and fosters nutritional improvement in products. The agency specifically requested comments on how it can balance the goals of consumer understanding and competition (56 FR 60421 at 60431).

50. Some comments did not agree with the objective of maintaining consistency among the definitions. One comment stated that consumers will not be confused by the use of nonconsistent terms. One comment stated that because the proposed definitions for absolute nutrient content claims such as "low" and "high" are based on uniform standards that apply across all food groups, many foods that can help consumers improve their diets will not meet the standards in these definitions.

It is important for effective consumer education to establish consistent definitions for descriptive terms whenever possible to limit the possibility of consumer confusion. Thus, FDA has not made changes in its regulations in response to these comments. However, should a situation arise in which a flexible approach to defining a term would promote public health goals or assist consumers in maintaining healthy dietary practices, the agency will consider adopting such an approach. In implementing the provisions of the act on nutrient content claims (e.g., through the petition process), the agency intends not to inhibit useful and informative competition in the marketplace, so long as it is still consistent with the three objectives stated above.

3. Synonyms

Section 3(b)(1)(A)(ix) of the 1990 amendments provides that regulations for nutrient content claims may also include similar terms that are commonly understood to have the same meaning.

To implement these provisions, the agency requested in the general principles proposal (56 FR 60421 at 60431) comments on a list of synonyms suggested by the Grocery Manufacturers of America (GMA), for the terms "no," "very low," "low," "significant," "high," and "very high." The agency also requested comments on a report by the Institute of Medicine (IOM) of the National Academy of Sciences (NAS'), entitled, "Nutrition Labeling Issues and Directions for the 1990's" (the IOM report) (Ref. 14) addressing concerns that a proliferation of synonyms on food labels will be confusing to consumers

who may believe that there are differences among the terms. Further, the agency requested comments on the use of synonyms for the nutrient content claims "free," "low," "high," and "source."

Section 403(r)(4)(A)(ii) of the act grants to any person the right to petition the Secretary (and FDA, by delegation) for permission to use terms in a nutrient content claim that are consistent (i.e., synonymous) with terms defined in regulations issued under section 403(r)(2)(A)(i).

51. Several comments stated that it is important to limit the number of synonyms, while some comments advocated that FDA ban the use of all synonyms. The comments argued that the 1990 amendments do not require synonyms, that the use of synonyms does not contribute to improved public health, and that synonyms are used by companies only to gain a competitive edge.

Some comments suggested that all synonyms put forward by GMA should be accepted. The comments generally contended that synonyms are necessary to allow manufacturers greater flexibility; that there are many truthful and informative synonyms for the basic descriptors FDA is defining; that all terms will carry some defined meaning; that use of multiple synonyms will encourage competition among products; and that as long as there is a single definition for a term and its synonyms, consumers will not be confused.

A few comments stated that FDA should permit undefined synonyms to be used in conjunction with either a consistent defined claim or a disclosure statement explaining the intended meaning. The comments argued that this approach would increase consumer understanding and confidence, without discouraging manufacturers' flexibility.

Another comment stated that qualitative research is needed to assess consumer understanding of descriptors before the publication of final regulations, and if such testing is not possible, definitions and synonyms should be tentative for 2 years and then reassessed.

FDA notes that many comments advocated either an extremely open or extremely restrictive approach to synonyms. However, FDA has not taken either of these positions. Because a goal of the 1990 amendments is to make nutrition information on the label or labeling of foods available in a form that consumers can use to follow dietary guidelines (H. Rept. 101–538, supra, 10), and the act envisions that synonyms for defined terms can be an appropriate means to communicate such information, the agency will evaluate synonyms according to the standard in the 1990 amendments, i.e., that the term is commonly understood to have the same meaning as a defined term. In doing so, FDA intends to be open to considering terms that meet this standard. However, FDA does not intend to permit any synonym that it believes would be unclear in meaning to consumers with respect to characterizing the level of a nutrient in a food. For instance, FDA does not consider the term "smidgen" to be commonly understood to mean "very low" in describing the level of a nutrient. Similarly, FDA does not consider the term "loaded" to be commonly understood to mean "high."

FDA disagrees with the comments that suggested that the terms and synonyms being established in this final rule should be permitted on a tentative basis for 2 years. FDA has sought to select terms and synonyms that are familiar to consumers. The standardization of these terms by regulation and the availability of nutrition labeling in conjunction with the claims, coupled with consumer education, will promote consumer understanding of their meaning. Thus, FDA believes that consumers will be able to use the terms and synonyms that it is defining to make informed dietary choices. Further, through petitions and rulemaking, FDA can change, add, or delete synonyms as new terms come to have established meanings or problems with defined terms become apparent.

FDA also disagrees with the suggestion that it permit undefined synonyms to be used in conjunction with either a consistent defined claim or a disclosure statement explaining its intended meaning, because the act requires that terms (including synonyms) used to characterize the level of a nutrient in a food be either defined by the agency or approved by the agency in response to a petition. There is no provision in the act that allows for the use of undefined synonyms in the absence of action by the agency.

In this document, FDA has considered various synonyms that have been suggested in the comments. The issues considered by the agency and its conclusions regarding specific synonymous terms are discussed in detail in the relevant sections of this document.

B. Terms Describing the Level of a Nutrient

1. Free

In the general principles and the fat/cholesterol proposals (56 FR 60421 and 60478), FDA proposed to define the term "free" for total fat, cholesterol, sodium, sugars, and calories. FDA also proposed to define the terms "no," "zero," "trivial source of," "negligible source of," and "dietarily insignificant source of" as synonyms for the term "free." The agency specifically requested comments on whether consumers commonly understand the meaning of all these terms to be, and whether the terms are in fact, synonymous.

In arriving at the proposed definition for "free" for each nutrient, the agency chose the level of the nutrient that is at or near the reliable limit of detection for the nutrient in food and that is dietetically trivial or physiologically inconsequential. The agency noted, however, that some manufacturers may add very small amounts of certain nutrients to aid in the manufacturing process for some products. FDA proposed not to allow use of the term "free" on such products, even if the products met the quantitative criteria for use of the term. However, the agency requested comments on whether "free" claims should be allowed on these products if they provide an appropriate disclosure statement and also on what such a disclosure statement should be.

FDA also proposed that "free" claims used on foods that are inherently free of a nutrient must refer to all foods of that type and not merely to the particular brand to which the labeling is attached. The agency requested comments on this provision.

a. Synonyms. A number of comments addressed synonyms proposed by FDA for "free" in the general principles and the fat/cholesterol proposals (56 FR 60421 and 60478). Many of these comments supported the use of synonyms for "free." Several comments agreed specifically with one or more of FDA's proposed synonyms for "free" such as "no" or "zero." One comment provided data showing that "free" and "no" are synonymous terms. Another comment provided data that "free" and "without" are synonymous terms.

52. At least one comment (a Ph.D. thesis) requested that the term "without" be a synonym for "free." The comment presented data in support of its request. This investigation (Ref. 15) was conducted at the University of South Dakota using 192 undergraduate students. The students' perceived notions of the amount of calories, fat, and cholesterol relative to 12 nutrient content claims terms were examined. The results demonstrated statistically that the participants perceived that "without" and "free" have the same meaning.

FDA agrees with this comment. The data presented, along with FDA's previous approval of the claim "without added salt," persuade the agency that "'without' should be a synonym for 'free'." Accordingly, the agency is revising new § 101.60(b)(1) on calories, new § 101.60(c)(1) on sugar, new § 101.61(b)(1) on sodium, new § 101.62(b)(1) on fat, new § 101.62(c)(1) on saturated fat, and new § 101.62(d)(1) on cholesterol, to allow "without" to be a synonym for "free."

53. One comment maintained that manufacturers are likely to abuse the terms "free" and "no."

FDA believes that most manufacturers will comply with the requirements of these regulations. However, manufacturers who violate the requirements for these definitions will be dealt with by appropriate regulatory action.

54. One comment suggested that "free" be used where there is an absence of a nutrient, and that a phrase such as "very small amount of" be used where the food contains very small amounts of a nutrient, even if the amount of the nutrient present is physiologically insignificant.

FDA rejects this suggestion. As discussed in the general principles proposal (56 FR 60421 at 60432), FDA believes that it is appropriate to apply the term "free" to a nutrient when a food contains that nutrient in a dietetically trivial or physiologically inconsequential amount, even though the nutrient is present at a level at or near its reliable limit of quantitation. With modern analytical methods, the level at which the presence of a nutrient may be quantified is becoming increasingly smaller. For example, there are almost no foods that can be said to be truly sodium free, yet the level of sodium present in some foods has no impact on the diet. Furthermore, the additional term would likely cause consumer confusion because it is ambiguous and would not be clearly distinguishable from "free" in a meaningful way.

55. One comment stated its support for the use of the word "none." Another comment suggested that "none" be used instead of "free" but gave no reason for this suggestion.

The comment did not provide sufficient supporting information to persuade the agency that consumers commonly understand "none" to have the same meaning as "free." Therefore, FDA is not providing for the use of "none" as a synonym for "free" at this time. However the agency advises that interested persons may submit a synonym petition for the use of this term as prescribed in new § 101.69.

56. Several comments supported the synonyms for "free" that contain "source of" language (i.e., "trivial source of," "negligible source of," "dietarily insignificant source of"). One comment stated that the de minimis nutrient threshold levels encompassed by such phrases are of no public health concern. Several comments disliked these proposed synonyms. Some of these comments asserted that these phrases could be confusing or misleading to consumers. One comment pointed out that the inclusion of the word "source" in some of the synonyms for "free" could confuse consumers because the agency had given another meaning to this word in the general principles proposal.

In this final rule, as explained later in this document, FDA is changing the descriptive term "source" to "good source" to clarify its meaning and relative position in the hierarchy of descriptive terms. As a result, FDA does not believe that the use of the words "———— source of" in some synonyms for "free" will be confusing to consumers. Therefore, FDA is maintaining the position that it took in the general principles proposal (56 FR 60421 at 60434) that the terms "trivial source of," "negligible source of," and "dietarily insignificant source of" are suitable synonyms for "free," provided that they are used on the labels or in labeling of foods in accordance with the agency's definition.

57. Another comment stated that, unlike "no" and "zero," which are absolute terms, the terms containing the language "————source of" could be misinterpreted.

FDA acknowledges that "free," "no," and "zero" are absolute terms that are synonymous to one another in their meaning. However, FDA also believes that the "———— source of" terms that it has listed as synonyms of "free" are appropriate for use on the food label and consistent with the agency's definition for "free" because they express that the nutrient is present at or near the reliable limit of detection and thus at a dietetically trivial or physiologically inconsequential level. Therefore, FDA concludes that no change is warranted in response to this comment.

58. One comment objected to the use of the phrases "trivial source of," "negligible source of," and "dietarily insignificant source of" as synonyms for "free" because such phrases equate the presence of trivial amounts of a nutrient with the absence of a nutrient. The comment asserted that people can experience life-threatening reactions to "trivial" amounts of substances.

FDA does not agree that these phrases are inappropriate as synonyms for the "free" nutrient content claims that are being defined in this final rule. As explained above, FDA defined the term "free" based on a dietarily insignificant amount of the nutrient in question, and these terms are consistent with that definition.

Further, FDA advises that the nutrient content claims that it is defining in this final rule provide consumers with information about nutrients in a food, and not about substances in foods that consumers may need to avoid because of allergies or intolerances. A consumer should read the ingredient list on the food label to determine whether a food contains a substance he or she needs to avoid.

59. Several comments suggested that FDA include the terms "not any," "not a bit," "not a trace," "never a bit," "never a trace," "negligible," "dietary isignificance," "trivial amount of," and "meaningless" as synonyms for "free."

These comments did not provide sufficient supporting information to persuade the agency that consumers commonly understand the terms "not any," "not a bit," "not a trace," "never a bit," "never a trace," "negligible," "dietary insignificance," "trivial amount of," and "meaningless" to have the same meaning as "free." Therefore, FDA is not providing for the use of any of these terms as synonyms for "free" at this time. However the agency advises that interested persons may submit a synonym petition for the use of any of these terms as prescribed in new § 101.69 of this final rule.

60. Some comments suggested that variations in spelling be allowed for descriptors and their synonyms.

Although FDA has not specifically provided for variations in the spelling of various descriptive terms or their synonyms, except for "light" ("lite"), the agency believes that reasonable variations in the spelling of these terms would be acceptable, provided that these variations are not misleading to consumers. However, should the agency encounter terms that use questionable variations in spelling, it will evaluate these variations on a case-by-case basis to determine whether they comply with section 403(a) and (r) of the act.

b. Statutory limitations on circumstances in which an absence ("free") claim may be made. The 1990 amendments describe the circumstances in which claims that state the absence of a nutrient may be made on a food. Section 403(r)(2)(A)(ii)(I) and (r)(2)(A)(ii)(II) of the act, respectively,

provide that a claim may not state the absence of a nutrient unless: (1) The nutrient is usually present in the food or in a food which substitutes for the food as defined by the Secretary (and FDA, by delegation), or (2) the Secretary by regulation permits such a statement on the basis of a finding that such a statement would assist consumers in maintaining healthy dietary practices, and the statement discloses that the nutrient is not usually present in food.

i. Substitute foods. In the general principles proposal (56 FR 60421 at 60432), FDA proposed to define when one food may be considered to substitute for another to eliminate any confusion that may arise over this issue. In § 101.13(d), FDA proposed that a substitute food is one that is used interchangeably with another food that it resembles in its physical, organoleptic, and functional characteristics, and that it is not nutritionally inferior to that food unless it is labeled as an "imitation." The agency also proposed in § 101.13(d)(1) that a food that does not possess the same characteristics as the food for which it substitutes must declare the difference on its label or in its labeling, adjacent to the most prominent claim. FDA also proposed in § 101.13(d)(2) that any declaration (i.e., disclaimer) made regarding the different characteristics of the substitute food should be in easily legible print or type, no less than one-half the size of the descriptive term.

The agency also stated in the proposal that it believes that identifying imitation foods that meet nutrient content claim definitions may provide a benefit to the consumer, even though they are nutritionally inferior. Therefore, FDA tentatively concluded that such foods should be allowed to bear nutrient content claims, as long as they are appropriately labeled.

61. A few comments agreed with FDA's proposed definition for substitute foods. Some of the supporting comments stated that regulations governing the use of substitute foods are necessary to avoid misleading consumers who are not aware of the dissimilarities between an original food and a food that serves as a substitute food. However, one comment stated that the agency lacks the legal basis to prescribe the use of disclosure statements on substitute foods as extensive as that proposed by the agency. This comment suggested that a disclaimer statement should not be required on substitute foods, and that the required statement is excessive and will result in a label that is confusing to consumers.

The agency disagrees with the comment that FDA has no legal basis to require disclaimer statements on substitute foods. As the agency stated in the proposal (56 FR 60421 at 60432), section 201(n) of the act provides that food labeling is misleading, and thus the food is misbranded under section 403(a) of the act, if it fails to disclose facts material to the consequences of the use of the food. For example, if a food has different performance characteristics than the food for which it substitutes, this fact must be disclosed in conjunction with the claim that draws a connection between the two foods. Under sections 201(n), 403(a), and 701(a) of the act, the agency has the authority to require disclaimer statements when these statements are necessary to disclose material facts.

The agency also disagrees with the contention that disclaimer statements will confuse consumers. The agency believes that this information is of value to consumers because it informs them about important aspects of the food that otherwise would not be evident.

62. Some comments addressed specific aspects of disclaimer statements. One comment that opposed the agency's proposed definition for a substitute food stated that the proposal is overly broad, and that FDA should limit the disclosure requirements to differences that materially limit the uses of a substitute food when compared to the food it resembles.

The agency has reconsidered its proposed requirements for disclaimer statements. FDA believes that "differences in performance characteristics" between a substitute food and an original food may include minor differences that consumers would consider relatively unimportant for that food (e.g., a different freezing point for a nonfat thousand island dressing substitute). The agency believes that such differences are significant only when they materially limit the use of the food compared to the use of the original food (e.g., "not recommended for frying"). FDA concludes that when the differences between the substitute food and the original food do not limit the use of the substitute, they need not be disclosed because they would not be considered to be material facts that relate to the consequences of the use of the food. Therefore, the agency is revising new § 101.13(d)(1) to state, that:

If there is a difference in performance characteristics that materially limits the use of the food, the food may still be considered a substitute if the label includes a disclaimer adjacent to the most prominent claim as defined in paragraph (j)(2)(iii) of this section, informing the consumer of such difference (e.g., "not recommended for frying").

Furthermore, to ensure that the disclaimer is presented with appropriate prominence, consistent with the requirements for other required supplementary information (e.g., referral statements), the agency is revising new § 101.13(d)(2) to read:

This disclaimer shall be in easily legible print or type and in a size no less than that required by § 101.105(i) for the net quantity of contents statement except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than one-sixteenth inch.

63. A few comments stated that "shelf life" should be deleted from the definition because future developments may result in superior substitute foods with a longer shelf life.

The agency rejects this comment. The agency believes that, for two foods to be considered to be used interchangeably, they should generally resemble each other with respect to shelf life. However, the agency points out that the definition does not require that the substitute possess the same shelf life characteristics as the original food. As revised, the regulation would only require disclosure of the shelf life of the substitute food if that information is a material fact, as discussed in the previous comment.

64. One comment requested that FDA provide clarification in the final rule that differences in shelf life can be disclosed through code dates or freshness guarantee statements.

When shelf life information is required under the revised provisions, it would be appropriate to disclose the information through code dates or freshness guarantee statements if this information is presented in a readily understandable manner, in accord with the other requirements for disclaimers.

65. One comment suggested that any differences in performance characteristics associated with substitute foods should be located in the bottom 30 percent of the PDP as provided for in proposed § 101.67(b). This comment argued that proposed § 101.13(d)(1) should be revised to conform to that provision.

FDA rejects this comment. The agency believes that the disclaimer should be adjacent to the most prominent claim as it proposed because of the importance of the information. Further, the agency also notes that in the final rule on the use of nutrient content claims for butter, which appears elsewhere in this issue of the Federal Register, it is revising new

§ 101.67 to be consistent with new § 101.13(d)(1).

66. One comment argued that the dietary, health, and economic consequences regarding the use of substitute foods have not been addressed. This comment stated that the nutritional science associated with substitute foods is insufficient to fully determine whether they should be considered equivalent to traditional foods.

FDA is not authorized under the act to judge the dietary, health, or economic consequences of the use of substitute foods. Under section 403(r)(2)(A) of the act, foods that substitute for other foods must satisfy certain requirements if they are to bear nutrient content claims that highlight differences between them and the foods for which they substitute (see, e.g., section 403(r)(2)(A)(ii)(I) of the act). By issuing these labeling provisions for substitute foods, FDA has not judged that substitute foods are equivalent to traditional foods. These provisions are intended to ensure that material differences between the use of the substitute food and the use of the original food are conspicuously stated on the label or labeling of the food, so that consumers can make fully informed judgments about their value and their usefulness in maintaining healthy dietary practices.

67. A few comments expressed the view that consumers may not understand the difference between substitute foods and imitation foods. One of these comments suggested that data should be used to evaluate consumer perception on the differences between these terms.

FDA is not aware of any consumer confusion from the use of the terms "substitute" and "imitation" on food labels, nor did these comments provide any information to show that such confusion exists. Imitation foods are a subgroup of substitute foods. Under § 101.13(e), imitation foods are defined as being nutritionally inferior to the foods for which they substitute and that they resemble. FDA believes that the labeling requirements for substitute, and imitation foods will enable consumers to understand the nature of each of these types of foods. Therefore, FDA is making no change in response to these comments.

ii. Foods inherently free of a nutrient. In the general principles proposal (56 FR 60421 at 60433), the agency proposed for calories in § 101.60(b)(1)(ii) and sodium in § 101.61(b)(1)(iii) that if a food is inherently free of the nutrient, without the benefit of special processing, alteration, formulation, or reformulation to lower the content of that nutrient, a "free" claim on such food must refer to all foods of that type and not to a particular brand. In the fat/cholesterol proposal, the agency proposed a similar requirement for foods inherently cholesterol free (proposed § 101.62(d)(1)(i)(D) and (d)(1)(ii)(E)) or fat free (proposed § 101.62(b)(1)(iii)).

FDA proposed to establish this approach as a general requirement for nutrient content claims for "free" and claims for "low" in § 101.13(e)(2). Conversely, the agency provided in proposed § 101.13(e)(1) that, if a food has been processed, altered, formulated, or reformulated to remove the nutrient from the food, it may appropriately bear the terms "free" or "low" before the name of the food. FDA specifically requested comments on the proposed provision allowing "free" or "low" claims on foods that do not usually contain, or are usually low in, a nutrient.

68. A few comments stated that the agency should not allow use of the statement "————, a (nutrient) free food," on processed foods that do not normally contain the nutrient. These comments contended that this approach would eliminate the use of claims where the only benefit is to the manufacturer.

The agency rejects this comment. The agency believes, as stated in the proposal (56 FR 60421 at 60433), that highlighting that a food is free of a nutrient can help consumers to maintain healthy dietary practices whether the food is inherently free of that nutrient or is processed to be that way. Further, FDA believes that when a food is inherently free of a nutrient as a result of how it has been formulated, the disclosure "————, a (nutrient) free food" is necessary to prevent "(nutrient) free" claims from being misleading.

69. One comment argued that FDA should consider use of the term "naturally low in fat" instead of "————, a fat free food." Another comment preferred more flexibility in the wording of nutrient qualifiers (e.g., "as always, sodium free" or "naturally sodium free").

FDA points out that new § 101.13(e)(2) does not dictate the precise wording that manufacturers are to use to advise consumers that the food inherently meets the criteria and to clearly refer to all foods of that type. Therefore, the agency believes that the regulation contains sufficient flexibility with respect to the wording of the required qualifier. FDA will assess qualifying statements used on labels to determine whether the wording used meets the requirements of the regulations and take action on those that do not. Clearly, all such possible qualifiers do not meet the regulatory criteria. For example, FDA believes that the term "always" as used in the disclosure statement suggested by the comment does not clearly indicate that all foods of that type are also free of the nutrient. Thus, it may be interpreted to mean that only that brand of the food is free of the nutrient, and, as such, the claim is misleading.

70. Some comments opposed use of the statement "a fat free food" on foods that are inherently fat free. These comments stated that foods naturally "fat free" are placed at a disadvantage as compared to foods that have been modified to lower their fat level. One comment suggested that use of the term "fat free" instead of "————, a fat free food" should be appropriate on foods that are inherently fat free.

The agency disagrees with these comments. FDA continues to believe that when a "fat free" claim is made on foods that are inherently free of that nutrient, the claim is misleading unless it is accompanied by a statement that all foods of that type are inherently fat free. Thus, the agency is not providing for the use of "fat free" without the disclaimer on foods that are inherently fat free.

71. One comment requested clarification of proposed § 101.13(e)(1). The comment noted that the language of that section allows only those foods that are formulated, reformulated, specially processed, or altered to remove a nutrient from the product to bear the claim "free" or "low" before the name of the food, without the generic statement that all foods of that type are "free" of, or "low" in, that nutrient. The comment asserted that it is not clear whether a food that has been formulated to not include a nutrient that could be present in the food would be allowed to bear a claim addressed by proposed § 101.13(e)(1). For example, potato chips, fried in vegetable oil are free of cholesterol because the oil is cholesterol free, while potato chips fried in lard are not cholesterol free because of the cholesterol introduced by the lard. The comment emphasized that such foods are not "inherently free" of a nutrient but have instead been formulated so that the nutrient is not added. The comment recommended that the agency allow the terms "free" and "low" to be used on such products.

FDA agrees that there is a need for clarification in proposed § 101.13(e)(1) to allow for the use of "free" and "low" claims on foods that are formulated in such a way that certain nutrients that may be present in the food are not added to the product. The agency

believes that formulating a food in a way that precludes certain nutrients from being added to the food is equivalent to processing a food such that the nutrient is removed from the product. Thus FDA has modified new § 101.13(e)(1) to state:

> Because the use of a "free" or "low" claim before the name of a food implies that the food differs from other foods of the same type by virtue of its having a lower amount of the nutrient, only foods that have been specially processed, altered, formulated, or reformulated so as to lower the amount of the nutrient in the food, remove the nutrient from the food, or not include the nutrient in the food may bear such a claim (e.g., "low sodium potato chips").

FDA believes that this amendment will alleviate any confusion concerning the appropriate use of "free" and "low" claims.

72. A few comments suggested that FDA should expand its criteria for claims regarding the absence of a nutrient to encompass foods produced by modern advances in technology, e.g., biotechnology, horticulture, or crop selection.

FDA's criteria for nutrient content claims apply to all foods. The agency is not aware of special needs with respect to foods of the types mentioned in the comment and cannot conclude at this time that special provisions in the regulations are needed for these foods.

c. Specific definitions

i. Sodium free and terms related to salt

73. Several comments objected to the provision in proposed § 101.61(b)(1)(ii) that a food containing added salt (sodium chloride) or any ingredient that contains sodium cannot be labeled "sodium free," even though it still contains 5 mg or less of sodium per serving. One of these comments stated that "free" terms should be based solely on the analytical definition, and that consumer education programs should be set up to explain the definitions. Other comments agreed that the food should not contain any added sodium chloride but believed that disallowing ingredients containing sodium was unnecessary and overly restrictive. A trade association for the cracker industry said that for years "sodium free" crackers have been used at hospitals for patients on sodium-restricted diets. Because these crackers are made with enriched wheat flour that naturally contains trivial amounts of sodium, they could not continue to be marketed as "sodium free" under the proposed rule. This comment requested that proposed § 101.61(b)(1)(ii) be entirely eliminated or modified to allow a "sodium free" claim when a food has ingredients that contain naturally occurring sodium.

Alternatively, some comments totally supported the proposed rule. They agreed that the listing of salt as an ingredient of a product bearing a "sodium free" claim is confusing, and, therefore, its addition should be disallowed. Other comments suggested that the confusion could be eliminated if the label of such a product explained that the product contains a trivial amount of sodium. Most of these comments preferred that such a disclosure appear in the ingredient statement.

The agency has reconsidered the provision that disallows the addition of sodium chloride or ingredients that contain sodium to foods that bear a "sodium free" claim and is persuaded that it is unduly restrictive. The agency accepts the recommendation that the proposed provision be eliminated, and that a disclosure statement be required to avoid consumer confusion about the quantity of sodium in the food. The agency is persuaded that it is the listing of salt (sodium chloride) or related substances that are generally understood by consumers to contain sodium (e.g., baking soda or ingredients with sodium as part of their common or usual name such as sodium ascorbate) that creates the confusion. Accordingly, the agency is revising new § 101.61(b)(1)(ii) to require that the listing of these ingredients in the ingredient statement be followed by an asterisk that refers to a disclosure statement appearing below the list of ingredients. The statement is to read: "adds a trivial amount of sodium," "adds a negligible amount of sodium," or "adds a dietarily insignificant amount of sodium." The agency concludes that ingredients that may contain trivial amounts of sodium, such as enriched flour used in making crackers, do not contribute to consumer confusion and, thus, do not need a disclosure statement.

74. One comment requested that any label on which the term "sodium free" appears be required to include the disclosure, "contains less than 5 mg of sodium per serving." This comment stated this disclosure would alert consumers to the possible presence of a dietarily insignificant amount of sodium, and, thus, an ingredient list that includes a sodium-containing compound would no longer be a potential source of confusion.

The agency disagrees with this recommendation because it believes that requiring a disclosure with all "sodium free" claims is not necessary and would add to label clutter. In the document on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**, FDA is concluding that less than 5 mg of sodium is a dietarily insignificant amount and may be declared as "0" in the nutrition label. The agency sees no reason to take a different position with respect to the nutrient content claim. Disclosing the quantitative amount of sodium on a label that bears a "sodium free" claim and declares "0" sodium in the nutrition label would only create consumer confusion. Accordingly, the agency is not revising new § 101.61(b)(1) to require the requested disclosure.

75. A few comments requested that products not meeting the "sodium free" definition because they contain 5 mg or more of naturally occurring sodium should be allowed to use the claim "unsalted" ("without added salt," "no salt added") without having to disclose "not a sodium free food." One comment stated that there is virtually no risk that a consumer would associate "unsalted" as being synonymous with "sodium free." Another comment requested that the term "unsalted" be a synonym for "salt free" foods. Other comments disagreed and supported the requirement for a disclosure.

The term "unsalted" ("without added salt" or "no salt added") on a food that is not sodium free and that does not disclose that it is "not a sodium free food" could mislead consumers, as explained in the proposed rule (56 FR 60435). The comments presented no evidence that consumers would not be confused by this claim without the disclosure. Therefore, the agency is not persuaded to change its position on the need for the disclosure. However, to reduce the amount of information required on the principal display panel, the agency will allow this disclaimer to be placed in the information panel. The referral statement required by section 403(r)(2)(5) of the act will refer the consumer's attention to the information panel. This statement will ensure that this material fact is brought to the consumer's attention through a statement made in conjunction with the claim. Accordingly, the agency is changing the required location of this disclosure in § 101.61(c)(2)(iii).

Furthermore, the agency does not agree that the term "unsalted" should be used as a synonym for the term "salt free." To confine "unsalted" claims only to foods that meet the "sodium free" definition, including foods bearing a "salt free" claim, would be overly restrictive. The agency is denying this request.

76. One comment stated that for over 25 years, cracker manufacturers have been making crackers with no surface

salt that are described on their labels as "Unsalted Tops * * * Crackers." These crackers are made with sodium chloride and baking soda and have never claimed to be low or reduced in sodium. The comment says that these products meet the desire of some consumers for crackers that taste less salty. The comment asked whether this name can continue to be used in light of proposed § 101.61(c)(2)(i), which specifies that the term "unsalted" may only be used on a food label if no salt is added to the food during processing. It requested that the rule be modified to allow for the use of the name "Unsalted Tops * * * Crackers" as well as other names in which the term "unsalted" is qualified and does not refer to the entire food.

The use of the term "unsalted," as it appears in the name "Unsalted Tops * * * Crackers," modifies the word "tops." When used in this context, "unsalted" does not refer to the salt content of the entire food. For this reason, the agency does not consider this use of the term "unsalted" to be subject to the requirements of new § 101.61 and does not believe that this rule needs to be modified to allow for the use of this name or other names in which the term "unsalted" is qualified in this manner. Accordingly, the agency has not revised the definition of "unsalted."

77. One comment stated that it is misleading for plain corn to claim "no added salt" when frozen corn does not have added salt.

In the absence of details in the comment, the agency presumes that this comment is referring to canned corn by the term "plain corn." The agency has a food standard (§ 155.130) for canned corn that permits salt as an optional ingredient and understands that salt is usually added to this product. The agency believes that if no salt is added to canned corn, the food that it resembles and for which it substitutes is canned corn, not frozen corn. Therefore, the agency concludes that it is not misleading for the product to bear the claim "no added salt."

ii. Sugar free. 78. At least one comment recommended that FDA define the term "sucrose free" instead of "sugars free."

The agency disagrees. Sucrose is only one of the sugars found in foods. For this reason, the agency believes that the term "sucrose free" would mislead consumers into believing that the food is free of all sugars. Accordingly, the agency is not defining "sucrose free."

79. At least one comment recommended that FDA define the term "no refined sugar."

The agency is not accepting these comments. The agency is concerned that consumers would be misled into believing that a food containing no refined sugar is better than a food containing refined sugar. The dietary guidelines (Ref. 7) advise Americans to consume sugars in moderation. Consumers need to understand that it is the amount of dietary sugar, not whether or not it is refined, that is important in following the guidelines. Accordingly, the agency is not defining the term "no refined sugar."

80. A couple of comments requested that the term "sugar free" be used instead of the term "sugars free." One comment said that the term "sugar free" would be in harmony with the term permitted in Canada and other countries. Another comment stated that although the term "sugars free" is technically correct, it is unfamiliar and will confuse the majority of consumers. The comment expressed doubt that consumers understand or care about FDA's reasons for proposing "sugars free" and believed that only a few consumers would notice that the listing in the nutrition label is for "sugars," not "sugar."

The agency is persuaded, based on the arguments made by the comments, that the term "sugars free" may be confusing to consumers. Accordingly, the agency is defining the term as "sugar free" in § 101.60(c)(1). The agency points out that this section provides that a food label may bear this claim if the food contains less than 0.5 g of sugars, as defined in new § 101.9(c)(6)(ii) in the final rule on mandatory nutrition labeling, published elsewhere in this issue of the **Federal Register** (redesignated from § 101.9(c)(6)(ii)(A) in the proposal). FDA proposed to define "sugars" as the sum of all free mono- and oligosaccharides through four saccharide units and their derivatives (such as sugar alcohols). However, as discussed in the final rule on nutrition labeling, in response to comments, the agency is changing the definition to include only mono- and disaccharides. Thus, the term "sugar free" refers to less than 0.5 g of mono- and disaccharides.

81. At least one comment requested that FDA define "sugar free" as free of all simple sugars.

FDA disagrees with this comment. As explained in the above section, the agency is defining "sugar free" as less than 0.5 g of sugars, that is mono- and disaccharides. FDA believes that this terminology is more precise than the term "simple sugars."

82. Numerous comments requested that the term "sugar free" be allowed to describe foods containing sugar alcohols (polyols). These comments suggested that FDA either should exclude sugar alcohols from the definition of "sugars" or should broaden the exemption in proposed § 101.13(o)(8) that allows the term "sugar free" on the label of chewing gums that contain sugar alcohols. The comments requested that foods containing sugar alcohols, such as soft candies, hard candies, breath mints, lozenges, and sodas, be included in the exemption. Alternatively, a few comments stated that allowing the claim "sugar free" on chewing gums would be confusing to consumers if sugar alcohols are included in the definition of sugars. One of these comments proposed that the claim on chewing gums should be "contains sugar alcohols" rather that "sugar free." Other comments suggested that the claim on chewing gums as well as other foods containing sugar alcohols should be "sugarless" to avoid confusion with foods meeting the definition of "sugar free." They believed that this term should be allowed only for foods that typically contain sugar, are modified to contain only sugar alcohols, and do not contain other carbohydrates.

The agency has reconsidered this issue and is persuaded that the term "sugar free" should be allowed to describe foods containing sugar alcohols. As described above, the agency is changing the definition of sugars to include only mono- and disaccharides. Thus, sugar alcohols are no longer included in this definition. A food containing sugar alcohols may bear a "sugar free" claim as long as it meets the requirements in new § 101.60(c)(1) for "sugar free" and in new § 101.9(c)(6)(iii) that polyol content be disclosed, as discussed in the final rule on nutrition labeling published elsewhere in this issue of the **Federal Register**. Accordingly, the agency is deleting proposed § 101.13(o)(8) because the exemption that is provided is no longer needed.

83. Numerous comments supported the statement "useful only in not promoting tooth decay" in proposed § 101.13(o)(8), to continue to allow on the label of chewing gums that claim to be "sugar free." Many of the comments requested that the statement be allowed on the labels of other foods containing sugar alcohols that claim to be "sugar free." One comment suggested that FDA should revise the definition of "sugars" to exclude sugar alcohols and revise proposed § 101.60(c)(1)(iii)(B) to allow the requested statement to accompany "sugar free" claims. This provision, as proposed, would require either the statement "not a reduced calorie food," "not a low calorie food," or "not for

weight control." Other comments suggested that FDA should broaden the exemption in proposed § 101.13(o)(8) to allow the requested statement to appear on other foods. Alternatively, at least one comment suggested only the statements "not a reduced calorie food" and "not a low (free) calorie food" are appropriate. The comment specifically suggested that FDA should disallow the statement "useful only in prevention of tooth decay" with "sugar free" claims. This comment also implied that FDA should disallow the statement "not for weight control" with "sugar free."

The agency has reviewed these comments and has determined that there is no compelling reason to disallow the statement "not for weight control." However, the agency has concluded that the statement "useful only in not promoting tooth decay" should not be allowed because it is an unauthorized health claim. In the general principles proposal (56 FR 60437), the agency stated that it intended to reevaluate the usefulness of chewing gums sweetened with sugar alcohols in not promoting tooth decay. The agency acknowledged that the data supporting the claim were over 20 years old and requested new data. The agency received data in response to the request and will make a determination on the validity of this claim in accordance with the final rule on health messages published elsewhere in this issue of the **Federal Register**. Accordingly, the agency is not revising § 101.60(c)(1)(iii)(B) to allow the statement "useful only in not promoting tooth decay" to appear with "sugar free" claims.

The agency is deleting the exemption in proposed § 101.13(o)(8) that would have allowed a "sugar free" claim on chewing gums containing sugar alcohols and the statement about not promoting tooth decay. As explained above, this exemption is no longer needed because the agency has decided not to define sugar alcohols as "sugars."

84. Many comments requested that FDA revise proposed § 101.13(o)(8) to allow the statement "Toothfriendly" to accompany "sugar free" claims on the label of chewing gums in place of the statement "useful only in not promoting tooth decay." In addition, these comments requested that such statements may be accompanied by a pictogram of a smiling tooth. These comments stated that the term "Toothfriendly" is more readily understood by consumers with limited reading and vocabulary skills. One comment said the "Toothfriendly" dental education programs have been successfully promoted in several European countries by "Toothfriendly Sweets International," a nonprofit organization dedicated to promoting dental health. The agency received at least one comment opposing the term "Toothfriendly." The comment contended that the "Toothfriendly" program is just another third party endorsement program similar to those the agency has considered in the past. It stated that the claim is unsupported by any evidence and would promote the consumption of foods that are completely without nutritive benefit.

The agency is denying this request because it believes that the statement "Toothfriendly" accompanied by a pictogram of a smiling tooth is an implied health claim that, unless a regulation is established, is unauthorized (see section 403(r)(1)(B) of the act). As discussed in the previous comment, the agency has not made a determination that chewing gums sweetened with sugar alcohols are useful in not promoting tooth decay.

85. A few comments stated that the definition of "sugar free" should be less than 4 g per serving. They said that they selected this value because it is the dietary requirement for diabetics. Another comment requested that the term "sugar free" be accompanied by the statement: "For use in diabetic meal plans. Not a reduced calorie food (if appropriate)."

The agency does not agree that "sugar free" should be less than 4 g of sugars per serving as explained in the general principles proposal (56 FR 60421 at 60436). The agency emphasized there that the definitions of nutrient content claims do not specifically address issues related to diabetes management practices, and that diabetes management should not be based solely on the consumption of "sugar free" foods. Rather, diet planning for diabetics should encompass the entire diet and be supervised by a trained professional. The agency notes that the American Diabetes Association (ADA) submitted a comment that expressed strong support for defining "sugar free" at less than 0.5 g per serving. It stated that the amount of sucrose or other sweeteners in their recipes should not be used in the context of support for defining this claim. Accordingly, the agency is not defining "sugar free" as less than 4 g per serving. Consistent with this policy on "sugar free," the agency also denies the request that "sugar free" claims be accompanied by the statement, "For use in diabetic meal plans. Not a reduced calorie food."

86. A couple of comments objected to the provision in proposed § 101.60(c)(1)(ii) that a food containing added ingredients that are sugars cannot be labeled "sugar free," even though it still contains less than 0.5 g of sugars. One comment stated that FDA should not distinguish between trivial amounts present naturally, and those present because they were added. Other comments supported the proposal. They agreed that the listing of a sugar, for example, as an ingredient of a product bearing a "sugar free" claim is confusing and misleading. One comment expressed concern that the agency is allowing ingredients containing sugars, such as fruit juices, to sweeten foods that bear a "sugar free" claim. Other comments suggested that the confusion could be eliminated if the label of a "sugar free" food that has ingredients containing sugars disclose that the amount of sugar is trivial. Most of these comments preferred that the disclosure appear in the ingredient statement.

The agency has reconsidered the provision that disallows the addition of ingredients that are sugars to foods that bear a "sugar free" claim and is persuaded that it is unduly restrictive. The agency accepts the recommendation that the proposed provision be revised and that a disclosure statement be required to avoid consumer confusion about the quantity of sugar in the food. The agency believes that it is the listing of sugar or ingredients that are generally known to contain sugars that creates the confusion. Accordingly, the agency is revising new § 101.60(c)(1)(ii) to require that the food contain no ingredient that is a sugar, or that is generally understood by consumers to be a sugar, unless the listing of the ingredient in the ingredient statement be followed by an asterisk that refers to a disclosure statement appearing below the list of ingredients. The statement shall read: "adds a trivial amount of sugar," "adds a negligible amount of sugar," or "adds a dietarily insignificant amount of sugar."

iii. "No added sugar," and "unsweetened"/"no added sweeteners". In the general principles proposal (56 FR 60421 at 60437), FDA proposed in § 101.60(c)(2) to permit the use of the terms "no added sugars," "without added sugars," or "no sugars added" (revised in this final rule to state "no added sugar," "without added sugar," or "no sugar added" as discussed in the section on "Sugar Free"). The agency said, however, that to use the claim five conditions must be met: (1) No amount of sugars, as defined in proposed § 101.9(c)(6)(ii)(A) (redesignated as § 101.9(c)(6)(ii) in the final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**), is added during processing or

packaging; (2) the product does not contain ingredients that contain added sugars; (3) the sugars content has not been increased above the amount naturally present in the ingredients by some means such as the use of enzymes; (4) the food that it resembles and for which it substitutes normally contains added sugars; and (5) the product bears a statement that the food is not low calorie or calorie reduced (unless the food meets the requirements for a low or reduced calorie food) and directing consumers' attention to the nutrition panel for further information on sugars and calorie content.

The intent of the agency in defining these terms was to aid consumers in implementing dietary guidelines that stipulate that Americans should "consume sugars only in moderation," consistent with the definition for "sugars" that FDA is adopting in new § 101.9(c)(6)(ii) in the final rule on mandatory nutrition labeling. In implementing the guidelines, the purpose of the "no added sugar" claim is to present consumers with information that allows them to differentiate between similar foods that would normally be expected to contain added sugars, with respect to the presence or absence of added sugars. Therefore, the "no added sugar" claim is not appropriate to describe foods that do not normally contain added sugars. In such cases, proposed § 101.60(c)(3) would provide for the use of a factual statement that the food is unsweetened, or that it contains no added sweeteners in the case of a food that contains apparent substantial inherent sugar content, e.g., fruit juices, without requiring that the food meet the definition for "sugar free."

87. Some comments addressed use of the "no added sugar" terms on foods containing fruit juice as an ingredient. One comment interpreted the proposal as providing that modified juice products and juice products that function as sweeteners are not to be considered as added sugars. The comment specifically requested that FDA clarify its position on this matter. Another comment stated that the use of fruit juices as sweetening agents caused problems for diabetics and suggested that the five requirements listed in new § 101.60(c)(2) for a "no added sugar" claim should be supplemented by a sixth criterion: That a food does not contain sugars in the form of fruit juice, fruit concentrate, applesauce, or dried fruit.

The agency advises that the purpose of a "no added sugar" claim is to identify a food that differs from a similar food because it does not contain the added sugars that would normally be present in the other food. For this provision to be of practical benefit to consumers, it must preclude use of the claim on a food where the sugars that are normally added are replaced with an ingredient that contains sugars that functionally substitute for the added sugars. Thus, the agency concludes that the use of any ingredient that contains sugars, including fruit juice and modified or concentrated fruit juice, for the purpose of substituting for sugars that would normally be added to a food precludes the use of the "no added sugar" nutrient content claim. To avoid misinterpretation of the regulation on this matter, FDA is revising new § 101.60(c)(2)(i) to state: "No amount of sugars, as defined in § 101.9(c)(6)(ii), or any other ingredient that contains sugars that functionally substitute for added sugars is added during processing or packaging."

88. One comment interpreted proposed § 101.60(c)(2) to mean that a "no added sugar" claim would not be precluded on a product such as an all-fruit spread if that product does not contain sugar-sweetened ingredients.

FDA advises that to qualify for a "no added sugar" claim, the ingredients in the all-fruit spread could not include any ingredient that meets the agency's definition of "sugars" (new § 101.9(c)(6)(ii)), or any ingredient that contains sugars that functionally substitute for added sugars (e.g., fruit juice) (new § 101.60(c)(2)(i)), nor any ingredient that contains added sugars (e.g., concentrated fruit juice) (new § 101.60(c)(2)(ii)).

89. A comment recommended that foods that contain only indigenous sugars, but not including sugars present in concentrated or otherwise altered ingredients or products, be exempt from the requirement for disclaimer and referral statements. This comment stated that a statement such as "no added sugar" is less a nutrient content claim than an assurance that the sweetness characteristics of a product are not derived from added processed sugars, such as sucrose or high fructose corn syrup, and that this information is essential to diabetics that have been instructed by a physician to seek out foods that do not have added processed sugar but instead are fruit juice based.

The comment suggested that the required disclaimer indicating that a food is not "low" or "reduced" in calories may be misleading to consumers, causing unjust alarm that a juice product is high in calories and unhealthy. As an alternative to the disclaimer, the comment favored a qualifying statement for foods sweetened with concentrated juices, such as "sweetened with concentrated grape juice."

A similar comment requested that FDA exempt pure fruit juices from the provisions of proposed § 101.60(c)(2) or revise this section by deleting proposed § 101.60(c)(2)(iv) and (c)(2)(v) (i.e., the requirements that the food that the product resembles and for which it substitutes normally contains added sugars, and that the product bear a disclaimer statement that it is not low calorie or calorie reduced and that directs the consumer's attention to the nutrition panel). The comment stated that a "no added sugar" claim on fruit juices had been used for many years without consumer confusion, that it helped to increase consumer awareness of the added sugars in flavored drinks, and that products that are pure juices do not contain added sugars. The comment also stated that consumers regard the terms "no added sweeteners" and "no added sugar" as synonymous, and that they do not regard juices as low or reduced calorie products.

The agency disagrees with the fundamental position of these comments that a special allowance for the "no added sugar" claim should be made when the sugars added to a food are inherent to the ingredient through which they are added. As discussed in comment 79 in section III.B.c.ii. of this document, the agency believes that it is misleading to imply that a food that contains inherent sugars is nutritionally superior to a food that contains refined sugars. Thus, the labeling of a product sweetened with juice concentrate, though it bears a factual statement identifying the source of the sweetener, would be misleading if it included the statement "no added sugar." The agency concludes that granting the allowances that these comments seek would permit the use of "no added sugar" in a manner that is inconsistent with the purpose of this claim, i.e., to aid consumers in implementing dietary guidelines that stipulate that Americans should "consume sugars only in moderation." Thus, FDA is not making any changes in response to these comments.

90. One comment expressed concern that the addition of concentrated juice to unconcentrated apple juice for the purpose of achieving uniformity in the finished juice may preclude the use of the term "no sugar added."

The agency advises that the addition of a concentrate of the same juice to achieve uniformity would not, in itself, preclude the use of a "no sugar added" claim, provided, the other conditions for the claim are met. (See also the document on ingredient labeling

published elsewhere in this issue of the **Federal Register**.) If a concentrate of another juice were added for the purpose of increasing the sugar content of the finished juice, the product could not bear a "no sugar added" claim.

91. One comment sought assurance that fruit juice from concentrate that has been reconstituted to normal strength would be able to make a "no sugar added" claim.

The agency advises that the addition of water to a juice concentrate to produce a single strength juice would not preclude the use of a "no added sugar" claim; however, the other conditions for the claim must still be met.

92. Several comments requested confirmation that fruits packed in fruit juice would be able to make a "no sugar added" claim under the provisions of proposed § 101.60(c)(2). One of the comments stated that the Brix of the juice would not be above that of the fruit itself, and another noted that no refined sugars would be used in the product but only fruit juices or concentrated fruit juice.

The agency concludes that juice-packed fruits that contain juice with the same sugars content as the single strength juice of the fruit would qualify for a "no sugar added" claim, provided that the other conditions for the claim are met. This food meets the criteria for the claim in § 101.60(c)(2). If these same fruits were packed in syrup or in juice concentrate, they would not qualify for this claim under § 101.60(c)(2)(ii) because syrup and juice concentrate are ingredients that contain added sugars.

93. One comment stated that if enzymes are used primarily for flavor or texture development, or for reasons other than to intentionally alter the sugars content of a product, then the food should be permitted to bear a "no sugar added" claim. The comment maintained that although such enzymatic processes may result in a slight increase in the sugar content of the product, the increase would not necessarily alter the sweetness profile of the product. The comment expressed the view that the agency's limitation in proposed § 101.60(c)(2)(iii) for "no sugar added" for such foods is overly restrictive and not in the best interest of consumers.

The agency agrees that proposed § 101.60(c)(2)(iii) should not preclude the use of enzymes or other processes where the intended functional effect of the process is not to increase the sugars content of a food, even though an increase in sugars that is functionally insignificant does occur. FDA concludes that such a prohibition would be overly restrictive and without benefit to consumers seeking to moderate their sugars intake because any increase in the sugars content of a food from such processes would be of little, if any, consequence in the total diet. Accordingly, FDA has revised new § 101.60(c)(2)(iii) in the final rule to state:

> The sugars content has not been increased above the amount naturally present in the ingredients by some means such as the use of enzymes, except where the intended functional effect of the process is not to increase the sugars content of a food, and a functionally insignificant increase in sugars results.

iv. Calorie free. 94. The agency received a few comments on the term "calorie free." These comments supported the proposed definition of less than 5 calories per serving. One comment preferred that the definition be less than 2.5 calories but did not object to the proposed definition.

Based on these comments, the agency concludes that no change in the definition of "calorie free" is necessary.

95. One comment requested that soda water not be used as an example of a "calorie free" food because some consumers may conclude that all diet soft drinks are "calorie free" foods.

To avoid confusion, the agency is revising new § 101.60(b)(1)(ii) to read: (e.g., "cider vinegar, a calorie free food").

v. Fat free. 96. Most of the comments on the definition of the term "fat free" supported the proposed definition of less than 0.5 g of fat per serving. A few comments disagreed with less than 0.5 g. Some of these comments stated that "fat free" should be zero fat, while at least one comment suggested that the definition should be 0.5 g or less of fat.

The agency points out that zero fat is not an option as a limit because it is analytically impossible to measure. The proposed definition of less than 0.5 g of fat is appropriate because it is the reliable limit of detection of fat in all types of foods, and thus analytically it equates to zero. Furthermore, 0.5 g of fat is low enough compared to the DRV for fat, which the agency is establishing at 65 g (§ 101.9(c)(9)), to be considered dietarily and physiologically insignificant. For example, a person consuming 10 servings per day of "fat free" foods would consume less than 5 g of fat from these sources.

The agency is not including 0.5 g in the definition because the comment that suggested this change provided no compelling reason for it. Less than 0.5 g of fat is consistent with the way "free" terms have been defined by FDA in the past and with the way the agency is defining other "free" terms in this final regulation. Accordingly, the agency has not revised this definition.

97. At least one comment suggested that "fat free" be defined in terms of the fat content per serving and per 100 g of the food. The comment noted that the density criterion would prevent foods with small serving sizes, such as crackers, from making a "fat free" claim.

The agency is not persuaded that a second criterion based on the amount of fat per 100 g is necessary for the definition of "fat free." The first criterion of less than 0.5 g of fat requires that the food contain such a trivial level of fat that even frequent consumption of foods that bear a "fat free" claim would not affect in any meaningful way the overall fat level in the diet. Accordingly, the agency has not revised the definition of "fat free." This conclusion applies equally to all of the "free" claims that are being defined.

98. A few comments recommended that "fat free" be defined solely on the basis of less than 0.5 g per 100 g.

FDA considered this approach of defining nutrient content claims solely on the amount of a nutrient in a specified weight of food. This approach has the advantage of presenting a nutrient content claim for a food in a way that is more consistent with labeling used internationally. In addition, it allows consumers a means to more readily compare very dissimilar foods. However, FDA does not believe that this approach alone is appropriate for defining nutrient content claims. Foods are consumed in various amounts depending upon their nature and use in the diet. The agency believes that nutrient content claims could be misleading and not useful to consumers when expressed solely in terms of 100 g of food because this approach does not reflect amounts customarily consumed for all foods. For this reason, FDA did not take this approach in defining the term "fat free." Accordingly, the agency is not revising the definition of "fat free" in this manner.

99. Several comments objected to the provision in proposed § 101.62(b)(1)(ii) that a food containing added fat cannot be called "fat free," even though it still contains less than 0.5 g of fat per serving. One comment stated that "the agency should not speak of good faith or bad; it is simply a matter of definition and materiality." It contended that whether the fat is inherent or added should not be relevant as long as the amount present is less than 0.5 g. Comments stated that this provision would deprive consumers of the benefit of many innovative, nutritious products and argued that it would discriminate

against foods in certain categories based on dietarily insignificant amounts of fat. For example, less than 0.5 g of fat is added to some salad dressings that would otherwise meet the definition of "fat free." Furthermore, one comment noted that the proposed rule may be difficult to enforce since fat that is inherent cannot be distinguished from added fat.

Alternatively, many comments supported the proposal. They agreed that the listing of soybean oil, for example, as an ingredient of products bearing "fat free" claims is confusing and misleading. One comment said that "fat free" is a misnomer if fat has been added to the food. A few of these comments believed that even the addition of ingredients containing fat, such as nuts, should be disallowed. Other comments suggested that the confusion could be eliminated if the label of products containing any ingredient that contains fat were required to bear a disclosure statement, such as, "soybean oil (trivial source of fat)." Most of these comments preferred that the disclosure appear in the ingredient statement.

The agency has reconsidered the provision that disallows the addition of fat to foods that bear the claim "fat free" and is persuaded that it is unduly restrictive. The agency has decided to revise new § 101.62(b)(1)(ii) in the same way that is has revised § 101.60(c)(1)(ii) on "sugar free" claims and § 101.61(b)(1)(ii) on "sodium free" claims because the same considerations apply with respect to each of these claims. The agency believes that it is the listing of fats or ingredients that are generally understood by consumers to contain fat (i.e., nuts) in the ingredient statement that creates the confusion, and that a disclosure statement about the amount of fat in the food will eliminate that confusion. Accordingly, the agency is revising new § 101.62(b)(1)(ii) in the final rule to require that the listing of fats or ingredients that are understood to contain fat in the ingredient statement be followed by an asterisk that refers to a disclosure statement appearing below the list of ingredients. The statement shall read: "adds a trivial amount of fat," "adds a negligible amount of fat," or "adds a dietarily insignificant amount of fat."

vi. "Percent fat free" claims. FDA proposed several provisions in the fat/cholesterol proposal (56 FR 60478) regulating the use of "percent fat free" claims to ensure that the consumer is not misled by these claims, and that, as the claim implies, the food does in fact contain only a small amount of fat. Specifically, FDA proposed in § 101.62(b)(6)(i) to require that "percent fat free" claims can only be made: (1) For "low fat" foods (i.e., foods containing 3 g or less of fat per serving and per 100 g of food) or (2) for "low fat" meal-type products (i.e., meal-type products containing 3 g or less of fat per 100 g of product).

The agency also proposed in § 101.62(b)(6)(ii) to require that a disclosure statement of the amount of total fat in a serving of food appear in immediate proximity to the most prominent "percent fat free" claim, and that such disclosure statement be in type no less than one-half the size of the type of the "percent fat free" claim. In § 101.62(b)(6)(iii), FDA proposed that the type size of all the components of the "percent fat free" claim must be uniform.

Finally, FDA proposed in § 101.62(b)(iv) that a "100 percent fat free" claim must meet all of the criteria for "fat free" claims (i.e., foods containing less than 0.5 g of fat per serving and not containing any added ingredient that is a fat or oil). Furthermore, the agency advised that if the food is inherently free of fat, the label will disclose that fat is not usually present in the food (e.g., "a 100 percent fat free food").

The agency specifically requested comments as to whether the proposed requirements were sufficient to prevent "percent fat free" claims from being misleading, or whether such claims should be prohibited entirely.

100. Although the majority of comments supported the proposal to permit "percent fat free" claims on low fat foods, several comments opposed permitting the use of this claim. The primary reason cited in these comments was that this claim is misleading and confusing to consumers. One comment further stated that if FDA allowed "percent fat free" claims, it should only allow them on foods that meet the definition of "fat free." Another comment suggested that such claims be restricted to meat and poultry products, because they help to identify leanness.

The agency acknowledges that under current regulations, the use of a "percent fat free" claim has the potential to be misleading and confusing to consumers, especially when this claim appears on foods that derive a high percentage of their calories from fat. However, the agency concludes that with implementation of the provisions of this final rule regulating the appropriate use of a "percent fat free" claim (i.e., being restricted to use on products that meet "low fat" definitions), the claim will not be misleading or confusing. Furthermore, the comments that requested that the use of this term be prohibited did not provide evidence to persuade the agency that the requirements, as proposed, were insufficient to prevent misleading claims on food labels. In addition, FDA advises that the purpose of a "percent fat free" claim on nonmeat products does not relate to leanness but to information regarding the total amount of fat present in a serving of the food.

Further, the agency believes that to allow "percent fat free" claims only on "fat free" foods would be unduly restrictive. Such claims on foods that are "low" in fat, can, if properly made, be useful in assisting consumers to maintain healthy dietary practices. Consequently, the agency is denying these requests to prohibit or restrict the "percent fat free" claim.

101. One comment stated that "percent fat free" claims on bakery products may encourage consumers to purchase such products because they are low in fat, but the comment noted with concern that bakery products are high in calories, sugar, or sodium.

The agency recognizes that certain low fat foods may contain varying amounts of calories, sugar, or sodium. However, the agency does not expect a single claim (e.g., "97 percent fat free") to provide information regarding all of the nutrients contained in a product. Information on calories, sugar, and sodium will be provided in nutrition labeling, and therefore, available to the consumer at the time he or she makes a purchase decision. Moreover, if the nutrient levels in the food exceed levels at which a disclosure statement is required, a disclosure statement must appear in close proximity to the claim.

102. A comment from a foreign government opposed permitting "percent fat free" claims. The comment stated that its laws did not permit such terms to be used because they are potentially misleading. The comment suggested that FDA should not allow such claims on products.

As discussed in the previous comment, the agency recognizes that a "percent fat free" claim under regulations currently in effect can be misleading and confusing to the consumer. However, the provisions that the agency is establishing in new § 101.62(b)(6) regulating the use of a "percent fat free" claim address the aspects of such claims currently in use that have the potential to make them confusing or misleading. Thus, the agency concludes that in light of the action that it is taking, it is not necessary to ban these claims.

103. Other comments suggested that the "percent fat free" claim should be based on the amount of total calories contributed by the fat and not on the weight of the product, because basing the claim on the weight of the product has the potential to be misleading.

The agency disagrees with the comment. FDA believes that consumers are most familiar with claims expressed in terms of g per serving, and not claims based on the percentage of calories contributed by fat. FDA further believes, as stated in the fat/cholesterol proposal, that "percent fat free" claims imply that the food contains very small amounts of fat (i.e., "low" fat), and that the food is useful in structuring a diet that is low in fat. Basing the "percent fat free" claim on a designated percentage of total calories from fat would not limit the total amount of fat present in the food. Thus, a food high in calories may be able to make a "percent fat free" claim under a calorie criterion, because the percentage of total calories contributed by the fat falls within an established guideline. Yet, the amount of fat in such foods could exceed the amount that is defined as "low" fat. On such a food, the "percent fat free" claim would be misleading. Accordingly, the agency is not permitting "percent fat free" claims to be based on the percentage of calories contributed by fat.

104. Some comments requested that the agency require disclosure of the percent of calories from fat and the amount of available calories (i.e., total calories minus calories attributed to dietary fiber).

The comments requesting disclosure statements of percent calories from fat and available calories did not provide evidence on which the agency could make a finding that such disclosures were necessary to prevent a "percent fat free" claim from being misleading. Therefore, the agency finds no basis for requiring those disclosure statements. Furthermore, the agency believes that disclosure statements based on percent of calories would confuse consumers when all other disclosure statements are based on amount of g per serving. Therefore, the agency is denying the request for these disclosure statements.

105. The comments on the proposed requirement of a disclosure statement in immediate proximity to the "percent fat free" claim which specified the amount of fat in the product were equally divided in support of and against the provision. Some comments opposing the disclosure statement argued that the disclosure statement was unnecessary because the food must meet the definition of "low fat" before a "percent fat free" claim can be made. The comments also pointed out that a referral statement will direct the consumer to the nutrition label where fat is declared.

The agency recognizes that the "percent fat free" claim may not be made on the label or labeling of a product unless the food bearing the claim is "low in fat." This fact ensures that foods bearing a "percent fat free" claim will not contribute excessive amount of fat to the total diet. Thus, upon reconsideration, FDA does not find it necessary to require that foods bearing a "percent fat free" claim also disclose the amount of total fat per serving adjacent to the claim. Further, as one comment pointed out, the "percent fat free" claim will have to be accompanied by a statement referring consumers to the nutrition label, and that the total amount of fat in the product will be provided there. In addition, as discussed in response comment 214, FDA has concluded that it is not necessary to include absolute amounts in the principal display panel. Therefore, the agency is persuaded by the comments that these requirements obviate the need for a statement, adjacent to the claim, which discloses the amount of fat per serving in the product bearing such a "percent fat free" claim, and the agency is deleting this requirement in the final rule.

106. Two comments that supported the "no percent fat free" claim stated that the 3 g limitation was too restrictive and should be raised to 4 g. A third comment supporting the "percent fat free" claim stated that the only criterion should be 3 g or less per serving and that there should not be a second criterion of 3 g or less per 100 g.

As discussed in the fat/cholesterol proposal (56 FR 60478 at 60491), a "percent fat free" claim emphasizes how close the food is to being free of fat. The agency believes that this claim implies, and consumers expect, that products bearing "percent fat free" claims contain relatively small amounts of fat and consequently are useful in maintaining a diet low in fat. Thus, the agency finds that the appropriate approach to defining a "percent fat free" claim is that it be based on the definition of "low fat." Having said this, the agency points out that these comments raise objections to the definition for "low fat." The agency's decision on the final definition of "low fat" is discussed elsewhere in this document.

107. A few of the comments supporting the provision that "100 percent fat free" claims appear only on "fat free" foods, requested that "100 percent fat free" claims should also be allowed on foods to which fat has been added, as long as the food still complies with the "fat free" definition.

Although the agency has reconsidered its definition of "fat free" to allow foods with added fat that meet the definition of "fat free" to make a "fat free" claim, the agency has not been persuaded that a "100 percent fat free" claim should appear on foods with added fat. The agency believes that a "100 percent fat free" claim places more emphasis on the complete absence of fat in the food, and therefore the food should not have added fat. Thus, the agency is not permitting a food with added fat to make a "100 percent fat free" claim.

108. One comment objected to all "percent fat free" claims under the proposal. This comment stated that a "100 percent fat free" claim can be made on a food that contains 0.4 g of fat per serving and 3 g of fat per 100 g if the fat is not added, e.g., crackers with no added fat that contain 0.4 g per serving. However, if the crackers had the same amount of fat but as added fat, the claim would have to say "97 percent fat free." The comment asserted that such inconsistencies would be misleading and confusing to the consumer. Further, another comment objected to the provision that allows some foods to claim "100 percent fat free" when in fact they contain more than 0.5 g of fat per 100 g of the food and are, therefore, not 100 percent fat free. This comment stated that proposed § 101.62(b)(6)(iv) only requires that a food bearing this claim contain less than 0.5 g of fat per serving. Thus, a food with a serving size of 20 g, for example, could contain 2.45 g of fat per 100 g of the food.

The agency agrees with the latter comment. The agency did not intend to allow foods containing 0.5 g or more of fat per 100 g to bear the claim "100 percent fat free." Accordingly, the agency is revising the final rule in new § 101.62(b)(6)(iii) to require that a "100 percent fat free" claim can be made only on foods that meet the criteria for "fat free," that contain less than 0.5 g of fat per 100 g, and that contain no added fat. This revision also addresses the problem raised in the first comment. Furthermore, the agency advises that in declaring other "percent fat free" claims, the claim must accurately reflect the amount of fat present in 100 g of the food. For example, if a food contains 2.5 g of fat per 50 g then the claim should be "95 percent fat free."

109. A few comments suggested that the "percent fat free" claim be defined separately from, and not include, the "low fat" criteria because the "low fat" definition is unduly restrictive and does

not adequately differentiate the two claims. The comments further suggested that "percent fat free" claims for foods that are between 90 and 100 percent fat free be allowed. They contended that setting a threshold level of 97 percent fat free (3 g or less per 100 g) discourages consumers from eating products that are fairly low in fat but do not conform to the proposed definition for "low" and therefore gives the impression that FDA is making good food/bad food distinctions.

As stated in response to comment 106 of this document, a "percent fat free" claim is properly viewed as a "low fat" claim because it emphasizes how close the food is to being free of fat. Furthermore, basing the "percent fat free" claim on the criteria required for "low fat" products provides the consumer with a consistent method of comparison with respect to "low fat," "fat free," and "percent fat free" claims such that accurate comparisons can be made among different products. To establish separate criteria for a "percent fat free" claim could cause confusing and misleading information to be disseminated to the consumer and, thus, be contrary to the purpose of the nutrient content claims provisions of the act.

The agency also rejects the comments proposing that claims of up to "90 percent fat free" be allowed. The agency believes that such a definition would not be consistent with consumers' expectations of the fat content of foods bearing this claim because it would allow "percent fat free" claims on foods with significantly greater amounts of fat than "low fat" foods.

Furthermore, the agency is not convinced by the comments or other available information that if FDA does not permit a "90 percent fat free" claim, consumers would be discouraged from purchasing products that are "fairly" low in fat (less than 10 g per 100 g) but that do not meet the definition for "low fat." In the absence of a "percent fat free" claim, consumers will still be able to consult the nutrition label to determine the total amount of fat contained in a product and to make purchase decisions based on this information according to their individual dietary preferences.

Although the agency does not agree that a "percent fat free" claim should be allowed for foods containing up to 10 percent fat by weight, the agency has reconsidered the basis and application of the weight-based criterion for "low fat" and "percent fat free" claims such that the weight-based criterion only applies to foods with reference amounts 30 g or less or 2 tablespoons or less (see comment 45). Further, foods with reference amounts of 30 g or less or 2 tablespoons or less may bear such claims provided that they contain 3 g or less fat per reference amount and per 50 g. Therefore, foods with small reference amounts containing 6 g or less fat per 100 g will be able to bear a "percent fat free" claim. Consequently, claims of up to "94 percent fat free" will be allowed on these products that also meet the criteria for "low fat." In addition, foods with reference amounts greater than 30 g or greater than 2 tablespoons that meet the "low fat" definition may bear "percent fat free" claims. The agency believes that permitting such claims is consistent with dietary guidelines for reducing fat intake, because it would allow such claims on a wider variety of foods for which increased consumption is recommended in national dietary guidance. This issue is fully discussed in section III.A.1.b. of this document.

110. One comment suggested that the "percent fat free" claim be allowed on products containing 5 g or less fat per 100 g. Another comment suggested that the "percent fat free" claim be allowed on products containing 5 g or less fat per serving and per 100 g; no more than 30 percent of calories from fat; and no more that 10 percent of calories from saturated fat. The comment asserted that these three criteria would ensure that a "percent fat free" claim is not misleading, yet be less restrictive than the provisions proposed in the fat/cholesterol proposal.

Another comment proposed that the definition for "percent fat free" claims be based on either: (1) The food being "low fat," where low fat is 4 g or less per serving and being at least 90 percent fat free, or (2) the product being 90 percent fat free but providing no more than 4 g of fat per serving; the label disclose the number of g of fat per serving in conjunction with the "percent fat free" claim; and the product be at least 2 g of fat per serving less than the weighted average fat level of other similar products. The comment asserted that these criteria would provide an effective and less restrictive means of drawing consumers' attention to a reduced-fat content food, while allowing the consumer more reduced-fat products from which to choose.

The agency considered the alternative criteria for "percent fat free" claims as suggested in these comments. The suggested approaches establish differences between the "low fat" and "percent fat free" claims that the agency believes are inappropriate. As explained in comment 106 of this document, consumers expect a product with a "percent fat free" claim to be low in fat, and the comments did not present evidence to FDA to demonstrate to the contrary. Consequently, the most logical approach for defining a "percent fat free" claim is to choose criteria that make the claim consistent with the definition of "low fat" or "fat free." Thus, the agency rejects the alternative approaches recommended in the comments. Furthermore, the comments suggested alternatives that require comparison of amounts of fat among different products. This approach is more consistent with the criteria used for comparative claims such as "reduced" or "less" and is not appropriate for nutrient content claims such as "percent fat free." Further, in addition to not being consistent with the definitions for "low fat" or "fat free," the suggested alternatives are based on extremely complex definitions that could result in consumer confusion concerning the meanings of the terms "low fat," "fat free," and "percent fat free."

vii. Saturated fat free. 111. A number of comments strongly recommended that FDA define the term "saturated fat free" and terms that would be synonyms for "saturated fat free." These comments argued that a "free" claim is one of the most powerful claims, and that saturated fat is one of the more important nutrients from a public health perspective. They stated that this claim would be extremely useful because the foods that would qualify are the foods that consumers are being encouraged to eat more frequently. Furthermore, the availability of this claim would provide an incentive for the development of new foods that are "saturated fat free."

Some of the comments responded to FDA's reason for not defining this term. The agency argued that since less than 0.5 g per serving is "fat free," one-third of this amount, or 0.17 g per serving, would be the appropriate definition for "saturated fat free." The agency did not propose a definition because it concluded that saturated fat could not be accurately measured at this level. The comments did not dispute this point, but they argued it is appropriate to define "saturated fat free" as less than 0.5 g of saturated fat per serving based on the same criteria used for "fat free" claims, i.e., dietary insignificance and reliable detection.

One of these comments contended that a food that is "fat free" logically must be free of saturated fat because saturated fat is included in the definition of total fat. Other comments suggested that the definition be less than 0.25 g per serving on the basis of dietary insignificance. These comments did not discuss problems with

detection, except for one comment that stated that it should not be difficult to reliably detect saturated fat at 0.25 g per serving. This comment pointed out that in the proposed rule on mandatory nutrition labeling (56 FR 60366) less than 0.25 g of saturated fat per serving is the level that can be declared as "0." Another comment noted that consumers would likely be confused if foods declaring "0" g of saturated fat in the nutrition label bear the claim "low in saturated fat" instead of "saturated fat free."

The agency is persuaded by the comments that the term "saturated fat free" would be useful to individuals trying to reduce their intake of saturated fat. It is defining this term as less than 0.5 g of saturated fat per serving because the majority of the comments on this proposed rule and on the proposed rule on mandatory nutrition labeling (56 FR 60366) that addressed this issue stated that a lower value cannot be reliably detected. FDA has been convinced by these comments, which showed that less than 0.5 g of saturated fat is the reliable limit of detection of saturated fat in all types of foods, and thus analytically it equates to zero.

The agency notes that it is aware of the concerns that trans fatty acids, which are unsaturated fatty acids, may raise serum cholesterol and has requested data on this issue. A review of the information submitted and of the published literature shows that the evidence that suggests that trans fatty acids raise serum cholesterol remains inconclusive, as fully discussed in the final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**. However, because of the uncertainty regarding this issue, the fact that consumers would expect a food bearing a "saturated fat free" claim to be free of saturated fat and other components that significantly raise serum cholesterol, and the potential importance of a saturated fat free claim, the agency believes that it would be misleading for products that contain measurable amounts of trans fatty acids to bear a "saturated fat free" claim. Thus, the agency is including a limit on trans fatty acids of 1 percent of the total fat in the definition of "saturated fat free" because the analytical techniques for measuring trans fatty acids below that level are not reliable. Accordingly, the agency is providing in new § 101.62(c)(1)(i) that the term "saturated fat free" ("free of saturated fat," "no saturated fat," "without saturated fat," "zero saturated fat," "trivial source of saturated fat," "negligible source of saturated fat" or "dietarily insignificant source of saturated fat") may be used on the label of a food if the food contains less than 0.5 g of saturated fat per serving and 1 percent or less of total fat as trans fatty acids.

Consistent with the requirements for other "free" claims, the agency is requiring in new § 101.62(c)(1)(ii) that the listing of ingredients generally understood by consumers to contain saturated fat must be accompanied by a statement such as "adds a trivial amount of saturated fat." Also, the agency is requiring in new § 101.62(c)(1)(iii) that foods meeting the definition without special processing must be labeled in a manner that makes this clear.

To accommodate this insertion, proposed § 101.62(c)(1) through (c)(3) is being redesignated as § 101.62(c)(2) through (c)(4), respectively. It should be noted that proposed § 101.62(c) required that all foods bearing claims about saturated fat should disclose the amount of total fat and cholesterol in the food in immediate proximity to such claims. As discussed in response to comment 138 of this document, the provision on the disclosure of cholesterol with these claims is required by section 403(r)(2)(A)(iv) of the act. Because FDA is now defining the term "saturated fat free," the provision on the disclosure of total fat is revised to require the disclosure of total fat with a "saturated fat free" claim unless the food contains less than 0.5 g of total fat per reference amount (i.e., unless the food meets the definition of "fat free"), in which case the amount of total fat need not be disclosed. The agency concludes that disclosure of the amount of total fat is necessary when a "saturated fat free" claim is made for a food that is not "fat free" to prevent consumers who do not differentiate between a "saturated fat free" and "fat free" claim from being misled by a "saturated fat free" claim (see comment 139 of this document for related discussion).

112. One comment requested that FDA define the term "very low saturated fat" as less than 0.5 g per serving. This comment stated that "saturated fat free" should be defined as less than 0.25 g per serving. Other comments requested that FDA define "very low" claims for other nutrients.

The agency rejects this request because it concludes that "saturated fat free" should be defined as less than 0.5 g per serving, as explained in the previous comment. Defining the term "very low saturated fat" is unnecessary because the proposed value for "low saturated fat" is only double the value for "saturated fat free." Furthermore, the agency is not defining any new "very low" terms because it believes that consumers would be confused by these terms in addition to the "free" terms. The term "very low sodium" is being retained because it has been in use for a number of years and is defined as 35 mg or less of sodium per serving, which is 7 times the cutoff level for "sodium free" and one-quarter of the cutoff level for "low sodium." Accordingly, the agency is not defining "very low saturated fat."

viii. Cholesterol free. 113. Most of the comments on the definition of the term "cholesterol free" supported the definition in proposed § 101.62(d)(1) of less than 2 mg of cholesterol per serving. A few comments disagreed. Some of the latter comments stated that a "cholesterol free" claim is misleading if the food contains any cholesterol. One of these comments suggested that a "cholesterol free" claim be accompanied by the statement, "this product may contain up to 2 mg of cholesterol." Other comments stated that "cholesterol free" should be less than 5 mg per serving, so that nonfat dairy products can make this claim. One of these comments said that changing the requirement to 5 mg or less would be an incentive to food manufacturers to reformulate products so as to make this claim. Another comment said that FDA has failed to establish that 5 mg of cholesterol would not also be dietarily insignificant.

The agency is not persuaded that the proposed value of less than 2 mg of cholesterol per serving should be changed or needs to be defined on the label. The agency selected this value because it represents the typical limit of reliable detection for existing analytical methods. A value of zero is not an option because it is analytically impossible to measure. Furthermore, 2 mg per serving is low enough compared to the DRV for cholesterol, which is 300 mg, to be considered dietarily and physiologically insignificant. As discussed in the tentative final rule on cholesterol terms of July 19, 1990 (55 FR 29456 at 29460), FDA believes that a limitation of 5 mg for the term "cholesterol free" is misleading. A person who consumes foods labeled as "cholesterol free" would expect that they would not contribute significantly to the cholesterol levels of his or her diet. Yet the consumption of 5 to 10 foods per day containing up to 5 mg of cholesterol per serving could furnish 25 to 50 mg of dietary cholesterol. This amount of cholesterol cannot be considered to be insubstantial. Moreover, the analytical limits on detecting cholesterol support a lower limit than 5 mg. Accordingly, the

agency has not revised the definition of "cholesterol free."

114. A couple of comments said that consumers are confused when they see ingredients containing cholesterol in the ingredient statement of foods bearing "cholesterol free" claims.

The agency agrees that consumers may be confused by reading that eggs, for example, are listed as an ingredient of a food bearing a "no cholesterol" claim. The agency has reviewed these comments with the many comments on fat being added to foods labeled as "fat free." The agency has been persuaded by these comments that a clarification of this issue is needed to avoid consumer confusion. The agency believes that it is the listing of ingredients, such as eggs, that creates the confusion. Accordingly, the agency is revising § 101.62(d)(1)(i)(B) and (ii)(B) in the final rule to require that the listing of ingredients that are generally understood by consumers to contain cholesterol be followed by an asterisk that refers to a disclosure statement appearing below the list of ingredients. The statement shall read: "adds a trivial amount of cholesterol," "adds a negligible amount of cholesterol," or "adds a dietarily insignificant amount of cholesterol." The agency points out that because of these inserted sections, proposed § 101.62(d)(1)(i)(B) and (d)(1)(i)(C) are redesignated as § 101.62(d)(1)(i)(C) and (d)(1)(i)(D), and proposed § 101.62(d)(1)(ii)(B) through (d)(1)(ii)(E) are redesignated as § 101.62(d)(1)(ii)(C) through (d)(1)(ii)(F).

115. A few comments requested that FDA ban all cholesterol content claims. The comments argued that dietary cholesterol has an insignificant impact on blood cholesterol levels compared to saturated fat, and that the response to dietary cholesterol varies from individual to individual.

The agency is denying this request. The Surgeon General's report (Ref. 4) and the NAS report "Diet and Health, Implications for Reducing Chronic Disease Risk" (Ref. 12) considered the evidence on the effect of diet on an individual's health. One of the main conclusions from these reports is that consumption of diets high in fat, saturated fat, and cholesterol is associated with increased risk of developing certain chronic diseases. These reports recommended that Americans reduce their consumption of these substances in their diets. To help Americans achieve this goal, the 1990 amendments authorize FDA to define nutrient content claims, including those relating to cholesterol content. Accordingly, the agency is not revising the final rule to ban cholesterol claims.

116. The agency received a number of comments on the proposed saturated fat threshold (i.e., limit) that allows foods bearing "no cholesterol" claims as well as other cholesterol claims to contain only 2 g or less of saturated fat per serving. About 20 comments opposed this threshold. About half as many comments supported the proposed rule and stated that a threshold of 2 g or less of saturated fat per serving is appropriate. One comment stated that this threshold should have a second criterion of 15 percent or less of energy (calories) from saturated fat. Similarly, another comment favored a second criterion of 6 percent or less of saturated fat on a dry weight basis. The comments recommending a different threshold were almost evenly divided between a higher value and a lower value. One comment requested that the threshold apply only to "cholesterol free" and "low cholesterol" claims, not to comparative claims. Other comments stated that foods bearing cholesterol claims should contain no saturated fat.

Many of the comments opposing the threshold on saturated fat with cholesterol claims were from manufacturers of dairy products that have up to 95 percent of their cholesterol removed. These products contain more than 2 g of saturated fat per serving. The comments stated that cholesterol claims should be allowed on these products regardless of their saturated fat content. They contended that the proposed saturated fat threshold is inappropriate and unduly restrictive because the relationship of cholesterol and saturated fat has not been satisfactorily defined. A few comments against the threshold favored disclosure of saturated fat. One comment said that disclosure of saturated fat, rather than a threshold, would be more consistent with the 1990 amendments (section 403(r)(2)(A)(iii)(II) of the act). They stated that a saturated fat threshold based on section 403(r)(2)(A)(vi) of the act fails to take into account the fact that certain foods containing more than 2 g of saturated fat may contain "substantially less" cholesterol than foods for which they might substitute.

Some of the comments for a higher threshold recommended a value of 3 g or less of saturated fat per serving. The comments said that this threshold would allow nuts and peanut butter to make a "no cholesterol" claim. A few comments stated that the threshold should be 4 g or less to be consistent with the level of saturated fat above which risk is likely to increase and disclosure is required. One comment stated that consumers believe that cholesterol is found in all fats and oils. They argued that claims are needed to help consumers select foods that do not contain cholesterol, rather than foods that do contain cholesterol (e.g., margarine for butter).

Most of the comments for a lower threshold recommended 1 g or less of saturated fat per serving and 15 percent or less of calories from saturated fat, to be consistent with the definition of "low in saturated fat." One comment suggested that the first criterion be 1.5 g or less of saturated fat per serving, and another comment suggested that the second should be no more that 7 calories from saturated fat per 100 calories.

These comments were concerned that the threshold proposed would encourage a proliferation of inappropriate cholesterol claims. Also, they were concerned that consumer education efforts would be hampered by a saturated fat limit of 1 g for "low in saturated fat" claims, of 2 g for cholesterol claims, and of 4 g for disclosure of saturated fat (e.g., a product bearing a sodium claim that contains more than 4 g of saturated fat per serving must disclose: "See [appropriate panel] for information on saturated fat and other nutrients"). The comments encouraged FDA to strive for consistency along with strictness and simplicity.

The agency is not persuaded that the saturated fat threshold should be eliminated or changed. FDA finds that there is general scientific agreement on the relationship between saturated fat and cholesterol and serum cholesterol levels. In the general principles proposal (56 FR 60421 at 60426), the agency noted that under section 403(r)(2)(A)(vi) of the act, it can by regulation prohibit a nutrient content claim if the claim is misleading in light of the level of another nutrient in the food. Further, FDA stated that it has tentatively made such a finding with regard to cholesterol claims and the presence of saturated fat, as fully discussed in the fat/cholesterol proposal (56 FR 60478 at 60495). FDA pointed out that NAS's "Diet and Health" report (Ref. 12) stated that "saturated fatty acid intake is the major dietary determinant of the serum total cholesterol and low-density lipoprotein (LDL) cholesterol levels in populations and thereby of coronary heart disease risk in populations" (56 FR 60482). Furthermore, an FDA survey has found that consumers are interested in cholesterol content claims because they believe that eating foods with no or low cholesterol will have a significant effect on their blood cholesterol levels and on their chances of developing heart

disease (Ref. 16). Consequently, FDA continues to believe that to ensure that cholesterol claims do not mislead consumers it is necessary to permit their use only when the foods also contain levels of saturated fat that are below a specified threshold level. Accordingly, the agency is denying the requests to eliminate the threshold. This decision applies to "cholesterol free," "low cholesterol," and comparative cholesterol claims.

The agency does not agree that disclosure of the amount of saturated fat in proximity to a cholesterol claim is sufficient to prevent consumers from being misled. As stated above, consumers expect foods with cholesterol claims to affect blood cholesterol levels, and saturated fat is the major dietary determinant of blood cholesterol levels. These expectations are not met if disclosure of saturated fat is permitted because the saturated fat is still present. Therefore, the agency is also denying the request to allow disclosure of saturated fat instead of a threshold.

Additionally, the agency does not agree that the saturated fat threshold should be a higher value or a lower value. The rationale for the threshold level of 2 g or less of saturated fat per serving is explained in the July 19, 1990, tentative final rule (55 FR 29456 at 29458). In summary, the value is consistent with the recommendations of recent dietary guidelines (Refs. 7, 12, and 17) that saturated fat intake should be less than 10 percent of calories. The agency believes that a saturated fat level that exceeds 2 g would make a cholesterol claim misleading because consumer expectations would not be met if such a food is not consistent with the recommendations of the guidelines with respect to saturated fat. For this reason, the agency concludes that levels of 2 g or less are not misleading and finds no basis for lowering the threshold below 2 g.

A review of the composition of food shows that a reasonable number of foods qualify for cholesterol claims under the criteria that FDA is establishing. For example, a number of oils including soybean, corn, safflower, and olive oil, qualify for a "no cholesterol" claim (Ref. 6). Accordingly, the agency is denying the requests to change the threshold.

Finally, the agency is not persuaded that it is necessary for the threshold to have a second criterion. The agency proposed a second criterion of 6 percent or less saturated fat on a dry weight basis in the July 19, 1990, tentative final rule (55 FR 29456). In response to comments stating that the second criterion was unnecessary and would unfairly penalize foods that have a high moisture content, the agency proposed to eliminate this provision. The agency still agrees that this provision is unnecessary and is not persuaded by the comments herein to reverse this action.

117. At least one comment suggested that a food bearing a "cholesterol free" claim should have a 3 g limit on fat content. Another comment believed that such a food should be "fat free."

The agency disagrees with these comments because it has concluded that disclosure of fat on a food bearing a "cholesterol free" claim is preferable to a fat limit as fully discussed in response to comment 143 of this document. The agency does not find that a cholesterol claim on the label of a food containing high levels of fat is misleading when the fat amount is disclosed in proximity to the claim because total fat per se does not affect blood cholesterol levels.

118. A few comments stated that a "cholesterol free" claim is misleading on a product that contains trans fatty acids. These comments stated that consumers select foods that contain no cholesterol to lower their blood cholesterol levels and argued that trans fatty acids increase these levels.

The agency understands the concerns about trans fatty acids expressed in these comments and has requested data on this issue. However, as discussed in comment 111 of this document, a review of the information submitted and of the published literature shows that the evidence that suggests that trans fatty acids raise serum cholesterol remains inconclusive, as fully discussed in the final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**. For this reason the agency believes that a "no cholesterol" claim on a food containing trans fatty acids is not misleading. Accordingly, the agency is making no change in the final rule in response to these comments. However, as explained in comment 111 of this document, the agency has included a limit for trans fatty acids as a criterion for a "saturated fat free claim," because of the implications of that claim and the particular importance of that claim.

2. Low

In the general principles and fat/cholesterol proposals (56 FR 60421 and 60478), FDA proposed to define the term "low" for total fat, saturated fat, cholesterol, sodium, and calories. The agency stated that it did not believe that the term "low" should necessarily mean that a nutrient is present in a food in an inconsequential amount, as with "free," but rather that the selection of a food bearing the term should assist consumers in assembling a prudent daily diet and in meeting overall dietary recommendations to limit the intake of certain nutrients.

FDA proposed the terms "little" or "few," "small amounts of," and "low source of" as synonyms for the term "low" and specifically requested comments on how consumers commonly understand the meaning of all these terms. The agency also asked whether the terms are in fact synonymous.

FDA also proposed that "low" claims used on foods that inherently contain low levels of a nutrient must refer to all foods of that type and not merely to the particular brand to which the labeling is attached. The agency requested comments on this provision.

a. General comments. 119. A few comments addressed the concept of using 2 percent of the DRV per serving as the starting point in defining "low" claims. These comments questioned FDA's statement that 2 percent or more of the DRV is a "measurable amount." They said that amounts under this level could be measured accurately as evidenced by the fact that less than 0.5 g of fat per serving, or less than 1 percent of the proposed DRV, is the cutoff proposed for the "fat free" claim.

The agency agrees with this comment that amounts of fat less than 2 percent of the DRV for this nutrient can be measured accurately. The agency believes that, in general, less than 0.5 g of fat per serving represents the cutoff below which fat cannot be measured accurately in all food matrices and thus was the level chosen to define "fat free" (56 FR 60484, November 27, 1991). The agency acknowledges that its discussion of a "measurable amount" being 2 percent or more of the DRV of a nutrient in a serving of a food is not clear (56 FR 60439). This terminology was taken from § 101.3(e), issued in 1977, which describes how foods are to be named, and under what circumstances the word "imitation" must precede the name of a food that has a decreased level of an essential nutrient. FDA determined that nutrients present at a level of 2 percent or more of the U.S. RDA were present in a "measurable amount" and thus were of sufficient importance to be considered in deciding whether a substitute product should be labeled as an "imitation."

In the proposed rule, the agency selected less than 2 percent as the starting point in defining "low" claims based on the precedent established in § 101.3(e) that a decrease of a nutrient in a food by this amount was not sufficiently important to the diet to justify concern. Thus, the agency

tentatively concluded that this level was appropriate to use in defining "low." In this context, the agency did not mean to imply by the words "measurable amount" that lower amounts could not be measured. Given this explanation, the agency concludes that no changes are necessary in response to these comments.

120. At least one comment requested that the definitions for the nutrient content claims "free" and "low" not overlap. For example, "low cholesterol" should be defined as 2 to 20 mg of cholesterol rather than less than 20 mg of cholesterol per serving.

The agency agrees that a "low" claim on a product that could make a "free" claim could be confusing. However, FDA concludes that it is not necessary to make these definitions mutually exclusive because it is unlikely that a "low" claim would be used on a food that is eligible to bear a "free" claim. Accordingly, the agency is denying this request. However, the agency advises manufacturers to use the most appropriate claim to avoid confusion.

121. A few comments requested that FDA define "low sugar." One comment requested that FDA define this term as 3 g or less of sugar per serving or less than or equal to 10 percent sugar for the cereal category. This comment stated that because there is such a large number of products from which to select, it is important that cereals that are low in sugar be able to communicate this fact to consumers. Of the 180 products that label sugar content, about 20 percent contain 3 g or less of sugar per serving. Also the comment stated that 3 g of sugar provide 12 calories, which is 10 percent of the calories contributed by a typical 1-ounce serving of cereal. This comment also requested that "very low sugar" be defined as one-half of the quantity for "low sugar" or 1 g or less of sugar per serving. Another comment recommended a definition of 5 g or less of sugar per serving. This comment stated that presently 20 percent of adult caloric intake is attributed to sugar. Using an arbitrary 25 percent decrease in this level, a reference diet of 2000 calories, and 20 servings per day, the comment computed a value of 5 g for the cutoff. Using the same rationale, this comment requested that "very low sugar" be defined as 3 g or less of sugar per serving.

The agency does not believe that these comments provide an acceptable basis for defining "low sugar." The fact that 20 percent of cereals may contain 3 g or less of sugar per serving is not a sufficient reason to define "low sugar" in this manner, even for cereal. Likewise, a value based on a 25 percent decrease from current intake is not a sufficient basis to define this term. To be consistent with the approach the agency has taken for other "low" definitions, a definition for a "low" level of sugar would have to relate to the total amount of the nutrient recommended for daily consumption, as discussed in the general principles proposal (56 FR 60439). However, because the available consensus documents do not provide quantitative recommendations for daily intake of sugars, FDA is not proposing a reference value for this nutrient. The agency concludes that without a reference value for sugar intake, the term "low sugar" cannot be defined. For the same reason, the agency is also not defining the term "very low sugar." Accordingly, the agency is not accepting the recommendations of this comment. The agency points out, however, that much of the information that these comments seek to convey can be communicated by use of a "reduced sugar" or "less sugar" claim made in accordance with new § 101.62(c)(4).

b. Synonyms for low. Several comments discussed synonyms for the descriptive terms "low" and "very low" that FDA defined in the general principles and fat/cholesterol proposals. The agency notes that it defined "very low" only in the context of sodium claims (i.e., "very low sodium").

122. One comment offered the term "lowest" as a synonym for "low" and suggested that it be applicable to all nutrients for which FDA is defining "low" nutrient content claims.

FDA disagrees with this comment because "lowest" is a comparative term that describes the position of a product with regard to one or more of its attributes relative to that of other products within a particular category. Therefore, FDA believes that "lowest" is not an appropriate synonym for "low," and the agency is not adopting this suggested term.

123. Two comments suggested that terms like "short" or "small" be permitted as synonyms for "low."

These comments did not provide supporting information to persuade the agency that consumers commonly understand the terms "short" or "small" to have the same meaning as "low." Therefore, FDA is not providing for the use of any of these terms as synonyms for "low" at this time. However the agency advises that interested persons may submit a synonym petition for the use of any of these terms as prescribed in § 101.69 of this final rule. The agency has, however, provided for the use of "a small amount of" as a synonym for "low."

124. One comment offered the terms "dab," "dash," "hardly," "insignificant," "minimum," "negligible," "next to nothing," "pinch," "slight," "smidgeon," "tinge," "trivial," "tiny," "touch," or "very little" as synonyms for "very low."

The agency notes that it has defined the term "very low" only for of sodium content claims and has not provided for any synonyms for this term. The comment did not provide supporting information to persuade the agency that consumers commonly understand the terms "dab," "dash," "hardly," "insignificant," "minimum," "negligible," "next to nothing," "pinch," "slight," "smidgeon," "tinge," "trivial," "tiny," "touch," or "very little" to have the same meaning as "very low." Therefore, FDA is not providing for the use of any of these terms as synonyms for "very low" at this time. However the agency advises that interested persons may submit a synonym petition for the use of any of these terms as prescribed in § 101.69 of this final rule.

c. Specific definitions. i. Low and very low sodium.

125. Some comments disagreed with the agency's proposal to retain 140 mg as the level for "low sodium, contending that the basis of the definition for this term should be consistent with that for other nutrients, which would result in "low sodium" being defined as 96 mg or less per serving, i.e., 4 percent of the DRV. One comment specifically opposed lowering the criterion to 96 mg per serving, noting that it is important to retain consistency with existing definitions. Others argued that the sodium/salt sensitive portion of the population is small in number, so that there would be little public health benefit in reducing the "low sodium" definition. Other comments generally contended that consumers are familiar with 140 mg through its widespread use in describing "low sodium" foods over the last 8 years, and that there have been no apparent problems. One comment proposed that "low sodium" claims should be allowed on foods containing 10 percent of the DRV, per serving or per 100 g. It provided no basis for this suggestion which would result in increasing the cutoff level for "low sodium" foods from 140 mg to 240 mg.

The agency has reviewed the comments and is not persuaded to change the proposed definition for "low sodium." As discussed in the general principles proposal (56 FR 60421 at 60441) and noted by some of the

comments, the descriptive terms for sodium have been in use for approximately 8 years, and the agency believes that consumers are familiar with them. In general, comments received in response to the 1989 ANPRM and at the public hearings that followed, did not indicate a need for change, and most of the comments to this rulemaking supported the existing criteria, even though it was not derived in the same manner (i.e., which would have yielded a value of 96 mg per serving) as other "low" claims.

The agency also disagrees with comments suggesting a definition for "low sodium" of 240 mg per serving. If the definition were established at this level, a person could easily exceed the DRV for sodium (e.g., if more than 10 foods are consumed per day which are "low sodium"). This result would be inconsistent with dietary recommendations and with the approach that FDA is taking in defining other terms. As discussed in the general principles proposal (56 FR 60421 at 60439), the agency believes that the selection of a food bearing the term "low" should assist consumers in assembling a prudent daily diet and in meeting overall dietary recommendations to limit certain nutrients. Therefore, the agency is retaining its criteria for "low sodium" claims.

126. Many comments agreed with the proposed definition for "very low sodium," stating that it is useful and has come to be understood by consumers. However, one comment stated that the term is not necessary.

The agency has reviewed the comments and is not persuaded to change the proposed definition for "very low sodium." "Very low sodium foods" will be useful to individuals in the population wishing to reduce their total sodium intake to a more moderate level and will be especially useful to individuals on medically restricted diets (see 56 FR 60441). In general, comments received in response to the 1989 ANPRM and at the public hearings did not indicate a need for change, and most of the comments to this rulemaking supported keeping the existing criteria. Therefore, the agency is retaining 35 mg as the eligibility level for "very low sodium" claims.

ii. Low calorie. 127. Many comments agreed with the agency's definition of "low calorie." Some comments, however, disagreed. One comment suggested that "low calorie" be defined at 4 percent of the DRV or RDI, rather than the 2 percent. One comment suggested that the maximum calorie level was too low, and that only a few products would qualify to make a "low calorie" claim.

The agency agrees with the majority of the comments that 40 calories or less is the appropriate per serving criterion for the "low calorie" definition. FDA is not persuaded by the comments or by its own review of the calorie content of foods (Ref. 18) that increasing the per serving allowance in the definition of "low calorie" is prudent if the term is to be useful to consumers attempting to control their intake of calories.

As explained in the general principles proposed rule (56 FR 60439), FDA is defining a "low" claim for a nutrient that is ubiquitous in the food supply as an amount equal to 2 percent of the DRV for the nutrient. While a DRV for calories has not been established, FDA used a reference caloric intake of 2,350 calories for reviewing the definition of "low calorie" and for establishing DRV's for other nutrients. As discussed in the RDI/DRV final rule published elsewhere is this issue of the **Federal Register**, FDA has changed the reference caloric intake to 2,000 calories. Using the general approach described above, 2 percent of 2,000 calories computes to 40 calories. Accordingly, the agency is not changing the per reference amount criterion for the definition of "low calorie."

128. One comment suggested that the definition of "low calorie" should be based on foods that can be eaten freely without adding significantly to the caloric content of the total diet.

FDA disagrees with this comment. The term "calorie free" already describes foods that can be eaten freely without adding significantly to the caloric content of the total diet. Accordingly, the agency is not defining "low calorie" in this manner.

iii. Low fat. 129. Only a few comments supported proposed § 101.62(b)(2) that defines "low fat" as 3 g or less per serving and per 100 g of the food. Most of the comments on this issue objected to the second criterion of 3 g or less per 100 g. Some of these comments suggested alternatives to the second criterion.

The second criterion for the term "low fat," as well as the second criterion for the other "low" terms, has been discussed in section III.A.1.b. of this document on the general approach to nutrient content claims. In this section, the agency is addressing the comments on the first criterion of 3 g or less per serving.

The majority of the comments recommended that "low fat" remain at 3 g or less per serving. About 20 comments requested that the cutoff be 4 g or less per serving. These comments argued that defining "low fat" in this manner could still lead to a significant reduction of fat in the total diet as well as allow more flexibility for product development. A few comments requested that the cutoff be at more than 4 g per serving.

Some of the comments that requested that the cutoff be 4 g or less presented the following rationale: A diet of 2,350 calories per day with 30 percent of calories from fat allows a maximum of 78 g of fat per day. The typical adult consumes 20 servings of food per day. These comments estimated that 13 of these servings contain fat. Dividing 78 g by 13 gives an average of 6 g of fat. Based on this reasoning, 4 g of fat would be below the average of 6 g (a 1/3 reduction) and could be considered to be "low fat."

These comments pointed out that if each of 13 servings of foods contained 4 g of fat, the total amount of fat would be only 52 g, well short of 78 g. Another comment based its calculations on 10 servings of food containing fat. It observed that if 5 of 10 fat-containing foods had 4 g, they would provide 20 g of fat in the diet. Thus, the other 5 servings could contain 11 g of fat each for a total of 75 g, which was the proposed DRV for fat. Other comments stated that 4 g or less of fat per serving is appropriate because even if all 20 servings of food a day contained 4 g of fat (i.e., less than 5 percent of the DRV), the daily total would slightly exceed the DRV.

The agency agrees with the majority of the comments that 3 g or less of fat is the appropriate per serving criterion for the "low fat" definition. FDA is not persuaded by the comments or by its own review of the fat content of foods (Ref. 19) that increasing the per serving allowance in the definition of "low fat" is necessary or prudent if the term is to be useful to consumers attempting to control their intake of fat.

As explained in the fat and cholesterol proposed rule (56 FR 60486), FDA is defining a "low" claim for a nutrient that is ubiquitous in the food supply as an amount equal to 2 percent of the DRV for the nutrient. To arrive at a definition when a nutrient is not ubiquitous, the agency proposed to increase the 2 percent amount to adjust for such a nutrient's uneven distribution in the food supply. This adjustment recognizes the practice of dietary planning in which a person consumes, in a day, a reasonable number of servings of foods labeled as "low," balanced with a number of servings of foods that do not contain the nutrient in question and a number of servings of foods that contain the nutrient at levels

above the "low" level and is still able to stay comfortably within the guidelines of the various dietary recommendations (Refs. 7, 12, and 17).

With respect to fat, current dietary guidelines recommend that a person consume a maximum of 30 percent of calories from fat, which in a diet of 2,000 calories per day would allow for consumption of a maximum of 67 g of fat per day. FDA is adopting this value rounded to 65 g as the DRV for fat. Two percent of the DRV is 1.3 g, which rounded to the nearest one-half g would be 1.5 g.

The agency is not using 1.5 g as the cutoff of a "low fat" claim, however, because fat is not ubiquitous in the food supply. Because fat is not ubiquitous but is found in more than a few food categories, FDA concludes that an appropriate upper limit for a "low fat" claim should be set at two times 2 percent of the DRV or 3 g per serving. The agency remains convinced that this amount is a reasonable definition for "low fat" because an average level of 3 g in 16 to 20 servings of food per day (balancing the number of foods that do not contain fat with those that contain higher levels of fat to yield an average of 3 g of fat per serving) would supply 48 to 60 g of fat daily, within the DRV of 65 g of total fat. An average level of 4 g in 16 to 20 servings would supply 64 to 80 g of total fat, exceeding the DRV Similarly, an average of 5 g would supply 80 to 100 g of fat. For this reason the agency concludes that 4 g or more of fat per serving is not an appropriate definition for "low fat." Accordingly, the agency is not making the suggested change.

130. Some of the comments that requested that FDA change the definition of "low fat" (proposed § 101.62(b)(2)) to 4 g or less of fat per serving also requested that FDA define "very low fat." They stated that 2 g or less of fat per serving could be considered "very low fat" if 4 g or less of fat were the definition of "low fat." One comment offered the rationale that on a per serving basis, "very low fat" should be 0.5 g to 2 percent or less of the DRV (based on 75 g of fat) for fat, and "low fat" should be 5 percent or less of the DRV.

The agency is rejecting this recommendation because it is based upon an increase in the proposed definition of "low fat," which the agency is not making as explained in the previous comment. Also, as discussed in response to comment 124 of this document, additional "very low" terms will be confusing to consumers. Accordingly, the agency is not defining "very low fat."

131. At least one comment recommended that "low fat" foods be defined only as those foods containing no more than 3 g of fat per 100 g. The reason given for this recommendation is that it would simplify the comparison of foods.

As explained in response to a similar suggestion for "fat free" claims (see comment 98 of this document), FDA does not believe that this approach alone is appropriate for the definition of nutrient content claims because it does not adequately account for the way foods are consumed.

132. A few comments objected to the agency's approach of defining "low fat" in terms of g of fat per serving (proposed § 101.62(b)(2)(i)). One comment recommended that a "low fat" food be defined as a food having no more than 30 percent of calories derived from fat. Other comments recommended limits of 25 percent and 20 percent of calories derived from fat. Similarly, another comment stated that a "very low fat" food should have no more than 10 percent of calories derived from fat.

The agency disagrees with this suggestion for several reasons. Dietary recommendations to obtain no more than 30 percent of calories from fat are aimed at the total diet, not at individual foods. The agency believes that expressing claims in terms of g per serving as the basis for all "low" nutrient content claims is preferable because this amount is absolute. The percent of calories from fat varies disproportionately with the total number of calories in a food. If the number of calories is low, the percent of calories from fat can be relatively high. For example, the percent of calories from fat for radishes is over 25 percent. Thus, they would not be considered a "low fat" food using one of the approaches suggested. In fact, radishes contain only about 0.3 g of fat per serving and qualify as a "fat free" food using FDA's approach. Consequently, FDA concludes that the requested approach can be extremely misleading, especially when applied to certain categories of foods that are consistent with recommended diets (e.g., fresh fruits and vegetables).

Furthermore, FDA recognizes that consumers are most familiar with nutrient content claims being expressed in terms of g per serving. Comments that the agency has received in response to the 1989 ANPRM and in the public hearings that followed also supported continued use of serving sizes in the definition of nutrient content claims, as did the IOM report (Ref. 14). Finally, one of the goals of nutrient content claims is to help consumers construct a diet that is consistent with dietary guidelines. Claims based on absolute per serving amounts are much easier to use in this way than claims based on percentages computed for the individual food. Accordingly, the agency is not defining "low fat" in terms of percent of calories from fat.

133. A number of comments suggested that FDA should vary the quantitative definition of "low fat" according to food category and designate as "low" those foods that are relatively low compared to other foods in the same food category. In support of this approach, the comments argued that a single criterion may cause consumers to avoid food categories in which no foods qualify for a claim, making the task of educating consumers about appropriate choices within those categories more difficult.

The agency considered this approach and is rejecting it for the reasons discussed in the general principles proposal (56 FR 60421 at 60439). In summary, the agency believes that relative claims can be used to highlight certain foods in the same food category. The use of different criteria for "low fat" foods in different food categories would make it difficult for consumers to compare products across food categories and to substitute one food for another in their diets. Furthermore, this approach would make it possible for some foods that did not qualify to use the nutrient content claim to contain less fat than foods in other categories that did qualify. FDA has received many comments asking for consistency among nutrient content claims to aid consumers in recalling and using the defined terms. In addition, the IOM report (Ref. 14) recommended such consistency. None of the comments provided any basis for why these factors should not be controlling. Accordingly, the agency will not vary the quantitative definition of "low fat" from food category to food category.

134. At least one comment suggested that foods be described as "low fat" if they contain one-third less fat than the "regular" food.

FDA disagrees with this terminology because it believes it is not appropriate. However, FDA agrees that foods with a one-third reduction in fat content compared to an appropriate reference food should be able to make a claim and is providing in new § 101.62(b)(4) that such foods may be described as "reduced fat" or "less fat." Consequently, the agency concludes that no change is warranted in response to this comment.

135. One comment suggested that a food that is "low fat" should also be

"low cholesterol," and that the descriptor should be "low fat/low cholesterol." Using the same rationale, the comment suggested that the claim "fat free/cholesterol free" be used in place of "fat free" and "cholesterol free." Another comment expressed concern about "fat free" being used to describe foods that contain high levels of cholesterol.

The agency believes that this approach is overly restrictive and is not in accord with section 403(r)(2)(B)(ii) of the act, which provides that cholesterol should be identified on the PDP (i.e., "See ———— panel for information on cholesterol and other nutrients") only at levels associated with increased risk taking into account the significance of the food in the total diet. The agency has determined that these levels for cholesterol are those exceeding 20 percent of the DRV or 60 mg of cholesterol per reference amount, per labeled serving size, or, for foods with reference amounts of 30 g or less or 2 tablespoons or less, per 50 g of food. Section 403(r)(2)(A) of the act, which makes special provisions for cholesterol, saturated fat, and fiber claims, makes no such provision for fat claims. Accordingly, the agency is making no change in response to these comments. The agency notes that it is unaware of any "fat free" foods that contain 60 mg cholesterol.

iv Low saturated fat. 136. The agency received several comments on proposed § 101.62(c)(1) which defines "low in saturated fat" as 1 g or less per serving and no more than 15 percent of calories from saturated fatty acids. Most of the comments supported the criterion of 1 g or less per serving. Other comments requested that the cutoff be a higher value. One comment stated that this claim should be defined only in terms of percent of calories from saturated fat but did not suggest a percentage. Another comment stated that it would be more appropriate to permit this claim on foods that are high in total fat and relatively low in saturated fat but did not make a specific recommendation.

The second criterion for the term "low in saturated fat" is discussed in comment 137 of this document. In this section, the agency is addressing the comments on the first criterion of 1 g or less of saturated fat per serving.

The comments recommending a cutoff of 2 g per serving stated that this value would be consistent with Canada's definition of "low in saturated fat" and with the proposed saturated fat threshold on cholesterol claims. They pointed out that FDA's rationale for the 2 g threshold is that it is consistent with current dietary recommendations that 10 percent of calories come from saturated fat. One comment complained that a cutoff of 1 g would result in canola oil being the only oil able to bear this claim. The comment said that this oil is very minor in both production and consumption in the United States. It alleged that FDA has failed to recognize the strong body of scientific evidence that consumption of polyunsaturated fat lowers blood cholesterol. The comment contended that in terms of its effect on blood cholesterol, the effect of the low saturated fat content of canola oil is negated by its polyunsaturated fat content. The comment said that it has been shown conclusively in humans that both corn oil and soybean oil are better than canola oil in lowering serum cholesterol. The comment argued that the proposed definition "is clearly discriminatory, arbitrary, and ill-serves the U.S. industry and the consumer."

Another comment, which supported a definition of 2 g or less of saturated fat per serving and no more than 15 percent of calories from saturated fat, presented data that it claimed showed that saturated fat intake both for the total population and the 90th percentile is basically identical whether the first criterion is 1 or 2 g per serving. It concluded that a cutoff of 1 g would unreasonably restrict consumer choices of foods with no dietary impact on saturated fat.

The agency has reconsidered this issue and agrees with the majority of the comments that 1 g or less is the appropriate per serving criterion for the "low in saturated fat" claim, which is the proposed value. FDA is not persuaded by the arguments or by its own review of the saturated fat content of foods (Ref. 20) that increasing the per serving allowance in the definition is necessary or prudent if the term is to be useful to consumers attempting to control their intake of saturated fat. FDA acknowledges that only a limited number of fats and oils will be able to make this claim but points out that in addition to canola oil, high oleic safflower oil, almond oil, apricot kernel oil, and hazelnut oil qualify. Also, mayonnaise type salad dressing and various types of low calorie salad dressings can make this claim. With respect to the statement that corn oil and soybean oil are better than canola oil in lowering serum cholesterol, the agency notes that this statement was not supported by data in the comment.

As explained in the fat/cholesterol proposed rule (56 FR 60486) and in the section on "low fat" in this final rule, FDA is defining "low fat" as 2 percent of the DRV for fat times two to adjust for the fat distribution in the food supply, or 3 g of fat per serving. Using the same approach for saturated fat and the recommendation of current dietary guidelines (Refs. 7, 12, and 17) that the consumption of saturated fat be less than 10 percent of calories, the agency concludes that "low in saturated fat" should be defined as 1 g or less per serving.

This conclusion reflects the fact that total fat and saturated fat have similar distributions in the food supply. An FDA analysis has determined that both total fat and saturated fat are present in over half of 18 USDA-defined food categories (Ref. 21). For the purpose of that analysis, a nutrient was considered to be "present" in a food category if over one-half of the foods in the category contained 2 percent or more of the proposed DRV. Further, the agency remains convinced that this amount is a reasonable definition for "low in saturated fat" because an average level of 1 g in 16 to 20 servings of food per day would supply 16 to 20 g of saturated fat daily, within the DRV for saturated fat of 20 g (§ 101.9(c)(9)(i)). An average level of 1.5 g in 16 to 20 servings per day would supply 24 to 30 g of saturated fat, exceeding the DRV. Similarly, an average level of 2 g would supply 32 to 40 g of saturated fat. For this reason, the agency concludes that 1.5 g or more of saturated fat per serving is not an appropriate definition for "low in saturated fat." Accordingly, the agency is denying the requests that the cutoff for the per serving criterion be increased or eliminated.

137. Some comments recommended that the second criterion in proposed § 101.62(c)(1), which defines "low in saturated fat" as 1 g or less per serving and no more than 15 percent of calories from saturated fatty acids, be eliminated, and a few comments suggested that it be changed to a lower value.

The comments that recommended that the second criterion should be eliminated said that this criterion prevents claims on some of the foods recommended by NCEP for lowering saturated fat intake. Also, one comment pointed out that when fat is reduced in a food that is relatively low in saturated fat, the percent of calories from saturated fat is increased (i.e., a food able to make this claim could be disqualified by fat removal). Other comments stated that the second criterion is not needed because manufacturers will no longer be able to manipulate serving size. Furthermore, one comment contended that there is no evidence that foods that are nutrient dense are consumed in excess. A few comments said that "percent of calories

from saturated fat" should apply to the total diet, not to individual foods, and that 15 percent is inconsistent with the guidelines. Values of 10 percent and 7 percent were recommended.

The agency is not persuaded by the comments that it should eliminate the second criterion or lower this value. The agency continues to believe that a second criterion is needed to prevent misleading "low" claims on nutrient-dense foods with small serving sizes. The second criterion in the agency's definition for "low in saturated fat" is for this purpose. A general discussion of second criteria for "low" claims may be found in section III.A.1.b. of this document.

The agency agrees with the comment that "percent of calories from saturated fat" generally should apply to the total diet, not to individual foods. For this reason, the agency did not accept the recommendation that a "low fat" food should be defined as having no more than 30 percent of calories derived from fat as discussed in response to comment 132 of this document. The agency also pointed out in comment 132 of this document that for a given level of fat, the "percent of calories from fat" varies with the total number of calories in a food, that is, this approach focuses on the relative amount of the nutrient present in the food rather than the absolute amount. If the number of calories is low, the percent of calories from fat is relatively high. The percent of calories from saturated fat can increase either by increasing the amount of saturated fat or by decreasing the amount of total calories. As one comment observed, removal of fat could make the percent of calories from saturated fat increase, conceivably disqualifying a food from making a "low in saturated fat" claim. However, as stated above, this second criterion is necessary to prevent misleading "low in saturated fat" claims. As explained in the fat and cholesterol proposed rule (56 FR 60478 at 60492), the agency selected a second criterion of no more than 15 percent of calories from saturated fat because it tentatively determined that the approach used in selecting the second criterion for the other "low" claims yielded a criterion that was too restrictive (i.e., less than 1 g of saturated fat per 100 g of food). Consequently, FDA sought a different approach and considered the criteria of other nations. FDA found merit in Canada's approach of no more that 15 percent of calories coming from saturated fat, although the agency does not agree with Canada's first criterion of 2 g or less of saturated fat per serving. While dietary recommendations are for less than 10 percent of calories in the diet being provided by saturated fat, the fact that saturated fat is not ubiquitous in the food supply would allow higher amounts in those foods that contain saturated fats to balance off those that are lower, resulting in a total daily diet that meets dietary recommendations.

An examination of food composition data (Ref. 20) reveals that a regulation that allows foods containing 1 g or less of saturated fat per serving and no more than 15 percent of calories from saturated fat to make a "low in saturated fat" claim results in a reasonable number of foods being able to make this claim. These foods include most fruit, vegetables, and grains; skim milk and other dairy foods made from skim milk; a few nondairy cream substitutes and dessert toppings; egg substitutes; mayonnaise type salad dressing, low calorie salad dressings, canola oil, and high oleic safflower oil; fish and shellfish; many cereals, breads, and soups; and some cookies and candies. However, evaporated milk, non-dairy desert toppings, and margarine spreads will not be able to make a "low in saturated fat" claim because the percent of calories from saturated fat in these foods exceeds 15 percent. "Low in saturated fat" claims on these foods would be misleading because they do not contain especially low levels of saturated fat.

The agency acknowledges that this definition prevents this claim from appearing on some of the foods that NCEP recommends be used as substitutes for other foods in achieving a lower intake of saturated fat. For example, the NCEP recommends using skim or 1 percent fat milk as a substitute for whole milk, and 1 percent fat milk will not be able to make a "low in saturated fat" claim. The agency agrees with NCEP's recommendations but does not believe that all such substitute foods, including 1 percent fat milk, are necessarily "low in saturated fat." The NCEP, in many cases, recommends selections that are "lower" in fat than the foods for which they substitue in the diet. The agency continues to believe that this claim should enable consumers to easily identify the foods that contain especially low levels of saturated fat, and that the proposed definition achieves this purpose. Accordingly, the agency is denying the request that the second criterion of no more than 15 percent of calories from saturated fat be eliminated or changed in value.

138. At least one comment requested that FDA eliminate the requirement in proposed § 101.62(c) that the amount of cholesterol be disclosed in proximity to the claim "low in saturated fat." The comment stated that disclosure of cholesterol is unwarranted because dietary cholesterol has no effect on serum cholesterol levels. Other comments supported the proposed rule with respect to disclosure of cholesterol. At least one comment stated that the cholesterol disclosure is too lenient. This comment stated that a "low in saturated fat" claim should only be allowed on foods that never contain cholesterol.

The agency points out that the provision on the disclosure of cholesterol with a "low in saturated fat" claim, as well as the other saturated fatty acid claims, is required by section 403(r)(2)(A)(iv) of the act. Accordingly, the agency is making no change in response to these comments. The effect of dietary cholesterol on serum cholesterol levels is discussed in response to comment 115 of this document requesting that all cholesterol claims be banned.

139. A few comments objected to the requirement in proposed § 101.62(c) that the amount of fat in a food be disclosed in proximity to the claim "low in saturated fat." One comment said that this provision goes beyond the demands of the 1990 amendments and is unwarranted. Another comment requested an exemption from fat disclosure for margarine. The comment said that it is unfair because disclosure is not required for butter. One comment stated that fat disclosure is only necessary for products that contain excessive fat. The comment recommended that fat disclosure be required only if the fat level exceeds 11.5 g per serving and noted that such a requirement would be consistent with the level at which fat is disclosed with cholesterol claims. Comments said that at the very least, fat disclosure should not be required at levels of 3 g or less per serving (i.e., a "low fat" food would not have to have a fat disclosure). Another comment recommended that if the fat level of a food exceeds 11.5 g per serving, the label should state, "high in fat." It said that stating the amount of fat is not meaningful to most consumers. Other comments supported the proposed rule with respect to disclosure of fat.

The agency agrees that this provision is not required in the 1990 amendments and is persuaded that fat disclosure should not be required at levels of 3 g or less per serving. The agency concludes that such disclosure is unnecessary because 3 g or less is the per serving criterion for the term "low fat." A consumer who does not differentiate between a "low in saturated fat" and "low fat" claim

would not be misled by a "low in saturated fat" claim as long as the fat level of the food is 3 g or less per serving. For uses of "low in saturated fat" on foods with more than 3 g of fat, disclosure of fat content is required to avoid misleading the consumer. For this reason, the agency is denying the requests that disclosure of fat content be required only when the fat content exceeds 11.5 g per serving. The fat content is a material fact at levels above 3g when a "low in saturated fat" claim is made.

Also, the agency is denying the request that margarine be exempt from fat disclosure. The disclosure of total fat on foods (except foods that are "low fat") that bear a "low in saturated fat" claim is necessary to ensure that consumers who do not differentiate between a "low fat" and a "low in saturated fat" claim are not misled by the latter claim. The agency notes that butter is not required to disclose fat because it does not bear a "low in saturated fat" claim.

Finally, the agency is not requiring that the label of a food with a "low in saturated fat" claim state that it is "high in fat" if it contains more than 11.5 g per serving. FDA has not defined "high in fat." In addition, 11.5 g was the proposed disclosure level. As explained in comment 13, FDA has raised the disclosure level to 13.0 g of fat. However, to require a "high in fat" statement on foods that bear a claim and contain more than that level of fat would be inconsistent with the disclosure concept in section 403(r)(2)(B) of the act.

140. At least one comment stated that the "low in saturated fat" claim is misleading on a food that contains hydrogenated oil (i.e., contains trans fatty acids).

As discussed in comment 111 and 118 of this document, the evidence suggesting that trans fatty acids raise serum cholesterol remains inconclusive. For this reason, the agency finds that it cannot conclude that a "low in saturated fat" claim on a food containing trans fatty acids is misleading. Accordingly, the agency is making no change in the final rule in response to this comment. However, as explained in comment 111 of this document, the agency has included a limit for trans fatty acids as a criterion for a "saturated fat free claim," because of the implications of that claim and the particular importance of that claim.

141. A few comments requested that "——— percent unsaturated fat" be allowed as a synonym for a claim about saturated fat. One of the comments stated that without the ability to make this claim, there is an economic incentive for manufacturers to substitute soybean oil for canola and safflower oil. They said the data do not support FDA's concern that positive claims about high fat will increase consumption.

The agency is not allowing the term "unsaturated fatty acids" to appear in the nutrition label because of uncertainty about its definition, specifically, the inclusion of trans isomers of monounsaturated fat, as discussed in the final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**. Therefore, the agency concludes that it would be inappropriate to define the term "——— percent unsaturated fat," and the agency is denying this request.

v. Low cholesterol. 142. Only a few comments supported proposed § 101.62(d)(2) that defines "low cholesterol" as less than 20 mg per serving and per 100 g of the food. Most of the comments on this issue objected to the criterion based on weight, and some of these comments suggested alternatives to this criterion.

The weight-based criterion for the term "low cholesterol," as well as for the other "low" terms, has been discussed in section III.A.1.b. of this document on the general approach to nutrient content claims. In this section, the agency is addressing the comments on the criterion of less than 20 mg of cholesterol per serving.

The majority of the comments recommended that "low cholesterol" remain at 20 mg or less per serving. A few comments requested that the cutoff be a lower value, and a few other comments wanted a higher value. The comments favoring a cutoff of 15 mg pointed out that many foods consumed throughout the day have ingredients that contain cholesterol (e.g., bread). They stated that the recommended intake of less than 300 mg of cholesterol per day could easily be exceeded if these foods are eaten in sufficient quantity. One of the comments favoring a cutoff of 30 mg also believed that "cholesterol free" should be less than 5 mg per serving. The comment contended that the cutoff for "low cholesterol" should be six times the cutoff for "cholesterol free" because the cutoff for "low fat" is six times the cutoff for "fat free."

The agency agrees with the majority of the comments that 20 mg or less cholesterol is the appropriate per serving criterion for the "low cholesterol" definition. As explained in the fat/cholesterol proposed rule (56 FR 60478 at 60486), FDA considered that a "low" claim for a nutrient that is ubiquitous in the food supply should be an amount equal to 2 percent of the DRV for the nutrient. To arrive at a definition when a nutrient is not ubiquitous, the agency proposed to increase the 2 percent amount to adjust for the nutrient's uneven distribution in the food supply. If the nutrient is found at measurable levels in foods from only a few food categories, the agency proposed to define "low" as three times 2 percent of the DRV. Cholesterol, which is found only in foods of animal origin, is in this group of foods. The DRV for cholesterol is 300 mg, 2 percent of which is 6 mg. Therefore, the value for "low cholesterol" computes to 18 mg, which rounded to the nearest 5 mg increment, is 20 mg per serving.

Consequently, the agency is denying the request that the cutoff for "low cholesterol" be less than 30 mg because it concludes that this value is too high to be useful to consumers attempting to control their intake of cholesterol. Moreover, the agency disagrees with the rationale presented for 30 g that the cutoff for "low cholesterol" should be six times the cutoff for "cholesterol free" based on a value of 5 mg, because the cutoff for "low fat" is six times the cutoff for "fat free." The agency emphasizes that the "low" values are derived from the DRV's, not from the limit of detection. Also, the agency is denying the request that the cutoff for "low cholesterol" should be less than 15 mg on the basis that is too restrictive. Cholesterol is not so widespread in the food supply that such low levels are necessary to help consumers to structure their diets to be consistent with dietary guidelines for cholesterol. A "low cholesterol" claim based on 20 mg will be useful to consumers in structuring a total diet that is consistent with dietary guidelines.

Accordingly, the agency is not revising the final rule to change the amount allowed per serving for a "low cholesterol" claim.

143. The agency received relatively few comments on the requirement for disclosure of total fat with cholesterol claims. Some of the comments supported the provision of the proposed rule that the amount of fat must be declared next to a cholesterol claim if the fat content exceeds 11.5 g per serving or per 100 g of food. Other comments favored disclosure at other levels of fat, including all levels of fat, while some comments opposed disclosure of any amount of fat. One comment said that disclosure of the amount of fat would not be useful to the average consumer and suggested the statement, "this product is not low in total fat."

A few comments stated that the term "low cholesterol" on the label of a food containing high levels of fat is misleading, even if the amount of fat is disclosed. These comments recommended that cholesterol claims have a fat threshold above which claims are disallowed. One comment requested that a "low cholesterol" claim, as well as a "cholesterol free" claim, not be allowed on foods containing more than 3 g of fat and 0.15 g of fat per g of dry matter. This comment argued that a limit on total fat is needed to prevent manufacturers from meeting the saturated fat threshold by replacing saturated fat with trans fatty acids. As discussed in response to comment 117 of this document, another comment proposed a 3 g limit on fat specifically for "cholesterol free" claims but did not refer to "low cholesterol" claims. One other comment requested that a "low cholesterol" claim not be allowed on food containing more than 5 g of fat and more than 20 percent total fat on a dry weight basis.

The agency has reviewed this issue and continues to believe that fat disclosure is preferable to a fat limit above which the claim "low cholesterol," as well as other cholesterol claims, cannot be made. The agency has the authority under the act to establish a fat limit with cholesterol claims. Section 403(r)(2)(A)(vi) of the act states that a nutrient content claim "may not be made if the Secretary by regulation prohibits the claim because the claim is misleading in light of the level of another nutrient in the food." The agency has used this authority to prohibit cholesterol claims on foods containing more than 2 g of saturated fat per serving, which is discussed in response to comment 116 of this document. However, the agency does not find that a cholesterol claim on the label of a food containing high levels of fat is misleading when the fat amount is disclosed in proximity to the claim because total fat per se does not affect blood cholesterol levels. Thus, consumer expectations regarding blood cholesterol levels are met as long as the food contains the requisite amount of cholesterol and 2 g or less of saturated fat per serving.

The agency proposed that amounts of fat exceeding 11.5 g per serving or per 100 g of food have to be disclosed. The 11.5 g amount represents 15 percent of the DRV for fat. Disclosure of the amount of fat, rather than the statement, "this product is not low in total fat," is in accordance with section 403(r)(2)(A)(iii) of the act. This section states that the amount of total fat shall be disclosed in immediate proximity to a cholesterol claim if a food, taking into account its significance in the total diet, contains fat in an amount that increases the risk for persons in the general population of developing a diet-related disease or health condition.

In response to comments requesting that FDA modify the disclosure level in § 101.13(h) to 20 percent of the DRV, the agency is changing the final rule to provide that disclosure levels for fat are those exceeding 13 g of fat per reference amount, per labeled serving size, or, for foods with a reference amount of 30 g or less or 2 tablespoons or less, per 50 g of food. The rationale for this change is presented in the final rule on health claims, published elsewhere in this issue of the **Federal Register.**

144. About 15 comments opposed the provision in proposed § 101.62(d)(1)(ii)(E) and (d)(2)(ii)(E) that the amount of cholesterol in certain foods bearing "cholesterol free" or "low cholesterol" claims must be "substantially less" than the food for which it substitutes (i.e., it must meet the requirements for a comparative claim using the term "less" in proposed § 101.62(d)(5)(i)(A)). The foods included were those that contain more than 11.5 g of fat per serving or per 100 g of food and that contain, only as a result of special processing, an amount of cholesterol per serving that meets the relevant criterion for a "free" or "low" claim. The proposed requirements for comparative claims that apply are that the food contain at least 25 percent less cholesterol, with a minimum reduction of more than 20 mg cholesterol per serving, than the reference food.

The majority of the comments opposed the minimum reduction of cholesterol of more than 20 mg. One comment contended that the requirement for a minimum reduction goes beyond the requirements of section 403(r)(2)(A)(iii)(I) of the act that the level of cholesterol should be substantially less than the level usually found in the food or in a food that substitutes for the food. Many of these comments opposed this minimum because it would disallow a cholesterol claim on products such as 2 percent milk that has up to 95 percent of its cholesterol removed. These comments also opposed the proposed saturated fat threshold because the dairy products that have undergone cholesterol removal contain more than 2 g of saturated fat per serving. These comments requested that a cholesterol claim be allowed on the label of a food, regardless of the food's fat or saturated fat content, provided that the food has at least 33 percent of the indigenous cholesterol removed, and that the content of total fat is disclosed.

At least two comments supported the proposed minimum but opposed the disclosure statement (i.e., disclosure of the percent that the cholesterol was reduced, the identity of the reference food, and quantitative information comparing the level of cholesterol in the product per serving with that of the reference food). At least one comment opposed the required minimum, the 25 percent reduction, and the disclosure statement. This comment stated that the claims "cholesterol free" and "low cholesterol" should refer to an absolute level of cholesterol rather than to a relative level.

The agency is persuaded by these comments that the minimum reduction of cholesterol of more than 20 mg is unduly restrictive because it discriminates against products containing relatively small amounts of cholesterol. Accordingly, the agency is eliminating this requirement in the final rule for the "cholesterol free" and "low cholesterol" claims as well as for comparative claims (as discussed in response to comment 158 of this document). However, the agency continues to believe that "substantially less" cholesterol should be interpreted as 25 percent less cholesterol than the reference food. Twenty-five percent represents the extent of reduction necessary to make a "less" or "reduced" claim. Consequently, the agency is denying the request that the labeled food contain 33 percent less cholesterol, or that no reduction in cholesterol be required.

Furthermore, under section 403(r)(2)(A)(iii)(II) of the act, the disclosure statement must appear in immediate proximity to the claim, as proposed. FDA is providing, however, in § 101.62(d)(1)(ii)(F)(2) and (d)(2)(iii)(E)(2) in this final rule that the quantitative information comparing the level of cholesterol in the product with that of the reference food may appear on the information panel in conjunction with nutrition labeling. The agency is making this change in § 101.13(j)(2)(iv) to prevent label clutter on the PDP, as discussed in response to comment 214 of this document. The request that a cholesterol claim be allowed regardless of saturated fat content is addressed elsewhere in this document (see comment 116 of this document), as is the need for fat disclosure with cholesterol claims (see comment 143 of this document).

vi. Lean. 145. FDA received several comments that supported use of the terms "lean" and "extra lean" with FDA-regulated meat products or meal-

type products in accordance with definitions of these terms as proposed by the Food Safety and Inspection Service (FSIS). Meal-type and main dish products are defined and fully discussed elsewhere in this final rule.

One comment requested that FDA allow use of the terms "lean" and "extra lean" on the labels of fishery products in a manner similar to that proposed by FSIS. The comment noted that the composition of some fishery products would prevent them from bearing the nutrient content claim "low fat" on their labels in accordance with the definition of this term in FDA's fat/cholesterol proposal. The comment also pointed out that FDA's general principles and fat/cholesterol proposals did not provide for use of the term "lean" or "extra lean" on the labels of fish products. However, if these foods were considered under FSIS' proposed regulation, a substantial number of them would qualify for use of the term "lean" or "extra lean" on their labels.

Another comment stated that FDA should permit product lines that contain both USDA- and FDA-regulated meal-type products to bear descriptive terms such as "lean" and "extra lean" that can be applied to the entire product line for labeling and advertising purposes. The comment further stated that, if FDA does not allow the terms "lean" and "extra lean" on food products regulated by the agency, then these terms will most likely not be used on any meal-type products. The comment also stated that the USDA proposed criterion for saturated fat should be eliminated because it is too restrictive.

These comments raise an issue that FDA finds has merit. By way of background, on November 27, 1991, FSIS published a proposed rule (56 FR 60302) on nutrition labeling of meat and poultry products. In that proposal, FSIS presented definitions of the descriptive terms "lean" and "extra lean" that would only be applicable to the meat and poultry products that FSIS regulates under the authority of the Federal Meat Inspection Act (21 U.S.C. 601 et.seq.) and the Poultry Products Inspection Act (21 U.S.C. 451 et seq.). FSIS proposed that the term "lean" could be used to describe a meat or poultry product that contained less than 10.5 g fat, less than 3.5 g saturated fat, and less than 94.5 mg cholesterol per 100 g. The term "extra lean" could be used to describe a meat or poultry product that contained less than 4.9 g fat, less than 1.8 g saturated fat, and less than 94.5 mg cholesterol per 100 g. FSIS also proposed to permit these terms to be used to describe multi-ingredient meal-type products.

Data supplied by the American Heart Association (AHA), in response to the April 2, 1991, FSIS ANPRM (56 FR 13564) on nutrition labeling of meat and poultry products, provided the basis for the criteria that FSIS used in its proposed definitions of these terms. These data consisted of levels for total fat, saturated fat, and cholesterol of selected fresh and processed "meat" items (various types of beef, veal, pork, lamb, poultry, and fish) on a "cooked weight" basis. Using recommended food consumption patterns and dietary guidance recommendations as bases, AHA selected threshold values for fat, saturated fat, and cholesterol levels of these muscle foods on a 1 oz and 3 oz "cooked weight" basis. Threshold values for "lean" represent approximately 7 percent fat in raw meat and 10 percent fat by weight in cooked meat. Threshold values for "extra lean" represent approximately 5 percent fat by weight.

The levels in FSIS' proposed definitions were derived by converting AHA's threshold values from a 1 oz to 100 g basis. Upon making this calculation, FSIS found that the values obtained approximated the agency's criterion for use of the terms "lean" and "extra lean" on the labels of meat and poultry products as discussed in a November 18, 1987, FSIS policy memorandum 7OB(Ref. 22).

Based on comments received in response to its nutrition labeling proposal (56 FR 60302), FSIS, in a final rule published elsewhere in this issue of the **Federal Register**, has changed the rounding rule that it originally used. In addition, FSIS has developed modified criteria for levels of total fat, saturated fat, and cholesterol such that the ratio of saturated fat to total fat would be 40 percent for both nutrient content claims. FSIS considers the ratio of 40 percent to be reasonable because it is representative of the ratio of saturated fat to total fat inherent in ruminant muscle. Although AHA's suggested criteria were based upon fresh and processed cooked meat (cut or ground), in its final rule, FSIS is adopting criteria on an "as packaged" basis to achieve consistency with that agency's past labeling policy.

Under the FSIS final rule, to bear the term "lean," a meat or poultry product must contain less than 10 g fat, less than 4 g saturated fat, and less than 95 mg cholesterol per reference amount and per 100 g. To bear the term "extra lean," the product must contain less than 5 g fat, less than 2 g saturated fat, and less than 95 mg cholesterol per reference amount and per 100 g for individual foods. The criteria in the definitions of these terms for meal-type products under the FSIS final rule are presented elsewhere in this final rule.

The comments supporting use of the terms "lean" and "extra lean" on the labels of meat products and meal-type products have persuaded FDA to include provisions in this final rule consistent with those of FSIS to provide for use of the terms "lean" and "extra lean" to describe certain comparable foods regulated by FDA under the act. In the proposal, FDA solicited comments on whether additional defined terms were needed (56 FR 60421, 60431), and these comments demonstrated that the agency needed to add terms useful for these types of foods. FDA has statutory authority to enforce the act's provisions that prohibit misbranding of all foods except for those products exempted under the act (section 902 of the act (21 U.S.C. 392)). Thus, FDA is responsible for regulation of the labeling of certain types of meat products (e.g., seafood, bison, rabbit, game meats) not regulated by USDA under the Federal Meat Inspection Act (21 U.S.C. 601–623 et seq.) or the Poultry Products Inspection Act (21 U.S.C. 451–469) or in situations in which these products are not subject to USDA regulation. In addition, FDA is responsible for regulation of meal-type products not regulated by USDA under either of the aforementioned acts.

The agency recognizes that seafood and seafood products play a comparable role in the diet to that of meat and poultry products and, like meat and poultry products, contribute to the total dietary intake of fat, saturated fat, and cholesterol. In addition, FDA-regulated meal-type products are consumed in the same manner as USDA-regulated meal-type products covered by the FSIS rule. FDA concludes that providing for use of the descriptive terms "lean" and "extra lean" as nutrient content claims on the labels of seafood (including finfish and shellfish) and meal-type products that it regulates would be of value to consumers in maintaining healthy dietary practices. The terms "lean" and "extra lean" will describe foods of these types with relatively lower levels of fat, saturated fat, and cholesterol. In addition, the agency recognizes that the same conclusion applies to other meat products regulated by FDA (e.g., bison, rabbit, game meats).

Analyses of FDA's Food Composition Data Base (Ref. 23), which is based on USDA's Agriculture Handbook Number 8 on food composition, show that many fish/shellfish products (on a raw basis with a reference amount of 110 g) would qualify to bear "lean" or "extra lean" claims under FSIS' definitions of these

terms that FDA is adopting. Haddock, swordfish, and clams, for example, could be appropriately labeled as "extra lean," while Spanish mackerel and Bluefin tuna would be eligible for use of the term "lean" on their labels. On the other hand, neither term could be used on such seafood items as shrimp, Chinook salmon, or any other seafood item with a composition that exceeds the limits on the levels of total fat, saturated fat, or cholesterol established for use of the term "lean." Similarly, for game meats and related FDA-regulated meat products (on a raw basis with a reference amount of 110 g), based on data from USDA's Agriculture Handbook Number 8 on food composition (Ref. 24), domesticated rabbit could be differentiated from deer (venison) because domesticated rabbit would qualify for "lean" and deer for "extra lean."

FDA's action in promulgating equivalent definitions of these terms will enable consumers to compare the nutritional values of meat products and meal-type products that may serve as substitutes for one another in a balanced diet. Therefore, FDA is including in this final rule § 101.62(e) that permits use of the terms "lean" and "extra lean" on individual foods and on meal and main dish products. Use of these descriptive terms for FDA-regulated meal and main dish products is addressed elsewhere in this final rule. Because the agency is including this definition in the final rule, it is redesignating proposed § 101.62(e), a provision that addresses misbranding, as § 101.62(f) in the final rule.

FDA recognizes that the definitions of "lean" and "extra lean" for meat items allow this claim to be used when cholesterol levels exceed FDA's disclosure levels for this nutrient in the food (i.e., 60 mg). The agency considered whether to prohibit these claims on FDA-regulated meat products that contain greater than 60 mg cholesterol. However, the agency concluded that it would be of benefit to consumers to permit the claim on meat products that have a cholesterol content exceeding the disclosure level because the claims identify foods relative to other foods in this broad food class that contain lower amounts of fat and saturated fat. Thus, use of these claims would assist consumers in selecting such foods in constructing a total diet. Furthermore, when the cholesterol level in the food exceeds FDA's disclosure level, § 101.13(h) requires a disclosure statement referring the consumer to the nutrition information panel for additional information about cholesterol content.

3. "High" and "source"

Section 3(b)(1)(A)(iii)(VI) of the 1990 amendments requires that the agency define the term "high." Section 403(r)(2)(A)(v) of the act states that foods bearing a "high" claim for fiber either must be "low" in fat, or their labeling must disclose the level of total fat in the food in immediate proximity to the claim with appropriate prominence. In the general principles proposal (56 FR 60443), the agency proposed definitions for "high" and for "source," terms that may be used to emphasize the presence of a nutrient.

The agency proposed in § 101.54(a) to exclude total carbohydrate and unsaturated fatty acids from coverage under the proposed definition for "high" and "source." The agency explained that a nutrient content claim for these nutrients would be misleading.

The agency proposed in § 101.54(b)(1) that the terms "high," "rich in," or "major source of" may be used to describe the level of a nutrient in a food (except meal-type products) when a serving of the food contains 20 percent or more of the proposed RDI or the proposed DRV for that nutrient. The agency also proposed in § 101.54(c)(1) that the terms "source," "good source of," or "important source of" may be used to describe a food when a serving of the food contains 10 to 19 percent of the proposed RDI or the proposed DRV.

The agency also proposed in § 101.54(d) that if a nutrient content claim is made with respect to the level of dietary fiber, that is, that the product is "high" in fiber, a "source" of fiber, or that the food contains "more" fiber, and the food is not low in total fat as defined in proposed § 101.62(b)(2), then the label must disclose the level of total fat per labeled serving in immediate proximity to the claim and preceding the referral statement required in § 101.13.

The agency requested comments concerning its approach of limiting the number of descriptors that emphasize the presence of a nutrient to two levels. The agency explained that it took this approach to assist consumer understanding of, and confidence in, nutrient content claims. The agency also requested comments on whether an additional term describing an upper level amount of a nutrient (such as "very high") is necessary and appropriate. The agency also requested comments on the use of synonyms for terms like "high" and "source" and on consumer understanding of the terms proposed as synonyms for "high" and "source."

a. Synonyms

146. A few comments agreed that "rich in" and "major source of" are appropriate synonyms for "high." However, many comments disagreed with the proposed synonyms. Many of the latter comments stated that the agency should not allow use of any synonyms because the use of synonyms will be very confusing to consumers and could easily mislead them. A few comments requested the additional synonym "excellent source of" for "high."

Other comments agreed that "good source of" and "important source of" are appropriate synonyms for "source." However, many comments disagreed with the proposed synonyms. A few comments requested the use of additional synonyms for "source" such as: "meaningful source," "significant source," "provides," and "fortified with." Some stated that the term "provides" informs consumers that the food supplies the nutrient in question and has been in common use on food labels for years further assuring consumer familiarity with it. Some stated that the term "fortified with" has also been used on food labels for years, and is easily understood by consumers.

The agency notes that section 3(b)(1)(A)(ix) of the 1990 amendments provides that, in defining terms used for nutrient content claims, the agency may include similar terms that are commonly understood to have the same meaning as defined terms. Thus, the 1990 amendments clearly give the agency the authority to allow for synonyms. Moreover, section 403(r)(4)(A)(ii) of the act authorizes any person to petition the Secretary (and FDA, by delegation) for permission to use terms consistent with those defined by the agency under section 403(r)(2)(A)(i). Therefore, it is clear that the act contemplates that synonyms can be used. Further, the agency still believes, as stated in the general principles proposal (56 FR 60421 at 60444), that certain synonyms should be allowed in order to provide some flexibility in the use of defined terms.

The agency has, however, reconsidered the proposed synonyms for "high" and has revised some of them in this final rule to include terms that it believes would be more readily understood by consumers, and that convey the qualitative aspects of "good source" and "high." FDA recognizes that the synonyms it is providing for involve judgment on its part, and that individuals may have different views on appropriate synonyms. Nonetheless, FDA believes that a limited number of

synonyms will provide flexibility for food manufacturers in making claims and has endeavored to exercise reasonable judgment in providing for some synonyms while avoiding granting so many synonyms as to promote consumer confusion about their meaning.

Thus, in § 101.54(b), FDA is retaining "rich in" and adding "excellent source" as synonyms for "high." The agency is also providing for the use of "contains" and "provides" as synonyms for "good source" in § 101.54(c). FDA has deleted the proposed synonyms "major source of" for "high," and "important source of," for "good source." FDA notes that the terms it has added to the final rule, "excellent source," "contains," and "provides" are terms that have been used in the past and thus consumers will be familiar with them.

b. Definitions

147. Several comments agreed with the agency's proposed definition of "high" and the rationale upon which it was based, while other comments disagreed with the proposed definition. A few of the comments argued that 20 percent of the RDI or DRV is too high and would lead to little consumer benefit because few foods would be eligible to bear a "high" claim. One comment suggested lowering the eligibility level to 15 percent of the RDI or DRV so that more products would meet the definition without unnecessary supplementation.

The agency recognizes that many foods will not be able to meet the definition for "high." However, the agency is not persuaded by comments suggesting that it lower the eligibility level in the definition of "high" for this reason. The agency tentatively concluded in the proposal, and continues to believe, that a criterion of 20 percent or more of the RDI or DRV provides an appropriate basis for upper-level nutrient content claims.

Furthermore, the agency does not agree with comments that few foods would be eligible to bear "high" claims. In arriving at a definition for "high," FDA used its food composition data base to examine the types of foods that contain nutrients at levels that meet or surpass 20 percent of the proposed reference value per serving (Ref. 35). For the majority of the 17 nutrients considered, at least 10 percent of the foods in the data base contained 20 percent or more of the proposed RDI or DRV. For these nutrients there was at least one and often more than one food category that contained a substantial number of foods containing 20 percent or more of the RDI or DRV. Those nutrients for which fewer than 10 percent of the foods in the data base contain 20 percent or more of the RDI or DRV were calcium, magnesium, copper, manganese, potassium, pantothenic acid, and vitamin A. However, even with these nutrients (with the exception of potassium), there were a substantial number of foods in at least one food category that would qualify for "high" claims if the proposed definition were used.

Thus, the agency concludes that the 20 percent eligibility level will permit a sufficient number of food items to bear a "high" claim to allow consumers to use the claim in selecting a varied diet, and that this level provides an appropriate basis for upper-level nutrient content claims and can readily be used by consumers to implement current dietary guidelines. Therefore, FDA is retaining the 20 percent eligibility level in the definition of "high."

148. Several comments suggested lowering the eligibility level of "high" and "source" for dietary fiber claims. They argued that the proposed levels are too restrictive given that fiber is not ubiquitous in foods, and that it would preclude some good sources of dietary fiber, such as fruits, vegetables and whole grain breads, from bearing a "high fiber" claim. Suggested levels were as follows: "high" as 3 g and "source" as 1 g per serving; "high" as more than 4 g and "source" as 2 to 4 g per serving; and "high" as 4 to 8 g and "very high" as greater than 8 g per serving.

The agency has reviewed the comments and is not persuaded to lower the eligibility levels for "high" or "source" claims for dietary fiber. The agency agrees that fiber is not ubiquitous in foods. However, FDA notes that there are some fruits and vegetables that do qualify for "high," and considerably more that qualify for "source," claims for fiber under the proposed definitions. Based upon nutrient values for the 20 most commonly consumed raw fruits and raw vegetables (56 FR 60880, November 27, 1991, and corrected at 57 FR 8174, March 6, 1992), at least 25 percent of the products listed would be able to meet the proposed definition for "source." Furthermore, the agency believes that it is important to maintain consistency in defining terms for all nutrients and food components. Therefore, FDA is making no change in response to these comments.

149. A few comments requested that FDA define "high" and "source" for soluble and insoluble fiber. The comments stated that the Expert Panel on Dietary Fiber for the Federation of American Societies of Experimental Biology (FASEB) estimates that the dietary fiber in the current diet is comprised of approximately 70 to 75 percent insoluble fiber and 25 to 30 percent soluble fiber, and that some individuals are seeking products with higher levels of the specific fiber components.

The agency has established a DRV for dietary fiber but not one for insoluble or soluble fiber because no quantitative guidelines for daily intakes of soluble and insoluble fiber components have been established. Therefore, the agency has no basis on which to define "high" for insoluble and soluble fiber and has not made the suggested change.

150. One comment suggested that "high" and "source" claims for protein should be based on protein quality as well as level because such claims may be misleading if a food contains a lower quality protein. The comment suggested as a second criterion that a "high" in protein claim be allowed only for foods with a protein digestibility-corrected amino acid score (PDCAAS) greater than or equal to 40, and that for a "source" of protein claim, the food must have a PDCAAS of greater than or equal to 20.

The agency notes that § 101.9(c)(7)(i), proposed as § 101.9(c)(8)(i), provides that the percent DRV for protein must represent the corrected amount of protein based on its PDCAAS. Thus, the agency has already factored in the PDCAAS (see the discussion of protein quality in the Mandatory Nutrition Labeling proposal). Therefore, the agency believes that adding a second criterion based on the PDCAAS for "high" and "good source" in protein claims is not necessary. To determine whether a product qualifies for a claim as "high" in, or as "good source" of, protein, manufacturers must use the percent DRV for protein in a food that represents the corrected amount of protein based on its PDCAAS.

151. Some of the comments recommended defining the term "very high" to provide for use of this claim when a food contains 30 percent or more of the RDI or DRV per serving, so that consumers can distinguish between foods with "high" levels of nutrients and those with significantly more. Some comments recommended that the agency permit the term "principal source" as a synonym for "very high." However, a few comments agreed with the agency's position that the term "very high" should not be defined because allowing such a term could discourage consumption of a wide variety of foods in favor of fewer highly fortified foods and supplements. Other comments

proposed a three- or four- level system for claims that emphasize the presence of a nutrient. One suggested a three level system is as follows: "source of" as 10 to 19 percent; "good source of" as 20 to 49 percent; and "excellent source of" as 50 percent or more. A suggested four-level system is as follows: "source of" as 10 to 19 percent; "good source of" as 20 to 34 percent; "very good source of" as 35 to 49 percent; and "excellent source of" as 50 percent or more.

The agency has reviewed these comments and is not persuaded that it should define terms that correspond to levels of a nutrient that normally do not occur naturally in foods, e.g., "very high." In the general principles proposal (56 FR 60421 at 60443), the agency stated that defining a term such as "very high" could discourage adherence to current dietary guidelines such as those stated in "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 7), which emphasize the need to select a diet from a wide variety of foods and to obtain specific nutrients from a variety of foods rather than from a few highly fortified foods or supplements. The comments provided no information to cause the agency to change its position.

152. A majority of comments agreed with the agency's proposed definition for "source," while a few comments disagreed. Generally, the latter comments contended that the agency should not define "source" because consumers cannot reasonably be expected to distinguish between foods that are "high" in a nutrient as opposed to foods that are simply a "source" of a nutrient.

The agency agrees that consumers may not be able to understand the distinction between the meanings of "high" and "source." For example, the term "high" has a quantitative connotation, while the term "source" merely connotes that a nutrient is present but does not signify the quantity present. Therefore, the term "source" alone does not enable the consumer to conclude that the level of nutrient present is less than "high." However, the agency believes that the term "good source" conveys the appropriate information for a midlevel content claim, i.e., that a dietarily significant level of the nutrient is present, but that the level present is not exceptional with respect to levels naturally found in foods. Therefore, the agency is revising in § 101.54 the primary term for midrange nutrient content claims from "source" to "good source."

Thus, FDA concludes that adopting a two-level approach to claims that emphasize the presence of a nutrient based upon "good source" (as a replacement for "source") and "high" as the representative terms will provide meaningful information to consumers consistent with the intent of these proposed definitions.

FDA is, however, making a change in § 101.54. In proposed § 101.54(a)(3), FDA referred to § 101.36, in which the agency proposed to set forth the requirements for nutrition labeling of dietary supplements. In October of 1992, the Dietary Supplement Act of 1992 was enacted, which imposes a moratorium on implementation of the 1990 amendments. In response to this moratorium, FDA is not adopting § 101.36 at this time. Therefore, FDA has deleted the reference to § 101.36 from § 101.54(a)(3). FDA intends to revisit this issue in accordance with the provisions of the Dietary Supplement Act of 1992.

153. One comment stated that for fresh fruits and vegetables, the eligibility level for "source" should be 5 percent of the RDI for a nutrient because several nutrients occur naturally in fruits and vegetables at levels below 10 percent of the RDI.

The agency is not persuaded that the criteria for a mid-range nutrient content claim should include a lower eligibility level for fresh fruits and vegetables. As stated in the general principles proposal (56 FR 60421 at 60444), the agency has long held that a food is not a significant source of a nutrient unless that nutrient is present in the food at a level equal to or in excess of 10 percent of the U.S. RDA in a serving. The agency is unaware of any evidence suggesting that this policy should be changed, and none was presented in any comments to the proposal. Therefore, the agency is not including a lower eligibility level in the definition of "source" for fresh fruits and vegetables.

154. Some comments disagreed with the agency's exclusion of total carbohydrates from coverage under the proposed definitions for "high" and "source." The comments stated that "high" and "source" should be defined for complex carbohydrates because health authorities recommend that consumers increase the amount of complex carbohydrates in their diets.

The agency does not agree that it should define "high" and "good source" for complex carbohydrates. The agency has concluded that it is unable to define "complex carbohydrates," as discussed in the final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**. Therefore, there is no basis for nutrient content claims about this nutrient.

155. One comment suggested establishing definitions for "source" for polyunsaturated fatty acids and monounsaturated fatty acids because health authorities recommend increasing the intake of unsaturated fat while decreasing the intake of saturated fat.

Because the agency has determined that a DRV for unsaturated fat (including polyunsaturated and monounsaturated fatty acids) is potentially misleading, as explained in the RDI's and DRV's final rule, published elsewhere in this issue of the **Federal Register**, the agency concludes that there is no basis for defining "high" and "good source" for unsaturated fat.

156. A few comments opposed proposed § 101.54(d) that requires that unless a food meets the definition for "low fat" (3 g or less fat per serving and per 100 g), a "high fiber," "source of fiber," or "more fiber" claim must be accompanied by a declaration of the amount of total fat per serving in immediate proximity to the claim and preceding the referral statement. These comments stated that this provision targets only fat as an unhealthy nutrient, and therefore it is discriminatory and anti-competitive.

The focus on fat in conjunction with fiber claims derives from the statute itself. As stated above, section 403(r)(2)(A)(v) of the act provides that a claim may not state that a food is high in fiber unless the food is low in total fat, or the label discloses the level of total fat in the food. Thus, § 101.54(d) is required by the statute, and the agency is retaining this requirement in the final rule. Moreover, it is consistent with the statute's focus on fat in conjunction with fiber claims to require a similar fat disclosure when a "good source" or "more" claim for fiber is made.

c. relative claims

Sections 3(b)(1)(A)(iii)(III), (b)(1)(A)(iii)(IV), and (b)(1)(A)(iii)(V) of the 1990 amendments require that the agency define the terms "light" or "lite" (referred to collectively in this document as "light"), "reduced," and "less," unless the agency finds that the use of any of these terms would be misleading under section 403(a) of the act. These terms are used for comparing the amount of nutrient in one food with the amount of the same nutrient in another food or class of foods. The comparisons are called "relative claims." In the general principles proposal, the agency proposed definitions for "light," "reduced," and "less," as well as the terms "fewer" and "more." In addition, the agency proposed in § 101.13(j), requirements

specifying: (1) The reference foods that may be used as a basis for comparing the level of nutrients in one food with the level of those nutrients in another food for the various types of relative claims; (2) the information about the foods being compared that must accompany the claim; and (3) the minimum absolute amount of a nutrient by which the food must differ from the reference food in order to make a relative claim.

The definitions for relative claims proposed in the general principles proposal placed "less" (or "fewer"), "reduced," and "light" on a continuum using two criteria, both of which a food would have to meet to bear a specific relative claim. First, the proposal would have required that a food be reduced in the particular nutrient by a specific minimum percentage, depending on the claim. Secondly, it would have required that the level of a nutrient in the food be reduced by a minimum absolute amount (e.g., 3 g fat). The agency believed that such a regulatory scheme would limit consumer confusion with respect to the meaning of these terms.

To provide a basis by which comparisons between two foods could be made using relative terms, the agency proposed three types of reference foods (56 FR 60421 at 60445). These reference foods were: (1) A composite value of all foods of the same type, referred to as an industry-wide norm (proposed § 101 13(j)(1)(i)), which could be used as a basis of comparison for all relative claims; (2) a manufacturer's regular product (§ 101 13(j)(1)(ii)) which could be used for "reduced," "less," and "more" claims; and (3) a food or class of foods whose composition is reported in a current valid data base (proposed § 101.13(j)(1)(iii)) for use with "less" and "more" claims.

However, the agency acknowledged that it is possible that because of the natural vagaries of the language (56 FR 60421 at 60458), the terms "reduced" and "less" (or "fewer") may have no innately understood differences. Consequently, the agency acknowledged that any proposed regulatory distinction between the two terms may still be misleading. Therefore, the agency discussed the possibility, as an alternative approach, of providing the same definition for "reduced" and "less" and requiring information describing exactly how the foods differ to accompany the claim. Under this scheme, the percent that the nutrient in the labeled food differed from the reference food, a comparison of the actual amounts of nutrient in the labeled food and the reference food, and the identity of the reference food would have been conspicuously disclosed on the PDP of the label. The agency did not, however, discuss what reference foods would be appropriate as the basis for these claims if they were given the same definition. In the proposal, FDA discussed the possibility of publishing a supplemental notice on this alternative. Although a document was drafted and made available at a hearing that the agency held in January of 1992, it was never published in the **Federal Register** and thus must be considered a draft. However, the agency has fully considered comments it received on the alternative approach in arriving at this final rule.

1 "Reduced" and "less" (or "fewer")

a General provisions

Relative claims have traditionally been defined by the agency using a minimum percentage reduction. Under existing regulations, to make a "reduced sodium" claim or a "reduced calorie" claim, for example, the food must be reduced by 75 percent in sodium (§ 101.13(a)(4)) or 33 1/3 percent in calories (§ 105.66(d)). Moreover, in earlier documents on cholesterol claims, the agency proposed to require that cholesterol be decreased by 75 percent for a food to make a reduced claim (51 FR 42584, November 25, 1986; 55 FR 29456, July 19, 1990). The minimum percentage reduction has been used by the agency to ensure that the level of the nutrient that is the subject of a claim in a food that bears a claim has been decreased by a significant amount compared to the reference food.

In the general principles proposal FDA proposed that for a food to bear the term "reduced," it must contain at least one-third fewer calories or 50 percent less fat, saturated fat, cholesterol, or sodium than the reference food. To bear the term "less" (or "fewer") the agency proposed that a food must contain at least 25 percent less of the nutrient than the reference food.

However, the agency was concerned about misleading relative claims that highlight a decrease in the amount of a nutrient on products that normally contain only a small amount of that nutrient. For example, if such claims were allowed on the basis of a percentage reduction only, a food containing 50 calories per serving could be reformulated to contain 33 calories (a one-third reduction) and thereby qualify to make a "fewer" claim. The agency was concerned that such claims would be misleading because the difference in the amount of the nutrient would be insignificant with respect to the total daily diet.

To ensure that claims for products having relatively small amounts of nutrient not bear a claim unless the difference in the amount of nutrient was significant relative to the total daily diet, the agency proposed that a product also be reduced by an absolute minimum amount in order to bear a claim. The agency proposed to require that the minimum reduction necessary for the food to bear a relative claim be equal to the value of "low" for that nutrient, i.e., a reduction of at least 40 calories, 140 mg of sodium, 3 g fat, 1 g saturated fat, or 20 mg cholesterol. Consequently, the agency proposed that the definitions for "reduced" and "less" claims be based on both a minimum percentage difference and a minimum absolute difference in the amount of the nutrient.

In the general principles proposal (56 FR 60421 at 60458), as discussed above, FDA also requested comment on an alternative approach under which "reduced" and "less" (or "fewer") would have the same definition, and there would be a numeric disclosure of the actual amount and the percentage that nutrient in the labeled food differed from the reference food Under this approach, there would not be a single, across-the-board minimum percent reduction required to support the claim, but any claimed reduction or difference in the level of a nutrient would have to be large enough to be nutritionally significant.

157. Many comments said that there was an insufficient distinction between the terms "less" and "reduced" to warrant separate definitions for these terms, and that use of the two terms was confusing. They suggested that "reduced" not be defined. Other comments suggested that "less" (or "fewer") was the redundant term and should not be defined. However, many more comments stated that "reduced" and "less" should have the same definition. These comments said that the distinction made by FDA is artificial and confusing, and that consumers do not understand there to be any real distinction between the two terms. Many comments said that declaration of the extent of the reduction is more meaningful than the descriptive term used because it provides more information about the nutrient content of the product. Some stated that separate definitions would make it more difficult for manufacturers to meet consumer demand for modified products that comply with defined terms.

The agency has reviewed these comments and is persuaded that the terms "less" and "reduced" may not

have two distinct nutrition meanings to the ordinary consumer, and that, therefore, it could be confusing if the terms were to have two distinct nutrition definitions. The agency considered eliminating one or the other of these terms but chose not to do so. Both of these terms are listed in section 3(b)(1)(A)(iii) of the 1990 amendments. While FDA could have decided not to define one of the terms listed in that section if it found that the use of the term would be misleading, the agency has no information on which to base such a conclusion for either "less" or "reduced."

The current use of both "reduced" and "less" suggests that both terms have a place in the market. The terms are commonly understood to have different meanings. "Reduced" applies to a characteristic of an entity that has been altered with the resulting entity differing from the original by only that alteration, while "less" encompasses "reduced" and can also apply to a difference in a characteristic between two distinct entities (Ref. 25). Accordingly, as discussed in detail below, the agency is revising new §§ 101.60(b)(4), 101.61(b)(6), 101.62(b)(4), (c)(4), and (d)(4), by providing the same definition for the terms "less" (or "fewer" in the case of calories) and "reduced," (See comments 158 through 160 of this document). It is also deleting the separate definition for "less" (or "fewer") proposed in §§ 101.60(b)(5), 101.61(b)(7), 101.62(b)(5), (c)(4), and (d)(5). Instead of distinct definitions for each of the two terms, the agency will rely on the information that accompanies the claim to inform consumers of the levels of reduction of a nutrient achieved by the labeled food. However, as is discussed in greater detail in comment 204 of this document, the agency believes that because of their different commonly understood meanings, the two terms may not always be used interchangeably.

158. There was only limited support for the definitions proposed for "reduced" and "less," which would have required a minimum percentage reduction and a minimum absolute reduction for a product to bear such a claim.

Generally, the comments expressed concern that the two part definition, particularly because of the minimum absolute reduction, was too strict. Many comments opposing the minimum absolute reduction requirement requested that it be deleted in the final rule. These comments said that such a requirement discriminated against products with small serving sizes. They cited situations in which the modified product might contain substantially less of a nutrient, on a percentage basis, compared to the reference food, but where the labeled food did not contain an amount of the nutrient sufficient for the food to be reduced by the minimum absolute amount. (One comment gave as an example, a serving of sour cream that contains 60 calories. A one-third reduction is 20 calories, which is only one-half of the 40 calories proposed as the minimum calorie reduction necessary in order to make a claim.) The comments stated that although differences in the absolute amount of a nutrient in such products might be small, the nutritional benefits derived from several servings of similarly modified foods over a day could have a significant impact on the level of the particular nutrient in the total diet.

Comments suggested a wide variety of alternative definitions, including various minimum percentage reductions, some with minimum absolute reductions and others without. Several comments that supported a definition based solely on a minimum percentage reduction stated that such a criterion is necessary to ensure that claims are made only for nutrient reductions that are nutritionally significant, especially for those foods containing large amounts of a nutrient. They gave as examples salty soups having 1,000 mg of sodium and candy bars with 300 calories.

Only a few comments preferred a minimum absolute reduction over a percentage reduction as a sole criterion. However, most of those comments voiced little reason for their preference. Of those commenting, a very few stated that without the proposed minimum reduction requirements, claims might be permitted on products where only very small reductions were made. They said that if the products were already very low in, or free of, the nutrient, such claims would be misleading.

A few comments suggested that a minimum absolute reduction other than the proposed values based on the definition for "low" should be used to control claims made for very small nutrient reductions, e.g., 20 or 30 calories, instead of the proposed 40 calories; 1.5 or 2 g fat instead of 3 g fat; 0.5 g saturated fat instead of 1 g; 35 or 100 mg sodium instead of 140 mg; and 10 or 15 mg cholesterol instead of 20 mg.

Some comments suggested that there should be no single, across-the-board minimum percentage difference or minimum absolute reduction, but that there should be a general requirement that the nutrient reduction be large enough to be nutritionally significant. Others suggested that "reduced" or "less" claims be permitted for any decrease in the level of a nutrient in a food so long as small improvements in a product were not exaggerated, and the absolute difference was disclosed. One comment suggested that any definition would serve as a floor representing the minimum amount of reductions that manufacturers would make, and that because of competitive forces, actual reductions would increase.

The agency proposed that both a minimum percentage reduction of a nutrient in a food and a minimum absolute reduction were necessary in order to ensure that meaningful reductions in the amount of nutrient in a food would occur, and thereby increase the likelihood that selection of nutritionally reduced foods would have a positive effect on an individual's overall dietary intake of the nutrient. The agency believed that a minimum absolute reduction was necessary to ensure that relative claims were significant and would not be made on products that, although they had a large percentage reduction, had only insignificant changes in the amount of nutrient. Such reductions could occur if relative claims were based only on a minimum percentage reduction in products that normally contain only a small amount of the nutrient. On the other hand, the agency was also concerned that products containing large amounts of a nutrient not have insignificant reductions compared to the amount of nutrient in the food and its overall contribution of the nutrient to the total diet.

The comments have convinced the agency that a definition using both criteria is too restrictive and will prohibit claims on a number of products that are useful in constructing diets consistent with dietary guidelines. However, the agency is not convinced, nor have the comments supported with data or other information, that having no minimum criteria will provide sufficient assurance that reductions in the level of a nutrient will be sufficient to prohibit misleading claims by assuring that only foods with nutritionally significant reductions may bear a "reduced" or "less" claim. Without such criteria, it would be difficult to ensure that nutrient reductions in a product were large enough to be significant in the case of products with a small amount of a nutrient or sufficient relative to the food's contribution of the nutrient to the total diet for products with a large amount of a nutrient.

In addition, the agency does not agree with the suggestion that additional labeling can be used to counteract a misleading claim that is used to represent a truly insignificant reduction in the level of a nutrient. Stating the absolute amount of difference, as recommended by the comment, would suggest that the product had undergone nutritionally significant reductions when it had not.

Therefore, FDA concludes that it is necessary to establish specific requirements to define when the difference in the level of a nutrient is large enough that claims about the difference are not misleading, and the terms "less" and "reduced" may be used.

The agency believes that of the options suggested in the comments, either a percentage reduction or a minimum absolute reduction offers the greatest assurance that the reductions achieved will be nutritionally significant.

The agency has evaluated both types of criteria. If an absolute minimum reduction were used as the sole criterion, there would always be a nutritionally significant change in the amount of the nutrient for all foods bearing the terms "reduced" or "less." However, the agency also considered the argument that was strongly made in the comments that a minimum absolute reduction for relative claims may unfairly discriminate against products with small serving sizes. Furthermore, the agency is persuaded by the comments that smaller reductions, in nutrient-dense foods traditionally used in small amounts for example, 20 calories in sour cream rather than 40 calories, may be beneficial to consumers and will not be misleading if changes in absolute amounts are declared. Although the agency remains convinced that only claims about significant changes in a product should be authorized, it acknowledges that for products with small servings, nutrient reductions that do not meet the proposed absolute minimum reduction requirements can be significant in the context of a daily diet.

Many foods with small serving sizes, crackers for example, may be consumed several times throughout the day. Thus, the agency agrees that the small absolute reductions that occur with consumption of each serving of such foods may have a significant cumulative effect on the amount of a nutrient consumed over the course of a day. The agency understands that label claims that highlight such changes could assist consumers in making useful changes in their diet.

However, if only a minimum absolute reduction is required in order for a product to bear a "reduced" or "less" claim, products with larger serving sizes that contain large amounts of a nutrient could still contain a large amount of the nutrient after reduction.

On the other hand, with a minimum percentage reduction requirement, more products containing small amounts of a nutrient would qualify to make "reduced" or "less" claims based on smaller absolute reductions in the amount of a nutrient than would be permitted under the requirements of the proposal. Such a criterion would also require larger, more nutritionally significant changes on products containing large amounts of the nutrient.

The agency has carefully weighed the concerns expressed by the comments. The agency believes that the terms "less" and "reduced" should be used only when a nutritionally significant reduction in the level of the nutrient has been reached so as not to mislead consumers into believing that a product would provide nutritionally significant reduction in the level of a nutrient when it would not.

The agency has determined that it is most appropriate to require a minimum percentage reduction rather than a minimum absolute reduction in order for a product to bear a "reduced" or "less" claim for the following reasons. First, the use of a minimum percentage reduction instead of a minimum absolute reduction is compellingly supported by comments and generally consistent with the agency's proposed approach. Secondly, it will allow more foods with smaller reductions in a nutrient to make a "reduced" or "less" claim. By eliminating the minimum absolute amount that a nutrient must be reduced for a product to bear a claim, the agency believes that manufacturers may have an additional incentive to produce modified products that are helpful in maintaining healthy dietary practices. Although these changes are smaller per product, they will cumulatively contribute overall to reduction in the amount of certain nutrients in the diet. Thirdly, this approach will assure nutritionally significant changes in products containing large amounts of a nutrient.

Therefore, FDA concludes that it is appropriate to require a minimum percentage reduction in the level of a nutrient in order for a food to bear a relative claim. Accordingly, the agency is deleting from new § 101.13(j)(3) and from the regulations on claims for specific nutrients (§§ 101.60(b)(4), 101.61(b)(6), 101.62(b)(4), (c)(4), and (d)(4)), the requirement for an absolute reduction in the level of a nutrient in order for the food to bear a claim.

159. Several comments suggested that to prevent relatively small quantitative reductions from being touted as large percentage reductions, as an alternative to a minimum absolute reduction, "reduced" and "less" claims not be permitted on products if the reference food qualifies for a "low" claim.

The agency is concerned that for products in which the level of a particular nutrient is very low, requiring only minimum percentage reductions would mean that very small, nutritionally insignificant changes could be made in the amount of the nutrient, and the product would still qualify to make a "reduced" or "less" claim. It agrees that the suggested approach would provide assurance that the changes made to qualify for a "reduced" or "less" claim are not so small as to not be nutritionally significant. The agency notes that the value for "low" is the level at or above which the amount of a nutrient becomes significant relative to the total diet. A difference between two foods in a nutrient that is present in both foods at a level that is less than that of nutritional significance is not a significant difference. Such differences cannot be considered meaningful relative to the overall diet because even the level of the nutrient in the reference food is so low that the impact of its consumption on total dietary intake of the nutrient is minimal.

Thus, the agency agrees with the comments that contended that it would be misleading for products to make a relative claim if the nutrient is present at a "low" level in the reference food. Consequently, the agency is prohibiting "reduced" and "less" claims that are based on a difference from a reference food that meets the requirement for a "low" claim with respect to the nutrient in question. The agency is revising new § 101.13(j)(3) to include this requirement.

The agency believes that the overall approach described above will provide the best balance between encouraging manufacturers to produce foods with significant nutrient reductions by authorizing them to tell the public about the products' attributes and protecting consumers from being misled by claims directing them to foods that are not meaningfully improved in nutrient content.

160. Many comments discussed the percentage that a food should be reduced to bear a "reduced" or "less" claim. They suggested a wide range of percentage reductions, from a 50

percent reduction for "reduced" or "less" for all nutrients (including calories) to a 10 percent reduction for all nutrients. Some comments stated that FDA has historically used a 10 percent reduction as the minimum amount required for nutritional significance, and, therefore, it was an appropriate basis for a "reduced" claim. Other comments said that small incremental nutrient changes such as 10 percent are beneficial to consumers and represent modifications that are achievable. The comments argued that banning label information about incremental changes is likely to hurt consumers and discourage innovation.

Many other comments stated that a 25 percent reduction was an appropriate minimum reduction requirement. These comments said that using this level would allow "reduced" and "less" to have the same definition as originally proposed for "less." In addition, they said that a 25 percent reduction is a nutritionally significant reduction.

One such comment said that there is a sound scientific foundation upon which to require a minimum percentage reduction of 25 percent. The comment included comparisons of target daily intakes to current intakes and concluded that a 25 percent reduction is fully consistent with the reduction in intake needed to achieve current national dietary goals for fat, saturated fat, and cholesterol. The comment also concluded that although these calculations suggested that a 40 percent overall reduction in sodium was necessary to reach dietary goals, a 25 percent reduction was more practicable. This comment said that its conclusion was based on experience in marketing foods with reductions in sodium. It said that it had found that smaller incremental reductions were necessary to avoid consumer rejection of altered foods. The comment said that taste preferences will change as consumers adapt to lower salt levels, and that a 25 percent incremental reduction at this time would be a practical approach to the 40 percent reduction that is ultimately desired.

Another comment stated that a 25 percent threshold for claims was appropriate because it is supported by a variety of international governments and organizations, including Codex Alimentarius.

A few comments said that a one-third minimum reduction in the level of a nutrient was an appropriate criterion for a food to bear a "reduced" or "less" claim. They stated that a one-third reduction was a significant reduction, and that it is consistent with the percentage reduction required for "reduced calorie" claims (§ 105.66). Other comments suggested that foods should be permitted to bear a "reduced" or "less" claim only if there was a 50 percent or greater reduction in a nutrient (including calories) than the reference food. They said that requiring this percentage reduction was important for consistency across the nutrients. Other comments said that a minimum percentage reduction of 50 percent was necessary to ensure that the reduction is truly nutritionally significant compared to the original food and is useful to consumers in following dietary guidelines. A very few comments suggested that the definition for "reduced sodium" and "reduced cholesterol" should be returned to the 75 percent reductions previously established or proposed.

The agency does not agree that it has established a precedent for using 10 percent as a criterion for a minimum percent reduction in the level of a nutrient. Current agency regulations (§ 101.9(c)(7)(v)) provide that a food is not a significant source of a nutrient unless the nutrient is present at a level that is 10 percent of the U.S. RDA, and that no claim may be made that a food is nutritionally superior to another unless it contains at least 10 percent more of the U.S. RDA of the claimed nutrient per serving than the other food. For "reduced" and "less" claims, on the other hand, the percentage is used as the basis for a direct comparison between the amount of the nutrient in each of the foods. Therefore, the agency concludes that this comment did not provide sufficient justification to permit "reduced" or "less" claims on products having only a 10 percent reduction.

In addition, in the final rule on sodium labeling (49 FR 15510 at 15521, April 18 1984), the agency stated that a 10 percent reduction criterion for comparative claims was too low because of product variability. The agency said that because of expected statistical distribution of a nutrient (in that case sodium) in the food, there is a measurable probability that the sodium content of a sample of a product for which a lowered sodium content claim was made would actually exceed the sodium content of a sample of the unaltered product. Because it had been suggested that such product variations may not be as common now as they were in 1984 because of manufacturers' ability to more precisely control the amount of nutrient in a product, the agency solicited comments on this suggestion. However, comments provided no data to substantiate that improvements in food technology or other factors make it practicable for manufacturers to reliably achieve a 10 percent reduction. Thus, in the absence of data to support a different finding, the agency concludes that, because of product variability, a 25 percent reduction is the lowest level of reduction that can be supported.

The agency's decision to require a 25 percent reduction as the basis for a "reduced" or "less" claim is also based on the recognition, as outlined in the general principles proposal (56 FR 60421 at 60451), that this level will provide an incentive for manufacturers to reduce the level of the relevant nutrients in their food and at the same time has the potential to produce meaningful changes in overall nutrient intake for consumers. The comments provided significant support of these conclusions.

While the agency agrees that large reductions (such as 33, 50 or 75 percent) in the levels of certain nutrients present in a food may increase the likelihood that these foods will decrease the nutrient intakes of individuals who select these foods, FDA cannot agree that these percentage reductions are the most appropriate criteria on which to base "reduced" and "less." The comments supporting levels higher than a 25 percent reduction did not provide evidence that a 25 percent reduction would not be adequate, nor did they specifically demonstrate why a higher level than 25 percent is needed.

FDA recognizes that it has previously provided guidelines and definitions for nutrient reductions in foods, and that these specified reductions were greater than 25 percent. However, the agency now believes that with the advent of mandatory nutrition labeling and an ever increasing interest in healthy eating, more manufacturers will attempt reductions in the levels of nutrients like fat, saturated fat, cholesterol, and sodium in their foods. With the definition set at the reasonably achievable level of a 25 percent reduction, more foods are likely to be available, and consumers will be able to select from more and different foods in order to meet dietary guidelines. Furthermore, as suggested by one comment, market competition will undoubtedly spur some manufacturers to exceed this minimal reduction, thereby resulting in foods with even greater levels of reduction.

Therefore, the agency has concluded that an appropriate minimum percentage reduction for the terms "reduced" and "less" is 25 percent. Accordingly, the agency has revised new §§ 101.60(b)(4)(i), 101.61(b)(6)(i), 101.62(b)(4)(i), (c)(4)(i), (d)(4)(i)(A), and (d)(4)(ii)(A) to reflect this change.

161. One comment stated that the percentage reductions expressed on the label should not exceed the actual amount of the reduction of the nutrient in the product. Thus, the comment argued that manufacturers should be prohibited from "rounding up" the amount of the reduction to make it appear greater than it actually is.

The agency advises that for a product to bear a claim, the level of the nutrient must be reduced by at least a certain value. Thus, the amount of the reduction must be equal to or greater than the specified amount. There is no provision for rounding up the difference in nutrient content.

It is not clear to FDA whether the "rounding up" referred to in this comment is the rounding off provided in the regulation on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**. If the comment was concerned about such rounding, the agency advises that declaration of nutrients in, for example, 5 calorie increments or 0.5 g fat increments, which is permitted in nutrition labeling under § 101.9(c), is not permitted in determining the difference in nutrient levels between two foods. However, as discussed in the preamble of the proposal on mandatory nutrition labeling (55 FR 29487, July 19, 1990), the rounded differences are nutritionally insignificant. The agency would not consider a claim to be misleading if the declaration of the difference in absolute amount of nutrient between the foods were rounded off in conformance with rounding provisions for nutrition labeling in § 101.9.

162. A few comments requested that the regulation provide for use of "modified" as a synonym for "reduced" or "less."

The agency does not consider the word "modified" by itself to be a nutrient content claim. While it implies the product has been changed, "modified" does not necessarily imply that the change is in the content of a nutrient. As discussed elsewhere in this document, the word "modified" is permitted for use as part of the statement of identity on foods that qualify for "reduced" or "less" claims. However, "modified" is intended to be used in the presence of these claims, not in lieu of them. The term advises consumers that the product has been changed, and the nutrient content claim describes the change. Accordingly, FDA is not amending the regulation as requested.

163. One comment requested that the agency provide for the term "lower" as a synonym for "less." The comment stated that the term was currently in use on a comparative basis.

The agency agrees that "lower" should be permitted as a synonym for "less." Although the comment provided no further verification of the meaning of the term, the "American Heritage Dictionary," 1976 edition, (Ref. 25) defines the term to mean "below a similar or comparable thing." Such a definition is consistent with the principles for "less" claims which are used to compare two similar or comparable foods. Accordingly, the agency is including in §§ 101.60(b)(4) and (c) (4), 101.61(b)(6), 101.62(b)(4), (c)(4), and (d)(4)"lower" as a synonym for "less" (or "fewer").

164. One comment suggested that "less" rather than only the term "fewer" should be allowed for calorie claims.

As was stated in the general principles proposal (56 FR 60451), the agency defined "fewer calories" instead of "less calories" because the term "fewer" is grammatically correct. The agency does not believe that it is appropriate to amend the regulation to specify use of an improper term. However, FDA does not ordinarily consider a product to be misbranded because it bears a label statement that is grammatically incorrect. Accordingly, because the criteria for "less" and "fewer" claims are the same, the agency will not consider "less calories" to be misleading.

b. "Reduced" and "less" claims for sugar

In the general principles proposal, FDA proposed a definition for "less sugars" that included a minimum percentage difference of 25 percent but did not include a minimum absolute amount criterion. The agency did so because the minimum absolute amount criterion for other nutrients was the amount proposed to be defined as "low." The proposed criteria for "low" claims were based on DRV's for the nutrients, and because there was no DRV for sugars, there was no "low sugars" definition. The agency solicited comments for an appropriate requirement that could be used as the second criterion for this claim and signaled its intentions to establish a second criterion if one were not forthcoming.

165. Only a few comments addressed the term. Some supported defining the claim "less sugars," while a few others suggested that the term "less sugars" is not useful to consumers, is misleading, and should not be used. However, those objecting did not provide information as to why this was so.

As discussed in comment 80 of this document, the agency has determined that the term "sugars free" may be confusing to consumers and therefore is providing for use of the term "sugar free." The agency believes that "less sugars" would also be confusing. Therefore, for consistency the agency has determined that "less sugar" is the more appropriate term to describe reductions in the sugars content. Further, because the comments provided no arguments why the term should be eliminated, and because the term would provide certain useful information to consumers in comparing the sugars content of one food to another, the agency is not persuaded that the definition for "less sugar" should be eliminated. Accordingly, the agency has retained this definition.

In addition, FDA has included use of the term "reduced" in the provision for "less sugar" (§ 101.60(c)(4)). Although the agency had not proposed criteria for "reduced sugar" claims, now that the term "reduced" and "less" have the same criteria, it would be inconsistent not to also permit use of "reduced sugar" claims.

166. Only one comment suggested a second criterion for the definition of "less sugar." It recommended that the claim be permitted only if the labeled food contained at least 2 g less sugar than the reference food.

The comment did not provide rationale or other information to substantiate the recommendation. Consequently, FDA still does not have a basis for a minimum absolute reduction to be used in lieu of a definition for "low sugar." However, as discussed above in response to comment 158 of this document, FDA is no longer using the minimum absolute reduction as a criterion for "reduced" and "less" claims.

In view of this fact, the agency is persuaded that the need for a second criterion for sugar is similarly diminished. The agency has established in new § 101.13(j)(3) (see comment 159 of this document) a requirement that a relative claim may not be made if the amount of nutrient in the reference food is less than the value for "low." Although for consistency, a similar requirement for sugars might be useful, the agency does not believe that there is a compelling reason to definitively establish the criterion, especially given the fact that the basis for such a criterion, a DRV for sugar, does not exist. The agency will evaluate on a case-by-case basis whether claims on food that emphasize a very small reduction in the amount of sugar are misleading.

2. "Light"

a. General

In the general principles proposal (56 FR 60421 at 60449), FDA said that although the term "light" or "lite" is primarily a relative claim that compares one food to another food, it is often used to directly describe the food itself in the way that an absolute claim such as "low calorie" is used. The agency proposed several circumstances in which the term "light" could be used.

167. Several comments were concerned about the way that the term "light" is used in the marketplace. A few comments asserted that the term "light" is purely marketing puffery. Other comments said that "light" has no scientifically acceptable meaning but instead has a multitude of meanings and as such will do more to mislead consumers than assist them in making better food choices. Another comment said that because of the various consumer interpretations of the meaning of the term "light," there needs to be further research on its meaning before the term can be defined. A few comments stated that because "light" has no meaning, it should not be defined.

Section 3(b)(1)(A)(iii)(III) of the 1990 amendments requires FDA to define "light" or "lite" unless it finds that the term is misleading. While the agency agrees that some current uses of the term are misleading, it has not made a finding that the term is inherently misleading, or that it cannot be used in a nonmisleading manner. The agency concludes that it has sufficient information, including consumer surveys cited in the general principles proposal (Refs. 26 and 27) and other information submitted in comments with which to establish an appropriate definition for the term. By defining "light" and the conditions for its use in a meaningful way, the agency intends to help alleviate the confusion caused by the many uses of the term and to ensure that products that bear the term are useful in maintaining healthy dietary practices.

168. A few comments stated that "light" is not an expressed claim, but rather that it is an implied claim. The comments pointed to the House report on the 1990 amendments (H. Rept. 101-538, 101st Cong., 2d sess. 19 (June 13, 1990)) which said that an implied claim is a statement that "implies that the product is low in some nutrient (typically calories or fat) but does not say so expressly" and cited "lite" as an example of such a claim. One comment went on to say that as an implied claim, "light" should be permitted with any nutrient content claim, provided that the food qualifies for the claim.

The agency acknowledges that the House report stated that "lite" was an example of an implied claim. However, the agency believes that this term is used as an expressed claim because, as discussed in the general principles proposal (56 FR 60421 at 60449), it has a history of use both as a relative claim and as an absolute claim. "Light" has been used as a direct statement of the level of both calories and fat in food (see § 101.13(b)(1)). In the proposal, FDA stated that in spite of the reference to "light" in the legislative history, it intended to treat this term as an expressed claim (56 FR 60421 at 60449 through 60450). The comments that addressed this issue did not provide any justification for not following the course that the agency proposed. Therefore, FDA is defining "light" as an expressed claim in this final rule.

b. Definition of "light" based on fat and calories

In the general principles proposal (56 FR 60421 at 60449) the agency acknowledged that "light" has been used for a number of years to connote a wide variety of meanings such as low or reduced calories; reduced fat, sugar, or sodium; light in weight, texture, or color; and thin or less viscous. The agency cited studies that showed a stable perception by the majority of consumers that "light" means that the caloric level has been altered. However, it noted that "light" has also been used to directly describe the food itself in much the same way as the term "low" has been used. Because the agency believed that the definition of the term "light" should be based primarily on consumers' perception that "light" means "reduced in calories," the agency proposed that a food be permitted to bear the term "light" without further qualification if the food had been specifically formulated or processed to reduce its calories by at least one-third compared to a reference food specified in § 101.13(j)(1)(i), with a minimum reduction of more than 40 calories per reference amount and per labeled serving size.

The agency also noted that it had recently allowed the term "light" to be included as part of the name of dairy products that are altered to have, in addition to one-third fewer calories, at least 50 percent less fat. The agency also noted that other normally high-fat products are using "light" to describe fat and calorie reductions. In view of these facts, and because the agency believed that products with large amounts of fat should not be labeled as "light" unless a substantial amount of the fat in the food was also reduced, the agency proposed that if the food derives 50 percent or more of its calories from fat, its fat content must also be reduced by 50 percent or more compared to the reference food that it resembles or for which it substitutes. The proposal also would have required a minimum reduction of more than 3 g of fat per reference amount and per labeled serving size in order to bear the term "light."

169. A number of comments supported the agency's view that the percentage of a food's calories that are derived from fat should be considered in determining whether the food contains a substantial amount of fat and should, therefore, be required to be reduced in fat for the product to bear the term "light." Several comments supported the agency's proposal that 50 percent or more of a food's calories from fat was an appropriate level at which fat reduction should be required. Another comment suggested that if 40 percent or more of a food's calories are normally derived from fat, a fat reduction should be required, but it offered no substantiation for the suggestion. One comment suggested that a food contains relatively high levels of fat if 30 percent or more of the food's calories are derived from fat. It noted that the 30 percent threshold relates to the dietary guideline that no more than 30 percent of the calories in the total diet should be derived from fat. The comment suggested that a food that normally contains more than 30 percent of calories from fat would be inconsistent with this guideline and therefore should be required to be reduced in fat in order to bear the term "light."

The agency has considered these comments and is not persuaded by the comments that it is necessary to change its determination that foods that normally derive more than 50 percent of their calories from fat should be reduced in fat to make a "light" claim. The agency acknowledges that the dietary guidelines recommend that Americans eat a diet that consists of 30 percent or fewer calories from fat. However, because fat is found in only about one-half of the food supply, it is not necessary that each food contain only 30 percent of its calories from fat for the total diet to meet this goal. Rather, because a diet would normally consist of a combination of foods containing various levels of fat, those foods that derive somewhat more than 30 percent of their calories from fat would be balanced by foods that contain less than 30 percent of their calories from fat. A diet consisting of both types of foods

would be consistent with dietary guidelines. Consequently, it would not be necessary for all foods that derive over 30 percent of their calories from fat to be reduced in fat to meet dietary guidelines. There were no comments that suggested the percentage of calories from fat should be raised to a higher percentage. Therefore, the agency is retaining the provision as proposed, that products that normally contain over 50 percent of their calories from fat contain a substantial amount of fat and should, therefore, have the amount of fat they contain reduced to qualify for a "light" claim.

170. While a number of comments agreed with the agency's assessment that "light" is primarily associated with reduced calorie content, a greater number of comments maintained that consumers primarily perceive "light" to mean lower in fat. One comment cited a 1989 Gallup Organization consumer poll stating that 8 out of 10 consumers select "light" products in order to reduce fat consumption. Others cited a survey reported in an article entitled "Americans to Make LIGHTER Choices in the 90's" that appeared in "Calorie Control Commentary," vol. 12, No. 1 (Spring 1990), stating that 83 percent of consumers select products labeled as "light" in the belief that such products are low in fat. One comment included a study that found that 46 percent of consumers think that products labeled as "light" should have "almost no fat" or "no fat at all." Another comment stated that "light" has been used for decades to refer to fat reductions without evidence of consumer misunderstanding. The comment included a survey of 1,000 trademarks using the word "light" and noted that 35 percent of those trademarks were associated exclusively or primarily with reduced fat content in products. Many comments favored allowing "light" claims for foods on the basis of fat reduction alone.

The agency has carefully reviewed these comments and, on the basis of the evidence presented in them, has been convinced that in addition to "reduced in calories," the term "light" is also commonly understood to mean "reduced in fat." Consumers apparently view reductions in fat as a major reason for purchasing "light" products. Therefore, FDA does not consider that the term "light" is appropriately used only on products in which there has been a reduction in calories. The term also is appropriate on products in which there has been a reduction in fat.

171. Many comments contended that the proposed definition for "light" is too restrictive, especially for foods that normally contain large amounts of fat. The comments maintained that certain products, such as butters, ice creams, chocolate-coated ice cream novelties, cheeses, cakes, brownies, muffins, frostings, peanut spreads, savory snacks (pretzels and chips), popcorn, and coffee creamers could not be altered to qualify for a "light" claim under the proposed definition. A number of these comments pointed out that many fat substitutes contain a substantial amount of calories, and that even though it is often possible to reduce the fat content in products by 50 percent, it is not always possible to also reduce the calorie content by one-third unless all or most of the fat is removed.

The comments stated that in the case of ice cream novelties, for example, because some of the preferred fat replacers, such as carbohydrate or protein solids, contain a substantial amount of calories, it is difficult to remove enough of the calories normally contained in the product to achieve a one-third calorie reduction solely by replacing the fat. To accomplish this calorie reduction, the comment said, would require that virtually all of the fat be removed and replaced with an ingredient such as polydextrose which has a lower calorie content than other fat replacers. However, in achieving this caloric reduction, the comments maintained, consumer acceptance is "lost along the way."

The comments asserted that similar problems occur with cheeses and other products. The comments contended that manufacturers' present inability to make products that can substitute for products normally high in fat, that are acceptable to most consumers, and that can meet the "light" definition will significantly reduce labeling and marketing incentives for such products. Several comments maintained that, as a result, many reduced fat alternatives will be removed from the market, and that development of more "light" products will be retarded. Several comments asserted that having fewer options will cause difficulty for consumers who wish to reduce their fat intake to 30 percent or less of their calories from fat, as recommended by dietary guidelines. They stated that, consequently, the criteria for use of the term "light" should not incorporate both a 50 percent fat reduction and a one-third calorie reduction for products with a substantial amount of calories from fat.

The agency has reviewed these comments and is persuaded that because of the difficulty in achieving "light" products that are reduced both in calories and in fat, the agency will not require that both nutrients be reduced for a food to bear the term. FDA believes that while the criteria for making a "light" claim must result in labeling that consumers can understand and rely on, the criteria should also be reasonably achievable to encourage manufacturers to produce altered products that will assist consumers in maintaining healthy dietary practices. The agency recognizes that it is difficult to achieve reductions of both calories and fat in a number of products containing more than 50 percent of calories from fat, particularly dairy products such as cheeses, ice creams, and frozen confections. In addition, consumers will not purchase, and therefore will not benefit from, altered products that do not meet their acceptance requirements.

In the general principles proposal, FDA stated that a majority of consumers associate "light" with a reduction in calories, even though there are other meanings for the term. However, as discussed in comment 170 of this document, the comments provided information that establishes that consumers strongly associate the term "light" with reduced fat levels. Thus, as discussed in more detail below, FDA no longer believes that a reduction in calories in the food is essential or is always expected by consumers who choose a food because it bears the term "light." Accordingly, the agency has deleted from § 101.56(b) the requirement that products that contain more than 50 percent of calories from fat be reduced both in calories and in fat to bear the term "light."

172. In the general principles proposal, FDA requested comment on whether it was necessary to prohibit a "light" claim on a product containing more than half its calories from fat that is reduced by one-third in calories but that has not also been reduced in fat by the required minimum. The agency asked for comment on whether the claim was misleading and should be prohibited, or whether a statement informing the consumer that the product was not reduced in fat would make the label not misleading. In response, the comments did not support the use of a label statement in alerting consumers that a particular product that was labeled as "light" was high in fat. In addition, although comments did not directly suggest that "light" be permitted on foods that derive one-half of their calories from fat that had been reduced by one-third in calories but not by one-half in fat, many comments did suggest that in such foods, fat reduction is necessary.

The Surgeon General's report (Ref. 4) and the NAS's report "Diet and Health:

Implications for Reducing Chronic Disease Risk" (Ref. 12), in considering the effect of diet on an individual's health, concluded that consumption of a diet high in fat, saturated fat, and cholesterol is associated with increased risk of development of certain chronic diseases. These reports and "Nutrition and Your Health: Dietary Guidelines for Americans" (Dietary Guidelines) (Ref. 7) recommend that Americans reduce their consumption of these substances in their diets. Given the significance of dietary intake of fat and saturated fatty acids, FDA believes that it is important to assist consumers in modifying their diets to reduce their intake of these food components and thereby to maintain healthy dietary practices. By ensuring that foods that normally contain large amounts of fat are substantially reduced in fat in order to bear the term "light," FDA believes that it will assist consumers in constructing diets that are consistent with dietary guidelines by providing substitute foods in which there is a large reduction in fats that will assist them in reducing the fat content of their diets. Therefore, FDA concludes that it would not be appropriate to permit the term "light" to appear on a food that normally derives one-half of its calories from fat that has not been reduced in fat content by the required minimum amount. Accordingly, because the term "light" implies that the food is useful in achieving a diet that conforms to dietary guidelines, foods with relatively high levels of fat (i.e., more than 50 percent of calories form fat) must be substantially reduced in fat if they would be useful in such diets. If the fat level in such foods is not reduced, the use of the term "light" in their labeling would be misleading.

To summarize, FDA concludes that consumers understand the term "light" to connote a reduction in fat as well as a reduction in calories, depending on the food involved. Accordingly, the agency has determined that it is appropriate for a food to bear the term when it has been sufficiently reduced in fat or, where appropriate, calories. (The amount of fat or calories necessary to constitute such a reduction is discussed below.) The agency is therefore providing in § 101.56 that the term "light" may be used when the labeled food differs from the reference food by a minimum percentage reduction in either fat or calories (comments 170 and 171 of this document). However, FDA also concludes that for foods that derive more than 50 percent of their calories from fat, the minimum percentage reduction in fat is necessary for the term "light" to not be misleading (comment 172 of this document). The agency, therefore, is providing in § 101.56(b)(1) a requirement for a minimum percentage fat reduction for such foods.

173. Of those commenting on the subject, a large number of comments stated that because it is a relative claim, "light" should be defined in the same manner as the other relative claims, "reduced" and "less." Many comments said that if "reduced," "less," and "light" all had the same definition, consumer confusion about the meaning of these relative terms would be diminished, especially if the exact nature of the modification was specified adjacent to the claim, as would be required by the accompanying information provisions. One comment said that allowing this more liberal definition for "light," but providing information on the exact nature of the reduction, was consistent with the policy of allowing other "light" claims provided the subject physical or organoleptic properties were specified. A few comments said that if FDA set reasonable parameters for use of the terms "light," "reduced," and "less," consumers would receive truthful, easy to understand information, and food manufacturers would be encouraged to produce foods with significant nutritional reductions because they would be able to tell consumers about their product's attributes.

Another comment said that defining "reduced," "less," and "light" at a lower standard than originally proposed for "light" would minimize the number of brand names prohibited on the grounds that the food did not meet the definitional requirements. One comment said that the same definitions for the term "reduced," "less," and "light" would significantly lower the cost to the manufacturer, and eventually to the consumer, by significantly reducing the costs associated with compliance. Other comments said that any definition would serve as a floor, and that competition and innovations in the market place would push actual reductions higher.

The agency has considered the arguments that because "light" is a relative claim, it should be defined in the same manner that the other relative claims "reduced" and "less" are defined. However, the agency is not persuaded by the comments that such a definition is appropriate. "Light" is a term that has special usefulness as a marketing tool for manufacturers to quickly and easily convey to consumers that the product to which the term is attached has been significantly reduced in the level of fat or calories. Although the agency recognizes that specifying the exact nature of the modification would help mitigate confusion caused by similar definitions for all relative claims, the agency is not convinced that defining "light" in the same manner that other relative claims are defined would be consistent with the special position of the term "light" in the marketplace and with the strong impression that products labeled as "light" are particularly useful in achieving a diet that is consistent with dietary guidelines as the available data and comments show.

The agency remains concerned about striking the proper balance between allowing manufacturers flexibility in the use of the term "light" and providing a definition that will ensure that products are improved significantly in the nutritional attributes addressed by the term. Striking the proper balance will provide consumers with meaningful product information and meaningful product choices. To define the term "light" with the same definition as for the terms "reduced" and "less" would sufficiently dilute the term so as to diminish its usefulness. Moreover, the agency is convinced that reserving the term "light" for those products that are more significantly improved will provide a greater incentive for manufacturers to continue to improve their products by providing a unique marketing vehicle by which such nutritionally significant changes can be highlighted for the consumer (See comment 174 of this document).

The agency recognizes the effect that any definition may have on brand names. However, FDA does not believe that it should permit or encourage "light" claims without further qualification on products that do not represent a major modification in fat or calorie consumption, as appropriate. Furthermore, the agency does not believe that the costs associated with compliance relative to distinctions between the two definitions for "light" and "reduced" and "less" are sufficient to warrant modification of this decision, and the comment did not provide cost information to substantiate its assertion. Accordingly, the agency is not providing the same definitions for "reduced," "less," and "light."

174. Comments expressed a variety of opinions as to the minimum percentage of fat by which a food should be reduced to qualify to bear the term "light." A number of comments objected to the 50 percent fat reduction requirement. They asserted that in certain product categories, it is not technically feasible to develop products that are reduced in fat by 50 percent or more and that are acceptable to the

consumer. The comments stated that consumers want products lower in fat but with organoleptic properties similar to the reference foods. Other comments noted a variety of manufacturing problems, such as undesirable changes in the texture, flavor, cooking applications, and storage requirements of a food, that are encountered with a 50 percent reduction in fat in a product. In addition, the comments maintained that replacement of the sensory properties of fat is difficult in low moisture content bakery products. The comments also asserted that a 50 percent or greater fat reduction in cheeses results in products with low consumer acceptance, higher moisture content, increased potential for bitter flavor development, poorer physical properties, such as rubbery texture, and microbial instability during curing and storage.

The comments also stated that a 50 percent or greater fat reduction in savory snacks, such as pretzels and chips, will have significant concomitant reductions in flavor and texture acceptability. Some comments contended that because of these problems, there is a greater likelihood that industry will develop and market fat modified foods with a one-third fat reduction than foods with a 50 percent reduction. The comments maintained that without these reduced fat products, consumers will be less able to achieve a diet composed of a variety of different foods (including products normally high in fat such as many dairy products) that is consistent with dietary guidelines.

Some comments suggested that the fat content need only be reduced by 25 percent in order to bear the term "light." The comments maintained that such a reduction would ensure truthful and nonmisleading "light" claims. One comment maintained that a 25 percent reduction was appropriate especially since the product was also required to have a minimum absolute reduction in fat of 3 g, which is significant.

A number of comments favored using "light" claims on foods whose fat content is reduced by one-third or more. Some comments suggested that a one-third reduction in fat was significant and would be desirable because it is consistent with a one-third reduction in calories. They maintained that it was easy for consumers to understand the meaning of the term "light" if a food must be reduced by a single percentage of either fat or calories in order to bear the term. One comment suggested that a one third or greater fat reduction would make a valuable contribution towards helping consumers to reduce fat intake.

Other comments stated that products should be reduced in fat by a minimum of 50 percent in order to bear a "light" claim. One comment, which acknowledged that the term "reduced" may have insufficient marketing appeal to encourage industry to create new, healthier products, proposed that "light" replace "reduced" altogether and suggested that the nutrient that is the subject of the "light" claim, for example fat, be reduced by 50 percent or more. Some comments stated that such a revised definition of "light" is desirable because the term "light" is a powerful marketing tool, and by reserving the use of "light" for truly significant reductions, FDA will create an incentive for food companies to develop new products that are nutritionally superior. One comment maintained that a 50 percent reduction in fat is sufficiently substantial to benefit consumers and feasible for industry to achieve. One of these comments suggested that 50 percent or "half as much" is an easy level for consumers to remember. Finally, one comment stated that a consumer study, conducted under their sponsorship by the University of Michigan, suggested that 78 percent of the respondents viewed "light" products to have at least a 50 percent reduction in fat.

The agency has carefully considered all of the comments. Although the agency recognizes the difficulties involved in reducing fat by 50 percent, it is not convinced that they are so great as to prevent manufacturers from producing and marketing a significant number of products with a large enough fat reduction to bear the term "light." The agency notes that the technology problems associated with fat reductions in baked goods would not be pertinent to such products' ability to bear a "light" claim because these products generally do not contain 50 percent of their calories from fat, and the 50 percent fat reduction is, therefore, not required. The same is true for certain savory snacks such as pretzels. A fat reduction is required only for products that derive more than 50 percent of their calories from fat.

The agency is not persuaded by the comments that a 25 or 33 1/3 percent reduction in the amount of fat is sufficient for a food to bear a "light" claim. The comments establish that "light" is a special term with particular marketing appeal, and as such it should have a higher standard than that used for "reduced" and "less" claims which may be used on the label of foods having a 25 percent reduction in fat. The agency believes that the definition for light should take into account consumers' perception of the term as it relates to reductions in fat. One example provided in the comments demonstrates that 78 percent of those surveyed believe that when "light" is associated with fat reduction, it means at least a 50 percent reduction in fat.

As discussed above, the agency believes that a standard for "light" should be higher than that for "reduced" and "less" claims because it would encourage innovation, leading to a greater variety of products with substantial reductions in fat, and thereby help consumers to make significant reductions in the amount of fat in the total diet. Although the agency recognizes that some products would achieve reductions greater than 25 percent if that level were the minimum fat reduction required for products to bear the term "light," additional product innovation will be encouraged because of the desirability of the term, and a wider variety of products with greater fat reductions will, in time, be developed in response to the definition that FDA is adopting. Encouraging the development and marketing of innovative fat reduced foods will provide consumers with a greater variety of foods from which to choose in building a total diet.

In addition, the agency is aware of a variety of currently marketed products, such as cheeses and cheese products, that do have reductions in fat in excess of 33 1/3 and 50 percent, including products that are fat free. With the variety of such products currently on the market, the agency is not persuaded that it is not possible to make and market consumer-acceptable products that are reduced in fat by more than 33 1/3 percent. Furthermore, manufacturers wishing to make and market similar products with fat reductions between 25 and 50 percent will still be able to inform to consumers, through use of the terms "reduced" and "less," that the product did contain a certain percentage less fat than their regular product or other similar products. Although the agency is aware from comments that such terms are less marketable than the term "light," these terms are a method of effectively communicating product changes to consumers.

In summary, FDA concludes that the 50 percent minimum fat reduction is an appropriate criterion for use of the term "light." Accordingly, the agency is retaining this provision in the final regulation.

175. One comment suggested that the term "light" should be permitted on foods whose fat content is 10 percent or less. It noted that this would conform to

the policy of FSIS for the term "light" and would be consistent with FSIS' definition for "lean."

The agency does not agree. Both agencies are developing regulations on use of "light" and "lean." In its Nutrition Labeling of Meat and Poultry Products proposal (56 FR 60302), FSIS adopted FDA's proposed criteria for "light" in place of the 10 percent or less fat content criterion used previously. Because FSIS is no longer using this criterion, the comment that FDA could harmonize the two agencies' policies by adopting the 10 percent or less criterion is not correct. Furthermore, FDA is adopting in this final regulation, FSIS' definition for "lean." Thus, these regulations will provide distinct definitions for both terms. The comment did not present any other rationale to justify its request.

176. Several comments recommended that a food be required to meet the definition of "low fat" to qualify for use of the term "light." One comment referred to a consumer survey that, it claimed, found that many consumers expect "light" foods to have "almost no fat" or "no fat at all." The comment also stated that if foods cannot meet these strict criteria now, "light" should be used only on the few foods that do qualify until food technology developments can achieve the appropriate changes. The comment argued that such an approach would encourage development of products with greater nutrient reductions.

The agency does not agree that a food should have to be "low fat" to bear the term "light." The agency acknowledges that many consumers expect "light" foods to not contribute significant amounts of fat. However, FDA does not agree that the submitted survey substantiates that consumers generally expect "light" foods to have "almost no fat" or "no fat at all." FDA's interpretation of the survey is that some consumers expect a "light" product to have "somewhat less fat" or "one-half the fat." The agency believes that requiring a 50-percent minimum reduction for foods that derive more than 50 percent of calories from fat will ensure that foods bearing "light" claims will not mislead consumers. In addition, FDA is requiring declaration of the percentage of fat reduction on all foods that bear "light" claims, not just those for which the reference foods derive 50 percent of calories from fat (§ 101.56(b)). This declaration will inform the consumer of the meaning of the term for each food that bears it.

The agency also does not agree that overly strict definitions for claims will encourage manufacturers to produce foods with greater improvements in nutrient content. As stated in the general principles proposal with respect to "reduced sodium" claims (56 FR 60421 at 60448), the current requirement for 75 percent sodium reduction is too strict. Consequently, very few foods bear the claim. The agency believes that consumers are more likely to make better food choices if a greater variety of improved foods is available, and if information on the improvement is available. Consequently, FDA is not adopting the suggestion in the comments to require that foods meet the definition of "low fat" to qualify to bear the term "light."

177. A few comments stated that the term "light" should be permitted to be used on products that are "low" in a nutrient. They stated that in the legislative history of the 1990 amendments, Congress said that it considered the term "light" to imply that a product is "low" or "reduced" in fat or calories. Another comment suggested that there are a large number of product labels that have enjoyed longstanding marketing under an interpretation of § 105.66 that "light" means either "low calories" or "reduced in calories," and that the agency should continue to allow the descriptor "light" to mean "low" or "reduced" in any nutrient.

The agency has reviewed these comments and is not convinced that the term "light" should be permitted to be used on products that are "low" in a nutrient. In proposing definitions for terms, FDA tentatively determined that it should provide unique definitions for each of the individual terms that the statute required FDA to define. However, the definitions, while distinct, provide for a range of terms to describe significant levels or differences in levels of nutrients. FDA has been persuaded by the comments that it is appropriate that the terms "reduced" and "less" have the same quantitative definition. However, the agency is not convinced by the comments that it would be appropriate for a product that is "low" in a nutrient to bear a "light" claim based only on the "low" level of that nutrient in the product. On the contrary, as discussed below in comment 179 of this document, a "light" claim is prohibited on foods for which the reference food is "low" in the nutrient. The agency has concluded that "light" implies a difference in nutrient content between two foods. Thus, in general, a reduction in a nutrient that is already "low" is insignificant, and a claim about that difference is misleading. The agency believes that the term "low" should be used to describe the level of the nutrient in such a food.

178. Most comments addressing the issue agreed with FDA's inclusion of calorie reduction as a component of the definition of "light." Most also agreed with the proposed requirement that a food's caloric content be reduced by one-third or more to qualify for use of the term. The comments said that such a reduction was significant and sufficient to justify a "light" claim. However, some comments proposed that the caloric content of a food be reduced by 50 percent or more in order for the food to be labeled as "light." One comment suggested that a 50 percent reduction in calories would be consistent with the level of fat reduction required for "light" claims and would reduce the number of insignificant claims.

The agency is not persuaded by the comments that a calorie reduction criterion for "light" claims other than the proposed one-third reduction is appropriate. The comments did not provide information to substantiate why a 50 percent calorie reduction was more appropriate. The agency discussed the one-third reduction requirement in the general principles proposal in reference to "reduced calories." It noted that because of the ubiquity of calories across all food categories, the reduction in calories in each food necessary to achieve an overall reduction of public health significance could be less than the 50 percent reduction necessary for other nutrients, including fat. Thus, given the difference in the occurrence of the nutrients in the food supply, a 50 percent reduction in fat and a one-third reduction in calories do perform a consistent function in the total diet. Moreover, permitting calorie claims at one-third reduction will allow a greater variety of nutritious foods to bear claims useful in reducing or maintaining calorie intake or body weight.

In addition, FDA has used the one-third reduction in calories as the basis for "reduced calorie" claims in § 105.66 since 1980. In that time, the agency has not found a problem with insignificant reduction in calories in foods bearing such claims. Accordingly, the agency is not revising in § 101.56(b) the percentage of calories that a food must be reduced in order to bear a "light" claim.

179. Many comments disagreed with the proposed requirement for a minimum absolute reduction of 3 g of fat or 40 calories for a food to bear a "light" claim. One comment asserted that the proposed minimum 40 calorie and 3 g criteria would eliminate "light" claims on sour cream, because those

criteria cannot be met while still retaining organoleptically acceptable products. Some comments proposed a minimum absolute reduction of 2 g of fat per serving.

FDA proposed the minimum absolute reduction requirement for "light" claims for the same reason that it proposed a minimum absolute reduction for "reduced" and "less" claims: to prevent claims for trivial reductions in nutrient content. In addition, the objections raised in comments about required minimum absolute reductions for "light" claims have the same basis as those for "reduced" and "less" claims. As was discussed in comment 158 of this document, the agency has become convinced that such a requirement discriminates against those products with small serving sizes, which could not bear "reduced" or "less" claims because they contain an insufficient amount of the nutrient to make the reduction necessary to justify a claim. The agency also was persuaded by the comments that the consumption of several servings of such products (bread for example) over the course of a day would result in significant reductions in the amount of a nutrient when considered cumulatively. Consistent with its position on "reduced" and "less" claims, FDA is persuaded that the minimum absolute reduction in the amount of a nutrient that a product must be reduced in order to bear a "light" claim, namely 40 calories or 3 g of fat, should be deleted. Accordingly, the agency is deleting this requirement from new § 101.56(b).

In addition, consistent with the requirements for "reduced" and "less" claims, the agency considers "light" claims to be misleading on products that base their reduction on reference foods that are already "low" in the target nutrient. As discussed in comment 159 of this document, the agency considers such a reduction to be trivial. Accordingly, the agency has prohibited such a reference food for products bearing a "light" claim in new § 101.56(b)(4).

180. The general principles proposal (56 FR 60421 at 60446) provided that like "reduced" and "less" claims, a "light" claim must be accompanied by a declaration of the percent of nutrient reduction, the identity of the reference food, and the absolute amount of calories and, where appropriate, fat in both the labeled food and the reference food. However, a number of comments suggested that for a "light" claim meaning "reduced calorie" or "reduced fat," a disclosure statement, qualifying statement, or other similar statement, such as the definition of the term, should appear on the label in close proximity to the "light" claim. One comment suggested that such a disclosure statement should incorporate the words "low" or "free" when they are appropriate, and that the disclosure should include a prominent comparison of both calories and fat in the food bearing the "light" claim and in the reference food. Some comments proposed that where a "light" claim is made based on fat content alone, a defining statement such as "light in fat" or "light in fat only," should appear on the label, and where a "light" claim is based on calories, a statement such as "light in calories" or "light in calories only" should appear. Several comments suggested that if a "light" product is not designated as "light" on the basis of reduced fat, it should bear a qualifying statement such as "This product is not lower in fat," and that if the product is not designated as "light" on the basis of reduced calorie content, it should bear a qualifying statement such as "This product is not lower in calories." The comments suggested that this clarification is necessary because many people are uncertain as to whether the "light" claim refers to reductions in fat or calories. Another comment proposed that where a "light" claim is made on the basis of fat content, there should be a prominent calorie disclosure which would list the percent reduction of calories compared to the reference food.

The agency advises that although the general principles proposal required accompanying information for the nutrient that has been reduced (i.e., the percent and the amount, compared to the reference food that the calories and, where appropriate, fat have been reduced), the agency did not propose to require this information for the nutrient that had not been reduced. While FDA has determined that declarations of absolute amounts of fat and calories may appropriately be made on the information panel instead of the PDP (see comment 214 of this document), the agency agrees with the comments that the term "light" may be misunderstood unless it is properly clarified. The agency concludes that because it is permitting the unqualified use of "light" when either a minimum percentage reduction in fat or a minimum percentage reduction in calories is met, but not necessarily both, the specific nature of the reduction for each nutrient must be declared. This declaration is necessary to prevent the term "light" from misleading the consumer into believing that the food has been significantly reduced in both calories and fat when it has not. This modification is in accord with suggestions in comments and is consistent with provisions of sections 403(a) and 201(n) of the act (a label is misleading if it fails to bear a material fact). Accordingly, the agency is modifying new § 101.56(b)(3) to require that the percentage that the fat is reduced, and the percentage that calories are reduced, be declared in immediate proximity to a "light" claim in conformance with the requirements of new § 101.13(j)(2), regardless of which nutrient is reduced by at least the minimum amount required in the definition.

However, the agency has determined that if a labeled product has a sufficiently small amount of fat or calories, so that it complies with the definition of "low" for the nutrient (whether normally or by modification), it would not be misleading if the percentage that the nutrient has been reduced is not specified on the label (see § 101.56(b)(3)(iii)). The absence of such information would not be misleading because the product is "low" in the nutrient and thus would be consistent with any expectations that the consumer might have that the product will be useful in achieving a diet consistent with dietary guidelines.

i. Other nutrients

The agency did not propose a definition for "light sodium" (56 FR 60421 at 60451). It stated that use of the term "light" to reflect a sodium reduction in a food would be misleading on products that were not also reduced in calories and, where appropriate, fat because consumers expected these nutrient reductions in association with the term "light." However, the agency tentatively concluded that the term "light" when used on a salt substitute would not be misleading in view of the long marketing history of these products, and because a salt substitute has virtually no calories and would, therefore, not be expected to be reduced in calories or fat. The agency, therefore, proposed that the term "light" could be used on a salt substitute if the product contained 50 percent less sodium than ordinary table salt.

181. Many comments agreed with the proposal that "light" should be defined for use on salt substitutes. They stated that "light" was an appropriate term on such products because they had essentially no calories. However, some comments stated that "light" would be confusing on a salt substitute because consumers associated the term "light" with reduced calories. Others said th "light" should not be permitted on a sait substitute as an unqualified term if the

product cannot meet the definition for "low sodium." A few comments stated that if "light" is defined for salt substitutes, the amount of sodium in the product should be declared. They said that information on the amount of sodium in a salt substitute is very important for persons who must restrict their salt intake.

The agency concludes that, as proposed, "light" is appropriate for use on salt substitutes. Salt substitutes bearing the term have had a long history of use without apparent consumer confusion. As one comment pointed out, the possibility of confusion is minimized because these products have no calories as well as no fat. Also, the agency is not persuaded that such products should be prohibited to bear a "light" claim if they are not "low sodium," i.e., 140 mg per serving, because such a rule would prohibit "light" claims on most, if not all, sodium reduced salt substitutes. Such a product would have to be reduced in sodium by approximately 85 percent to qualify for the claim.

Further, the agency advises that it recognizes that salt substitutes bearing the term "light" are used primarily by persons who are trying to limit their sodium intake, and that the amount of sodium in such a product is important information. The amount of the nutrient, in this case sodium, that is in the labeled product compared to the reference product (table salt) is required to be stated on the information panel. This statement should provide adequate information for consumers about the amount of sodium in the product. Accordingly, FDA is not changing the proposed provisions for "light" claims on salt substitutes.

182. Several comments suggested that the term "light" without qualification should be permitted for use on foods reduced in sodium. The comments suggested definitions of "nutritionally significant reduction in the amount of sodium" and minimum percentage reductions of 25, 33 1/3, or 50 percent. The comments cited a report of a study by the Calorie Control Council, "Americans Find 'Light' to Their Liking" (Ref. 27), in support of their suggestion that the term "light" should be authorized for use on products that are reduced in sodium. According to the comments, the study demonstrates that 71 percent of those surveyed knew that "light" is used to refer to a variety of product qualities such as lower in calories, fat, cholesterol, or sodium or lighter in texture, color, taste, or weight. The comments stated that their experience suggested that consumers perceive "light" to mean reduced in "more than one macronutrient," and that the term was widely used in the market place. One comment said that "light" should be defined for sodium, so that if a company could not comply with the "light" fat or "light" calories requirements, they would not be prohibited from using the term "light."

Other comments disagreed, saying that "light" claims for sodium should not be defined because consumers associate "light" with calorie content. They suggested that any product bearing the term "light" will be perceived as containing fewer calories and not less sodium. One comment cited a recent Canadian study (Tandemar Research, Inc., Consumer Use and Understanding of Nutrition Information of Food Package Labels (Jan. 1992)), in which only 3 percent of those surveyed volunteered that "light" meant "less salt," as support for its claim that "light" should not be defined to describe a reduction in sodium. Another comment related experience in marketing a product that was reduced in sodium as part of a line of "light" products, saying that there had been a number of complaints from consumers who were confused because they expected the product to be reduced in fat, not in sodium, and consequently the company had dropped the product from the "light" product line.

Another group of comments suggested that "light" should be defined for soy sauce and other low calorie foods that are used primarily as salt substitutes. They said that like salt substitutes, these products also contained virtually no calories. They added that even if a "light" claim on one of these products was misinterpreted to mean "reduced in calories or fat," no harm would come to the consumer because these products had an insignificant amount of fat and calories. Therefore, such a product would not be misleading. Yet another comment suggested that foods that are used in place of salt, but that are not calorie free, should be required to meet a calorie/fat based definition for "light."

The agency has carefully considered all of these comments concerning use of the term "light" without qualification to reflect reductions in sodium. As discussed above, the agency remains concerned that the use of the term "light" without qualification on products that are reduced in sodium but not reduced in fat or calories would be misleading to consumers because of consumers' expectations that a product labeled as "light" has been reduced in fat or calories. The agency has already considered the study by the Calorie Control Council (Ref. 27) and acknowledges that "light" has been used to connote a wide variety of meanings, such as reduced sodium and lighter in texture, color, or weight. However, the same study suggests that controlling calories (85 percent of respondents) and fat (83 percent) were two of the major reasons for use of "light" products. In addition, the report of the Calorie Control Council summary used by FDA stated that 69 percent of those surveyed cited "lower in calories" as the first response when asked the meaning of the term "light." Clearly, although consumers do consider that "light" can mean "light" in sodium, they are primarily concerned with fat and calorie reductions in "light" products. Therefore, the agency remains convinced that "light" claims without qualification on products would be misleading if the product did not have significant reductions in fat or calories. Accordingly, the agency is not providing a definitions for "light" for use on all products having only reductions in sodium.

However, on careful consideration of the comments, the agency is persuaded that, like "light" claims on salt substitutes, "light" claims without qualification on sodium reduced products containing only a few calories and little fat (i.e., a "low calorie," "low fat" food) are not misleading to consumers and can assist consumers in maintaining healthy dietary practices. The food meets the expectations of the consumer that the product is useful in achieving a diet consistent with dietary guidelines for calories and fat, albeit because the food was normally low in fat and calories rather than low in fat and calories by modification. Consequently, the agency has determined that if the sodium content of a "low calorie," "low fat" food has been reduced by 50 percent, it may appropriately bear an unqualified "light" claim. This determination is consistent with the suggestions in the comments and the definition proposed for "light" on a salt substitute. Further while other percentage reductions were suggested, no justification for any of those other reductions was provided in the comments. Accordingly, the agency is providing for this use of "light" as a 50 percent reduced sodium claim in § 101.56(c).

183. A few comments suggested that "light" sodium claims would not be misleading if a disclosure statement such as "this product is not lower in fat or calories" or other qualifying information about the nature of the modification was specified adjacent to the term. One comment cited the findings from the Calorie Control Council's study that 67 percent of those

responding believe that "light" is appropriate to differentiate product qualities so long as the term is clearly explained.

The agency has carefully considered these comments. Given the significant traditional association between the term "light" and sodium content, and the dietary guidelines that suggest a reduction in sodium intake (Ref. 7), FDA has concluded that while an unqualified "light" claim for sodium would generally be misleading, it is appropriate to provide for such a claim with respect to sodium content for use on foods that contain more than 40 calories and 3 g of fat per reference amount if the claim is appropriately qualified. The agency has determined that such a claim can be used to highlight a large, that is, a 50 percent or more, reduction in the sodium content of such food. Such a requisite reduction is consistent with the definition of "light" for fat and for sodium on foods that contain less than 40 calories and 3 g of fat per reference amount.

Therefore, to ensure that this additional "light" claim for sodium does not mislead or confuse consumers, FDA has concluded that it is necessary to tightly limit the circumstances in which it may be used. Thus, FDA is requiring in § 101.56(c)(2)(i) that this use of the term "light" must be qualified to distinguish it from the unqualified use of the term that describes reductions in fat or calories. The qualified term that FDA is defining is "light in sodium." Second, to convey to consumers that "light in sodium" is a single term, and to ensure that a misleading impression is not created by manipulations in type size, FDA is requiring in § 101.56(c)(2)(i) that the entire term be presented in uniform type size, style, color, and prominence. Consequently, if a manufacturer wishes to use the term "light" in a brand name to describe a reduction in sodium, the qualifying phrase "in sodium" or the statement "light in sodium" must appear in immediate proximity to the term "light," in uniform type size, style, color, and prominence.

Therefore, in § 101.56(c)(2), FDA is providing for a qualified "light in sodium" claim when there has been at least a 50-percent reduction in sodium content of a food as compared to an appropriate reference food (see § 101.13(j)(1)). In addition, for reasons that are similar to the discussion in comment 179 with respect to light claims for foods that are low in fat or calories, the agency believes that a "light in sodium" claim on a food whose reference food is already "low in sodium" would be misleading. Therefore, in § 101.56(c)(2)(iii) the agency is prohibiting such a claim except for meals and meal-type products (see comment 272).

184. A few comments suggested that "lightly salted" should be permitted, particularly for use on nuts. The comments suggested that the definition should be either one-third less added sodium or 140 mg of sodium per serving ("low sodium"). The comments said that because of a long history of use, consumers were familiar with the term "lightly salted." The comments also stated that "lightly salted" was an easy way for consumers to identify products with less added salt. One comment requested an exemption for "lightly salted nuts," saying that it would be similar to the "sugar free" exemption proposed for chewing gum.

The agency agrees with the comments that "lightly salted" is a claim long used, for example, on nuts, to mean that less salt has been added to the labeled product than to the regular product. In this sense, it is used as a relative claim. As such, "lightly salted" may be an appropriate term to reflect such a salt reduction. However, to be consistent with the other uses of the term "light," the agency has determined that the product must have at least 50 percent less added sodium than the regular brand. In addition, as discussed in comment 75 of this document, the agency has determined that a claim of "no added salt" would be misleading on products that are not sodium free, unless the label has a statement "Not a sodium free food" or "Not for control of sodium in the diet." Consistent with that determination, a comparable disclaimer, i.e., "Not a low sodium food," must be placed on the information panel of "lightly salted" products that are not "low" in sodium. This disclaimer will assist the consumer who may wish to control his or her sodium intake by consuming the labeled product rather than the regular version of the product from being misled into thinking that the labeled product is "low" in sodium when it is not. In addition, because this is a relative claim, the appropriate accompanying information, as specified in § 101.13(j)(2) is required. Accordingly, the agency has provided for "lightly salted" in § 101.56(g).

185. A few comments suggested that "light cholesterol" should be defined. The comments suggested definitions ranging from the criteria for "low cholesterol" to 50 percent less cholesterol. They said that to ensure such a claim was not misleading, the statement, "this product is not lower in fat or calories" could be added to the claim. However, the comments provided no justification as to why the agency should promulgate such a definition other than the finding from the Calorie Control Council Study cited previously that "light" has been used to refer to products lower in cholesterol.

The agency is not convinced by the comments that a "light" claim is appropriate on products that are reduced only in cholesterol. As discussed above in comments 170 and 182 of this document, consumers most associate "light" with reductions in fat, calories, and in certain respects, sodium. There is not the same strong association between "light"and cholesterol content. Although the report on the Calorie Control Council study mentions cholesterol as one of many qualities with which the term "light" has been associated, the report does not provide a basis to distinguish cholesterol from these other qualities as it does with fat, calories, and sodium. Thus, the agency does not consider the mention of cholesterol in the Calorie Control Council report to provide adequate justification for a "light cholesterol" claim. It does not establish a particular association between "light" and cholesterol reduction. Consequently, the agency is not providing a definition for "light" for use on products that are reduced only in cholesterol.

186. A few comments also suggested that "light saturated fat" should be defined. The definitions suggested for this term ranged from "a nutritionally significant reduction in the amount of saturated fat" to 50 percent less saturated fat. There was no justification other than the report of the Calorie Control Council's study.

As with cholesterol, the agency is not convinced that a "light" claim is appropriate on products that are reduced only in saturated fat. In the report of the Calorie Control Council Study used by FDA (Ref. 27), saturated fat is not specifically mentioned as a quality associated with use of the term "light." Consequently, the agency has no basis to determine that consumers perceive "light" to mean reduced in saturated fat. Lacking any other justification, the agency is not persuaded that use of "light" is appropriate on products that are reduced in saturated fat.

187. A few comments suggested that "light sugar" claims should be permitted. One comment stated that a "light sugar" claim should be defined to mean that the food had 25 percent less sugar and at least 5 g less sugar than the appropriate reference food. Other comments stated that "light sugar"

should be defined to mean 50 percent less added sugar. However, none of the comments provided a rationale for why "light sugar" should be defined.

The agency has reviewed these comments and is not convinced that there is sufficient reason to provide a definition for this term. The agency has determined that definitions of "light" for nutrients other than calories, fat, and, on certain products, sodium would be misleading. In addition, although the agency has not defined "less added sugar," the term "less sugar" could be used to communicate changes in the amount of sugar in the food of the sort that could be communicated if the agency adopted the suggested definition for "light sugar." However, lacking an adequate justification for the term "light sugar," the agency is not convinced that such a definition should be established. Accordingly, the agency is not providing for a definition for this term.

ii. Other uses of the term "light"

In the general principles proposal (56 FR 60421 at 60451) the agency proposed that the unqualified use of the term "light" not be permitted on the label or in labeling of a food unless the term was used to describe a reduction in calories and, where appropriate, a reduction in fat (discussed above) or on a salt substitute that contained at least 50 percent less sodium than salt. However, the agency proposed that the term "light" could also be used to describe physical or organoleptic characteristics of a food so long as that attribute adequately qualified the term "light," e.g., "light in color" or "light and fluffy," and was in the same type size, style, color, and prominence as the word "light" and in immediate proximity thereto. The agency also proposed that if the term "light" had been associated through common use with a particular food, such as "light brown sugar," to the extent that the term "light" had become part of the statement of identity, such use of the term would not be considered a nutrient content claim.

188. A majority of those commenting on the subject had no objections to products bearing the term "light" to refer to other physical or organoleptic properties of a product, so long as that property was specified. They said that in these circumstances, consumers are aware of the meaning of the term "light." However, a few comments objected to allowing such "light" claims. One stated that use of the word "light" to describe color, texture, or taste may mislead some consumers and undermine credibility of the term.

The agency acknowledges that the term "light" has at times been used in describing the physical characteristics about a product without appropriate qualifying information. An example of such a claim is "light" used to describe an oil that is "light" in color but is not altered in nutrient quality. This use is clearly misleading. However, the agency is not convinced by the comments that a claim using the word "light" to describe a physical or organoleptic property, if it adequately characterized the nature of the claim, such as "light in color" or "light and fluffy," would be misleading because the word "light" would be defined as part of the claim. In new § 101.56(e)(2), FDA is requiring that product attribute in question (e.g., the color or the fluffiness of the product) be placed in immediate proximity with the term "light." Accordingly, the agency concludes that its regulations provide adequate assurance that this type of claim will not be abused, and therefore, it is adopting the provisions (new § 101.56(e)) that provide for such claims as proposed.

189. Several comments agreed with the proposal that the physical or organoleptic properties of the food that are described in such claims should be identified immediately adjacent to, and in the same type size, style, and color as, the word "light." One comment said that without this requirement, the claim would be misleading, and the same uses of "light" that exist in today's marketplace will be perpetuated, undermining the basic purpose of the 1990 amendments. However, other comments objected to this type size requirement, saying that the attribute information should not be required to be the size of the claim. Suggestions were that the attribute should be in type one-half the size of the word "light," one-half the size of the brand name, one-half the size of the name of the food, or as prominent as the statement of identity. Another comment said that there should be no type size or placement requirements for the defining attribute. Another comment said that the graphics requirement for this information was so unreasonable and burdensome as to constitute a virtual prohibition for use of the term.

The agency has considered these comments and is persuaded that the type size requirements proposed for the information that defines a "light" claim about a physical or organoleptic property of a product would be burdensome, and that this information need not be as large as the claim to effectively clarify the physical or organoleptic properties of the labeled product. However, because of the special nature of the term "light," and the great potential for its misuse, the agency believes that it is essential that this defining information be declared adjacent to the term, and that the word "light" not have undue prominence relative to this information. The agency believes that to severely diminish the size of the defining information, or to remove it spatially from the claim, would affect the ability of the information to clarify what might otherwise be a misleading claim. FDA concludes that by permitting such information to be as small as half the size of the term "light," it will eliminate the burdensomeness of the proposal and yet still insure that the information was sufficiently prominent so as to mitigate any misimpressions caused by the use of this term. Accordingly, the agency is revising § 101.56(e)(2) to permit the defining information to be one-half the type size of the word "light."

190. Of those commenting, a majority agreed that if the term "light" had, through common use, come to be part of the statement of identity (e.g., "light brown sugar"), the term "light" need not be further defined or qualified. However, a few comments disagreed. They said that all such physical or organoleptic uses of the term should be specifically clarified no matter what the history of use of the term was. Another comment stated that this provision should be narrowed in scope so that this unqualified usage of the word "light" would be limited to situations in which the term reflected physical or organoleptic properties of the food, such as color or weight and not nutritional qualities.

The agency advises that the provision in proposed § 101.56(f) was intended to apply only to use of "light" to describe physical and organoleptic properties of the food. It was not intended to permit uses of "light" that are contrary to other parts of the regulation. Accordingly, FDA has modified new § 101.56(f) to clarify the permitted use of the term. Where the word "light" has come to be part of the statement of identity through longstanding use of the term, it is generally used to characterize a product not in comparison to a regular product, but to a contrasting version of the product e.g., "light brown sugar" versus "dark brown sugar." Without use of the term "light" to distinguish the food from its counterpart, there would be confusion as to the specific identity of the product. Therefore, the agency concludes that for such products, the word "light" is fundamental to an understanding of the product's identity. Consequently, in such circumstances, FDA is allowing, under § 101.56(f), the

use of the term "light" without qualification other than the other components of the identity statement.

191. Another comment suggested that because of a 60-year history of use, the term "light," without qualification, should be allowed on a particular brand of fruit cake to differentiate it from the "dark" version of the same brand of fruit cake.

The agency agrees that it would be appropriate in this long standing situation, for the manufacturer to use the word "light" without qualification to differentiate a version of a particular brand of fruit cake that is "light" in color from a version of the same brand of fruit cake that is "dark" in color. However, FDA advises that for this use the term "light" must appear in the statement of identity, e.g., "light fruit cake." In addition, FDA would expect the dark version of the product to be labeled "dark fruit cake," so that the terms "light" and "dark" have the same conspicuousness on the label. The agency believes that such a use is not misleading to consumers because it is clear from the relative use of the terms "light" and "dark" that the word "light" in this instance refers to the color and not to any other properties of the fruit cake.

192. One comment requested that the agency clarify and codify the method for a manufacturer to demonstrate that its use of the term "light" on a product is permissible because the term has come, through long use, to be part of the statement of identity.

The agency believes that the situations in which such a demonstration would be appropriate are sufficiently few that specific provisions are not necessary to implement this procedure. When the use of the term is broadly applicable to a class of products, a petition would be appropriate. There is provision in part 10 (21 CFR part 10) for this type of request. However, the agency does not believe that it is generally necessary to submit a formal petition to address this matter. Except for those regarding brand names, petitions are broadly applicable to a class of products and do not address a single manufacturer's product. If a manufacturer wishes to have advice on whether a product's use of the term "light" in its statement of identity is appropriate, the manufacturer may submit to the agency evidence to substantiate the longstanding, nonmisleading use of the term for this purpose. The agency will review each situation on a case-by-case basis and notify the manufacturer whether the label declaration is appropriate.

193. Another comment asked for advice on whether its brand name "Sunny Delight" was subject to the requirements for "light" nutrient content claims.

The agency advises that the term "Sunny Delight" would not, by itself, constitute a nutrient content claim. The ordinary meaning of the word "delight," as long as it is presented as a single word without any use of printing, hyphenation, or spelling that unduly emphasizes "light," does not state or imply the level of a nutrient. However, FDA also advises that it will evaluate label statements using forms of the word "light" to determine if they are used in a context in which they make claims that a nutrient has been reduced in the food.

iii. Additional terms

194. One comment stated that additional terms such as "extra light" or "ultra light" should be defined. They said that the state of California allows these definitions to describe reductions in milk fat and urged the agency to define "light" with enough flexibility to allow this labeling to continue. The comment said that "extra light" should be defined as a two-thirds fat reduction, and that "ultra light" should have no fat (a 100 percent fat reduction) compared to whole milk.

The comments have not provided sufficient justification for the terms "extra light" or "ultra light." Therefore, the agency is not providing definitions for those terms at this time. The agency is not persuaded that the consumer would understand the differences among "light," "extra light," and "ultra light," especially since definitions for such terms would be available for use on a wide variety of food. In addition, the comment did not present justification for establishing an additional definition for use on foods that appear to qualify for "low fat" and "fat free." The agency advises that, under new § 101.69, the person who submitted the comment, or any other interested party, may submit a petition to the agency, with substantiating information, requesting definition for these terms.

195. A few comments disagreed with the idea of defining "light" and "lite" as synonyms. One comment suggested that sound alike spellings for "light" (e.g., "lite") should be prohibited. Another comment suggested that the term spelled "l-i-t-e" should be used to refer to calorie reductions and the spelling "l-i-g-h-t" should refer to other product qualities.

The agency does not agree that the terms "lite" and "light" should not be synonymous. The agency points out that the statute required that the agency define "'light' or 'lite'" (section 3(b)(2)(A)(iii)(III) of the 1990 amendments). From this instruction, the agency can reasonably conclude that Congress intended that the two spellings of the term be synonymous. Further, under the statute, to not define both of these terms, the agency would need to find that one of them was misleading under section 403(a) of the act. The comment gives the agency no basis to make this finding, nor is one apparent to the agency. In addition, the agency believes that because of similarity of the terms "lite" and "light," the suggested distinct definitions for the two spellings of the term would cause confusion to consumers and would indeed be misleading. Accordingly, the agency is not changing the status of the terms "light" and "lite" as synonyms.

iv. Dietary Supplement Act

FDA proposed to require in § 101.56(a)(3) that if a food bears a "light" claim, it must be nutrition labeled in accordance with §§ 101.9, 101.10, or 101.36, as appropriate. However, as stated above, the Dietary Supplement Act of 1992 established a moratorium on the implementation of the 1990 amendments with respect to dietary supplements. As a result, FDA is not adopting § 101.36 at this time. To reflect this fact, FDA has deleted the reference to § 101.36 from § 101.56(a)(3). FDA has also deleted references to § 101.36 from §§ 101.60(a)(3), 101.61(a)(3), and 101.62(a)(3).

3. "More" claims

Although the 1990 amendments do not require that FDA define the term "more," the agency proposed a definition and requirements (proposed § 101.54(e)) for use of "more" to describe a food in the general principles proposal (56 FR 60421 at 60453).FDA proposed that a comparative claim using the term "more" may be used to describe a food, including a meal-type product, that contains at least 10 percent or more of the RDI for protein, vitamins, or minerals or of the DRV for dietary fiber or potassium than the reference food that it resembles and for which it substitutes (proposed § 101.54(e)(1)(i)).

Further, the agency proposed that when the claim is based on a nutrient that has been added to the food, fortification be in accordance with the policy on fortification of foods in § 104.20 (21 CFR 104.20) (new § 101.54(e)(1)(ii)). Also, the agency proposed to require that the identity of the reference food, the percentage (or

fraction) that the nutrient was increased relative to the RDI or DRV, and quantitative information comparing the level of the nutrient in the product per labeled serving size with that of the reference food that it replaces be declared in immediate proximity to the most prominent such claim (proposed § 101.54(e)(1)(iii)).

Further, the agency proposed to permit a comparative claim using the term "more" on a food to describe the level of complex carbohydrates in a food, including a meal-type product as defined in proposed § 101.13(l), provided that the food contains at least 4 percent or more of the DRV for carbohydrates than the reference food, and that the difference between the two foods is only complex carbohydrates as defined in proposed § 101.9(c)(6)(i). The identity of the reference food and quantitative information comparing the level of complex carbohydrates with the level in the reference food that it replaces would have had to be declared in immediate proximity to the most prominent such claim (proposed § 101.54(e)(2)).

Finally, FDA proposed to permit a comparative claim using the term "more" to describe the level of unsaturated fat in a food, including meal products as defined in proposed § 101.13(l), provided that the food contains at least 4 percent more of the DRV for unsaturated fat than the reference food, the level of total fat is not increased, and the level of trans fatty acids does not exceed 1 percent of the total fat. Under the proposal, the identity of the reference food and quantitative information comparing the level of unsaturated fat with that of the reference food that it replaces would have had to be declared in immediate proximity to the most prominent such claim (proposed § 101.54(e)(3)).

The agency specifically requested comments on certain specific aspects of the proposed definitions of "more" for describing levels of complex carbohydrates and unsaturated fatty acids (56 FR 60421 at 60453 through 60454). First, both of the proposed definitions deviated from FDA's past requirements for superiority claims which, as stated above, have been based on a food having 10 percent more of the U.S. RDA of a nutrient per serving than the food to which it is being compared. Secondly, the provision in the "more" definition for unsaturated fatty acids limiting the level of trans fatty acids to 1 percent of the total fat was included because the agency believed that it would be misleading for products containing significant levels of trans fatty acids to bear claims of more unsaturated fatty acids in light of recent data suggesting that trans fatty acids act like saturated fat in raising serum cholesterol.

196. A few comments were opposed to the proposed definition of "more." The comments argued that claims for "more" should not be permitted because the 10 percent eligibility criterion is too small to be of significance to consumers. One comment suggested that claims of "more" be expressed in 5 percent increments to prohibit food companies from rounding up to make the increased nutrient level appear greater than it actually is. A few comments stated that the definition for "more" should be similar to the definition for "less," and that the food should contain 25 percent "more" of the nutrient than the reference food to be eligible to bear the term "more." A few comments were concerned that a 25 percent eligibility criterion may lead to over fortification of foods in order to be eligible to bear this term.

The agency has not been persuaded to change the definition for "more." As discussed in the general principles proposal (56 FR 60421 at 60453), the agency believes that a 10 percent greater level of a nutrient relative to the RDI or DRV in a serving of a food is nutritionally significant and is also necessary to ensure that there is truly a difference in the foods being compared. This level is the minimum level of a nutrient that must be provided by a food for the food to meet the definition of "good source" in this final rule. Consistent with this requirement, a food must provide at least an additional 10 percent of the DRV or RDI compared to the reference food before it can be designated as a better source, i.e., having "more" of the nutrient.

The nutrition labeling regulations allow for the standard practice of rounding values to the nearest percent when determining levels of nutrients (new § 101.9(c)(8)(iii)). However there is no provision in the final rule that allows for inappropriate rounding up of values when making claims.

Additionally, the values represented by a "more" claim must be truthful and not misleading. The agency considered requiring at least a 25 percent increase relative to the RDI or DRV as compared to the reference food in arriving at the proposed definition for the term "more." As discussed in the general principles proposal (56 FR 60421 at 60453), FDA rejected this approach because of the agency's concern that a level higher than 10 percent of the DRV or RDI would result in inappropriate fortification of foods in an attempt to make superiority claims. Therefore, the agency is retaining the proposed definition of "more" in the final rule.

197. A few comments disagreed with the proposed requirements for use of the term "more" for complex carbohydrates. The comments generally argued that defining "more" for complex carbohydrates but not defining "high" in this regard is inconsistent, and that further scientific evidence about the benefits of consuming complex carbohydrates is needed.

As discussed in the final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**, the agency has determined that it cannot presently define, and, therefore is not defining, "complex carbohydrates." FDA has concluded that there is not sufficient consensus about the meaning of the term or appropriate analytical methodology for a specific definition for "complex carbohydrates." Therefore, the agency is not providing for the term "more" for complex carbohydrates in the final rule.

198. Most of the comments disagreed with the proposed definition for "more" for use with unsaturated fat. Most comments expressed the view that "more unsaturated fat" should not be defined until there is more scientific evidence to support the benefits of the claim. The comments were concerned that allowing the claim at this time will confuse consumers about the benefits of increased consumption of unsaturated fat. One comment suggested eliminating the additional criterion for trans fatty acid in the proposed definition because no conclusive evidence exists that trans fatty acids function like saturated fatty acids. One comment requested that the agency define "more" for monounsaturated fat.

The agency agrees that a definition for "more unsaturated fat" is unnecessary. As discussed in the final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**, the agency has decided not to establish a DRV for "unsaturated fat." FDA has been persuaded by comments that the use of the term "unsaturated fat" is potentially confusing, does not provide useful information, and could result in consumer deception. Therefore, the agency is not defining "more unsaturated fat" or "more monounsaturated fat" in this final rule.

199. A few comments disagreed with the proposed requirement that a food containing added nutrients must be in compliance with the agency's fortification policy to be eligible to bear the term "more" on its label. The comments noted that this policy is only a guideline.

The agency concludes that this requirement is appropriate. As discussed in the general principles proposal (56 FR 60421 at 60453), the fundamental objective of the agency's policy on appropriate fortification of foods is to establish a uniform set of principles that serve as a model for the rational addition of nutrients to foods. While it is true that the fortification policy is only a guideline, in the context of new § 101.54(e)(1)(ii), FDA has subjected the use of § 104.20 (21 CFR 104.20) to notice and comment rulemaking. Interested persons were given notice that FDA intends to use that provision as more than a guideline. Such persons had an opportunity to object to provisions of that regulation and explain why such provisions did not provide an appropriate basis on which to limit the use of "more" on food labels. No comments did. Therefore, the fact that part 104 (21 CFR part 104) is generally intended to be used as a guideline has no significance here.

In that policy, FDA clearly states its concern that random fortification of foods could result in deceptive or misleading claims for foods. In authorizing a claim for "more," the agency is making a finding that the claim will assist consumers in maintaining healthy dietary practices (see section 403(r)(2)(A) of the act). The agency cannot make such a finding for nutrient additions that are not consistent with the fortification policy. Therefore, FDA is retaining the requirement that foods bearing the term "more" comply with the agency's fortification policy.

200. A few comments expressed interest in use of the terms "fortified" and "enriched" as synonyms for "source." The comments were of the view that these terms should be permitted because they are easily understood by consumers as a result of their use in food labeling for many years.

The agency believes that the terms "fortified" and "enriched" are not synonymous with the term "source" but more appropriately may be defined in the same manner as the term "more." "Fortified" and "enriched" convey the meaning that there is "more" or a nutrient in a food compared to another food. This approach is consistent with the agency's fortification policy § 104.20(h)(3), which states that when labeling claims are permitted, the term "enriched," "fortified," "added," or similar terms may be used interchangeably to indicate the addition of one or more vitamins or minerals or protein to a food, unless an applicable Federal regulation requires the use of specific words or statements. Section 403(r)(2)(A)(i) of the act limits the terms that can be used to those provided for by § 101.54(e).

Therefore, the agency is providing, in this final rule, for the use of the terms "fortified," "enriched," and "added" with the same quantitative definition as the term "more" when these terms are used to describe the level of a nutrient that has been added to a food. However, as discussed in greater detail in the section of this document on reference foods, there are circumstances in which the term "more" is appropriately used but "fortified," "enriched," and "added" are not. These circumstances, which are delineated in new § 101.13(j)(1)(i), turn on whether the comparisons are being made to similar (bread to bread) or dissimilar (bread to rolls) foods.

4. Reference foods

a. Reference foods for "reduced" and "less"

201. Many comments suggested that if "reduced" and "less" were defined in the same manner, they should both be permitted to use the same types of reference foods, i.e., a manufacturer's regular brand or a food in a valid data base in addition to an industry-wide norm.

Because the agency has determined that "reduced" and "less" should have the same quantitative definition, the agency believes that it is appropriate for these two terms to be permitted to have many of the same types of reference foods (see new § 101.13(j)(1)(ii)(B)). In many circumstances, these terms can be used interchangeably.

Consequently, the agency has concluded that the manufacturer's regular brand, another manufacturer's regular brand, and a representative value for a broad base of foods of the particular type, are appropriate reference foods for both "reduced" and "less" claims. Accordingly, the agency is providing in new § 101.13(j)(1)(ii)(B) that "reduced" and "less" claims may use as a reference a food or class of foods whose composition is reported in a representative valid data base.

However, as discussed in greater detail in comment 204 of this document, not all reference foods that are appropriate for "less" claims are appropriate for "reduced" claims. Even though these terms are based on the same percent reduction, reductions from a certain class of reference foods, those foods that are different than the labeled food but that would fall in the same product category (e.g., potato chips as a reference food for pretzels) are not appropriately described, simply as a matter of English, by use of the term "reduced." Claims that are designed to draw consumers' attention to such reductions are more appropriately phrased using the term "less." FDA has reflected this fact in new § 101.13(j)(1)(i) and has modified §§ 101.60(b)(4), 101.61(b)(6) and 101.62(b)(4), (c)(4), and (d)(4) accordingly.

In this context, the agency notes that because it has determined that "light" claims should be subject to a more rigorous standard than the other relative claims, it is limiting the reference foods that are appropriate for use with "light" claims. Under new § 101.13(j)(1)(ii)(A), FDA is requiring that the reference for a "light" claim be limited to a representative value for the type of food that bears the claim. This value may be drawn from such sources as a valid data base, an average of the three top national or regional brands, or a market basket norm.

These determinations are explained in more detail in response to the comments that follow.

202. Several comments stated that use of nutrient values from data bases as references for claims should not be limited to the kinds of data bases cited as examples in proposed § 101.13(j)(1)(iii). They suggested that other published or unpublished data bases should be available for use as a basis for claims because established data bases like USDA's Handbook 8 (Ref. 24) are not updated frequently enough to keep up with product innovation. The comments contended that more flexible data bases should be used. In addition, one comment stated that the established data bases are not truly average values because they do not account for variations in preparation of foods. For example, the comment stated, they do not provide the fat content of potato chips cooked in a variety of oils. Some comments requested clarification, including examples of what constitutes a valid data base. One suggested that there is inadequate control over the quality of the data going into a data base.

The agency recognizes the limitations of data bases. Data bases, as they apply to relative claims, are intended to be used to determine representative values for nutrients in a particular type of food for the purpose of determining nutrient differences on which to base a claim. They are not intended to provide all-inclusive nutrient values, such as nutrient values for potato chips cooked in a variety of oils. The agency recognizes that while published data bases, by their nature, are often not up-

to-date, they do provide a reference that is readily available. Further, the agency advises that while USDA's Handbook 8 (Ref. 24) was cited in the proposal as an example of an acceptable data base, it is not the only data base available for use as a reference for relative claims.

On July 23, 1992, the agency published (57 FR 32796) a notice of availability of a draft document entitled "Nutrition Labeling Manual, A Guide for Developing and Using Data Bases." This draft manual has now been subject to review and comment and is being made available in final form with the publication of the regulations. This manual details the parameters that the agency believes to be appropriate for data bases used for nutrition labeling. Because the use of descriptive terms is directly related to these same nutrient values, data derived from data bases, as described in this manual, would be appropriate for use as a basis for relative claims.

203. Some comments said that products that have been improved in order to bear nutrient content claims, especially those meeting the definition of "light," should not be included in data for reference values to be used as the basis for claims. They stated that if nutrient values of improved products were included, some improved products would eventually be disqualified from bearing claims because the data base would change as additional modified products become available.

The agency believes that all improved foods, including those that bear "light" claims, should be considered when deriving appropriate reference foods on which to base claims. To the extent that the claim is based on a reference food that is representative of a particular type of food, for the claim to not be false or misleading, the reference food should fairly reflect the market. Thus, the effect of improved foods on the market must be reflected in the reference food. The agency agrees that this position may well result in a progression of the overall nutrient values of marketed foods in a direction that is consistent with dietary guidelines, but this result is consistent with the 1990 amendments.

204. Some comments specifically supported basing claims on a comparison of dissimilar products within a product category, e.g., potato chips to pretzels. They said that without the ability to make such claims, there would be no incentive for the industry to develop reformulated products. Several other comments suggested that "reduced" claims should not be based on the difference in amount of a nutrient in dissimilar products, such as a potato chip compared to a pretzel, but that such claims should be limited to comparisons between similar products (potato chips to potato chips).

One comment stated that comparisons between dissimilar products could result in consumer confusion and would increase the possibility of misleading claims. The comment said that consumers view a "25 percent less fat" claim as a comparison to another version of the same type of food as the food that bears the claim. It went on to say that unless all products of a particular type (e.g., pretzels) make the same claim, consumers could be misled into thinking that products making the claim are nutritionally superior to those that do not, despite the fact that such claims refer to a different type of food. The comment suggested that if cross-food comparisons are permitted, additional restraints on their use are needed. As an example, the comment asked whether a "reduced sodium" claim could be made for pretzels simply because they contained 25 percent less sodium than potato chips. The comment stated that using the term "reduced" to represent such a comparison could mislead consumers.

The agency has evaluated these comments and is convinced that comparisons using the terms "light" and "reduced" are only appropriate for use in comparing similar foods, e.g., a reformulated version of a manufacturer's product to the original product (potato chips to potato chips). These terms say that there has been a change in the level of a nutrient in a given food and, therefore, are only appropriate to reflect actual changes in the level of a nutrient. Thus, they are not appropriate for use to reflect differences between two dissimilar foods (pretzels to potato chips).

The term "less," on the other hand, can have the same connotation as "reduced" and "light," or it can denote the existence of a difference between two products without implying that there has been a change in nutrient level in the product that bears the term. For example, a "reduced" claim would clearly be misleading under section 403(a) of the act if it were used on the label of a pretzel to describe that the pretzel had 25 percent less fat than potato chips if there had been no change to the pretzel to achieve the difference in the level of the nutrient, and the pretzel bearing the claim was no different than other pretzels. On the other hand, the agency is also convinced that comparisons between products that are dissimilar but within the same product category, and that can generally be substituted for one another in the diet, are useful to point out alternative food choices. This type of comparison can provide the consumer with valuable information useful in making food selections to achieve a diet consistent with dietary guidelines.

The agency does not believe that the consumer will be led to believe that claims comparing dissimilar products are applicable only to the brand bearing the claim because the use of the claim with the reference food, e.g., "25 percent less fat than potato chips," will adequately characterize the claim. Accordingly, the agency in new § 101.13(j)(1)(i)(A) is providing that the term "less" may be used to compare dissimilar foods within a product category, and in new § 101.13(j)(1)(i)(B) is limiting the reference foods for "light" and "reduced" claims to products similar to the product bearing the claim (e.g., potato chips to potato chips).

In addition, the agency points out that the 1990 amendments repeatedly state that claims provided for in this regulation and other regulations promulgated under this statute must not be misleading (e.g., section 403(r)(2)(A)(vi) of the act and section 3(b)(1)(A)(iii) of the 1990 amendments). In these regulations, FDA has attempted to provide clear guidance to manufacturers on how to state claims and on what foods are appropriate as reference foods. However, these provisions do not mandate precise phrasing for each permissible claim. Particularly for use of dissimilar foods as reference foods, the regulation does not specify what "product category" means. The agency has intentionally used a flexible standard. This flexibility is intended to facilitate useful comparisons on foods that are generally interchangeable in the diet (for example, "apples have less fat than potato chips") while prohibiting meaningless or misleading claims. As a consequence, manufacturers will have to use judgment in developing claims to ensure that the claims comply with the regulations and are not misleading under section 403(a) of the act. The agency advises that it will determine on a case-by-case basis whether a claim is misleading because its overall context or presentation is misleading.

205. Several comments stated that in addition to using the nutrient values of a manufacturer's own brand of food as a basis for a "reduced" or "less" claim, similar claims should also be permitted based on comparisons of the product to another manufacturer's brand of the same food. In addition, comments stated that a recognized regional or national brand, with a significant market share,

that is competitive to the product making the claim should also be an appropriate reference food for "reduced" or "less" claims. They said that allowing for brand-to-brand comparisons would provide incentives for development of new products consistent with dietary guidelines.

The agency has evaluated these comments and has determined that use of a competitor's product as a reference food for "reduced" and "less" claims could be appropriate if done in a nonmisleading manner. A competitor's product used for comparison should be an accurate reflection of the products competing with the labeled product. Using a brand of product that is markedly different from the typical foods of the type that includes the labeled food has a great potential to result in a misleading claim. The agency would not, however, consider comparisons between the labeled product and competing products of the type with which the consumer is familiar (e.g., a market leader) to be misleading under section 403(a) of the act unless the competing product is significantly dissimilar in its nutritional attributes.

Accordingly, the agency is providing in new § 101.13(j)(1)(ii)(A) that for relative claims other than "light," another manufacturer's product may be used as a reference food.

206. A few comments suggested that products that had previously been offered for sale but are not currently being sold should be considered appropriate reference foods for products bearing "reduced" and "less" claims. Comments suggested that such a product should be useable as a reference food for up to 6 months or 1 year after being taken off the market.

The agency agrees that it would not be misleading to highlight changes in the formulation of the labeled food, even though the old version of the product is not being marketed. Such claims could be used to point out changes in the level of a nutrient in the new product that would assist consumers in maintaining healthy dietary practices. However, FDA believes that such comparisons to discontinued products should be limited. The agency advises that it would not consider comparisons to such products misleading, provided the labeling for FDA regulated products is attached to that product no more than 6 months after the product has been discontinued from the product line. Any such comparisons after that time would be misleading because of the absence of the old "regular product" for which the new product is a substitute. As the new product replaces the old product, the new product becomes the manufacturer's regular product, thus eliminating the old product as an alternative food choice. Without this alternative choice, the comparison becomes meaningless. In addition, the agency points out that similar time restrictions are appropriate when comparing a labeled product with a competitor's product. In the event that a competitor discontinued a product, the agency believes that claims using that food as a reference would also only be appropriate for 6 months after discontinuation of the product. After that time such claims would no longer be valid because the old product would have become unavailable for consumers either to purchase or to compare.

b. Reference foods for "added," "enriched," and "fortified"

As discussed in comment 200 of this document, the agency is providing for the additional terms "added," "enriched," and "fortified" (referred to collectively for purposes of this discussion as "added"), which will have the same quantitative definition as the term "more."

The agency believes that the difference in meaning between "reduced" and "less," discussed above, also exists between "added" and "more." Comparison of the level of a nutrient between two dissimilar foods using the word "added" is misleading because the term "added" implies that the labeled food is the same as the reference food except for the addition of the nutrient. On the other hand, like "less," the term "more" would not necessarily be misleading in a comparison of two dissimilar foods within a product category that can generally be substituted for one another in the diet. The term "more" states that there is a difference between the two foods but does not imply that difference is a result of modification of the food bearing the term. Accordingly, the agency is reflecting this distinction in new § 101.13(j)(1)(i).

c. Reference foods for "light" products

In the general principles proposal (56 FR 60421 at 60445 through 60446), FDA proposed that an "industry-wide norm" be the only reference for "light" claims. The agency said that because of the special nature of this term, the reference should take into account all foods of a particular product class so as to provide the broadest base and the least opportunity for abuse of the term. The general principles proposal defined an industry-wide norm as "a composite value weighted according to a national market share on a unit or tonnage basis of all the foods of the same type as the food for which the claim is made."

207. A few comments agreed with the concept of an industry-wide norm, saying that maintaining a high standard for the reference for "light" claims would ensure the term's utility, and that such claims would not be misleading. However, an overwhelming majority of the comments that addressed the issue forcefully disagreed with this concept, especially since the industry-wide norm was the only basis proposed for "light" claims. The comments said that the standard of an industry-wide norm was ambiguous and could lead to erroneous comparisons between foods because of the difficulty in deriving such values. Some comments asked who was going to derive the industry-wide norm, while others, recognizing that manufacturers were responsible for label information, said that because of the difficulty in deriving the industry-wide norm, different manufacturers were likely to reach different nutrient values for similar foods. The comments said that the industry-wide norm was: (1) Too complicated to derive because it encompassed 100 percent of the foods of a particular type; (2) excessively restrictive; and (3) prohibitively expensive because of the cost involved in obtaining all the necessary marketing and nutrition information. The comments went on to say that an industry-wide norm is impractical because of frequently changing formulations, variations in products from region to region, and wide variations within certain food types even within a region.

The agency has reviewed the comments and has concluded that requiring use of an industry-wide norm as proposed would be impracticable because of the amount of data needed to include 100 percent of the foods of a particular type, because such data are not always available and because of frequently changing formulations and product variation. In addition, the agency acknowledges that the cost of acquiring such data would be very high. Accordingly, the agency finds that using the proposed industry-wide norm as a reference is unworkable and is deleting the requirement from new § 101 13(j)(1)(i).

However, because an industry-wide norm was proposed as the sole reference for products making "light" claims, as explained in response to the comments that follow, the agency has developed alternative references for "light" foods.

208. Several comments suggested that a manufacturer's own brand or another version of the food from a different manufacturer or competitor should be

an acceptable reference food for a "light" claim. They said that this reference food is appropriate especially when the labeled food was a "light" version of an existing product.

The agency disagrees. As stated in the proposal, FDA believes that for "light" claims, comparisons to a single food in a product class may be misleading, particularly when the reference food differs significantly from the norm for the product class and contains the nutrient at a level that is at the extreme end of the range for the product, e.g., deluxe chocolate chip cookies. Using such a single product as a reference for a "light" claim would result in skewed comparisons in which a product that would normally be considered average for the product type could qualify to make a "light" claim. Clearly such a claim would be misleading to a consumer who, based on it, concludes that the labeled product has 50 percent less fat or one-third fewer calories, than similar foods of the same type.

Because the comments did not provide information to persuade the agency that a provision permitting use of single foods as references for "light" claims will not result in misleading claims, the agency does not consider a manufacturer's own product to be an appropriate reference food for a "light" claim.

209. A few comments stated that the reference for "light" should be based on a market basket norm or a less comprehensive version of the industry-wide norm, e.g., 70 percent of market volume instead of 100 percent of the product.

Although these alternatives are less comprehensive than the 100 percent of the market share based industry-wide norm, they still present problems in their derivation, either because the marketing data collection and nutrient analyses are expensive, especially for small manufacturers, or because they are almost as difficult to derive as the industry-wide norm. Therefore, the agency concludes that such a comprehensive standard is too burdensome to be required as a reference food for products bearing the term "light" and will, therefore, not compel manufacturers to use such a high standard for a reference. However, the agency believes that these composite values would in all likelihood be representative of the market and thus would be an appropriate representative reference for a product bearing the term "light." While the agency is not requiring these specific references, it encourages manufacturers to use them where feasible.

210. Other comments stated that values from a valid data base would be appropriate references for "light" claims.

It is possible that nutrient levels from a data base can provide the appropriate reference against which "light" comparisons could be made. A data base is an appropriate reference if it is representative of the nutrient values for foods that are similar to the food for which the claim is being made and that are currently on the market (see Nutrition Labeling Manual, A Guide for Developing and Using Data Bases). However, the agency cautions that broader, general data bases such as USDA Handbook 8 (Ref. 24) may not be representative of a single food because they may not represent the current market, especially when such data are for a rapidly changing food category such as bakery products or snack foods. Therefore, such data bases should be used with caution.

211. Several comments suggested other types of references for use with "light" claims, such as a leading national brand (e.g., one of the top three brands or a brand with 5 percent or more of the market share), or a top regional brand (for that region only). Comments noted that there needs to be a reference for manufacturers to use who only sell "light" products.

As discussed in comments 209 and 210 of this document, FDA is concerned that when a "light" claim is made, it be based on a reduction in the amount of the nutrient in the product compared to the level of that nutrient in a reference food that is accurately reflective of the foods of that specific type of food on the market. For example, if a "light" claim were made on chocolate ice cream, the agency would expect that reference the nutrient levels would not be derived exclusively or disproportionately from nutrient values from high fat or premium chocolate ice creams. Such a claim would clearly be misleading.

To the extent that values such as those suggested in the comments are representative of the market place, they would be appropriate references for "light" products. The leading national or regional brand also might be an appropriate reference food if the food is firmly and convincingly established as the market leader. However, if there were two market leaders with widely different nutrient profiles, selecting the one with the slightly higher market share for comparison could be misleading.

In summary, the agency has determined that any food or group of foods would be appropriate as a reference for a "light" product if their nutrient levels are convincingly reflective of a broad base of foods of the type that includes the product bearing the claim. Accordingly, the agency is revising new § 101.13(j)(1)(ii)(A) to provide that the reference for a "light" claim must be nutrient values for a food or group of foods whose nutrient values are accurately representative of a broad base of individual foods of the same type as that bearing the claim, e.g., an average value determined from the top three national (or regional) brands of the food, a market basket norm, or from a representative valid data base.

However, when claims are based on reference nutrient values derived from one of a variety of sources, most of which may be unknown or generally unavailable to the average consumer, the agency is concerned that in order for consumers to fully understand such claims, the basis upon which the reference nutrient values are derived be available to consumers on request. Individual reference foods are identified with the claim and thus the reference nutrient value derived from that food would be available by checking its nutrition labeling. In contrast, broad based reference nutrient values derived form average values, market basket norms, data bases, and similar sources are not ordinarily readily available to the public. Therefore, to fully inform consumers, firms that use a broad based reference nutrient value as a basis for a claim must be prepared to make information on how they derived the reference nutrient value available to consumers on request. In addition, the information must also be made available to appropriate regulatory officials on request. This additional requirement will assist regulatory officials in determining compliance with the requirements for appropriate reference nutrient values for products bearing a claim to ensure the claim is not false or misleading. Accordingly, the agency is providing for this requirement in new § 101.13(j)(1)(ii)(A).

5. Accompanying information

In the general principles proposal (56 FR 60421 at 60446), the agency stated that relative claims would be misleading unless they are accompanied by certain material facts that are necessary for consumers to understand the comparisons that are being made. The agency tentatively concluded that the percent and amount of difference of a nutrient in the labeled product compared to the reference food are material facts under sections 403(a) and 201(n) of the act. The agency proposed that this information accompany the relative claim that is in the most

prominent location. The agency also proposed that this information be in type size no less than one-half the size of the claim but no less than one-sixteenth of an inch.

212. A number of comments agreed with the proposed requirement that for a food to bear a relative claim, the product to which the food is being compared must be identified on the label. They said that naming the reference food provides information about the basis on which the claim is made and makes the other required information relevant. In addition, a majority of the comments agreed that the percentage (or fraction) that a nutrient in a product is changed should also be stated. However, a few comments stated that none of this type of information was necessary.

Because the latter comments did not present information to support their assertion, the agency concludes, that consistent with the proposal, the percentage difference of the nutrient compared to a reference food and the identity of the reference food are facts material to the claim under section 201(n) of the act. Without this information the consumer cannot fully evaluate the claim or understand the utility of the food that bears the claim in maintaining healthy dietary practices. Therefore, a claim without declaration of the percentage difference and the identity of the reference food would be misleading under section 403(a) of the act. Accordingly, the agency is retaining this requirement.

213. The comments were less in agreement regarding the necessity of retaining information about the amount of the nutrient in the product compared to the amount in the reference food. Although many comments agreed that this information was useful in assisting a consumer to evaluate the claim and to understand the role of the food in maintaining healthy dietary practices, many felt that the information was not necessary because it could be ascertained from other information on the label, such as the percentage that the nutrient in the labeled food was different from that in the reference food. Others stated that the amount of the nutrient in the labeled food compared to the amount in the reference food was redundant of the information indirectly provided by the minimum difference in the amount of the nutrient that must be achieved for the food to qualify to bear the claim.

The agency has reviewed these comments. FDA finds that a quantitative comparison between the labeled food and the reference food is not a redundant requirement. First, as explained in comments 158 and 179 of this document, the agency is not retaining the requirement of a minimum absolute reduction from the reference food because the agency has concluded that such a requirement is not necessary to ensure the validity of the claim and would only serve to deprive consumers of useful information. Consequently, the amount that the nutrient has been reduced will not be redundant of the definition of the claim. In addition, the amount of the nutrient in a food compared to the reference food is not readily discernable from the other information on the label but would be attainable only by a mathematical calculation using the percentage reduction and the nutrition information. Consequently, the agency concludes that the stated amount of the nutrient in the labeled product compared to the amount in the reference food is necessary for consumers to fully and easily evaluate and understand these claims and for it to be useful to them in maintaining healthy dietary practices. Therefore, the agency is retaining this requirement.

214. Several comments agreed with the proposed requirement that the accompanying information be adjacent to the most prominent claim. However, others disagreed. Some stated that the accompanying information should appear wherever the claim is made. A few comments suggested that it should be permitted to be located next to any claim. Others objected to any specific provisions and recommended that there be a general requirement that accompanying information appear prominently and conspicuously. Still others stated that the information could be placed on the information panel with a notation, for example an asterisk, on the PDP to encourage consumers to turn the package to the information panel for the accompanying information.

A larger number of comments took a different approach and suggested that requiring declaration of the absolute amounts of the nutrient in addition to the identity of the reference food and the percentage difference in the nutrient between the two foods resulted in too much information being required to directly accompany the claim. They stated that this information adds to label clutter on the PDP. Comments said that this provision would make it difficult, if not impossible, to provide information necessary to market the product, especially for multi-language labels. They suggested that all or part of this information, particularly the absolute amount of the nutrient in the product compared to the reference food, should be placed on the information panel. On the other hand, other comments suggested that the amount of the nutrient in the labeled food compared to the reference food was more important than the other accompanying information, and it should be retained on the PDP.

The agency has reviewed these comments and has reconsidered the proposed requirement that all the accompanying information be next to the most prominent claim. FDA evaluated the need for each of the three components of the explanatory information for the consumer to understand the claim at the point of purchase and has concluded that because the relative claim describes a difference in nutrient content between two foods, the identity of each food is essential for the consumer to understand the claim. In addition, a description of the difference in nutrient content between the two foods is needed with the claim because such a description actually defines the relative claim. The agency concludes that the most readily understood description of the difference between two foods is the percentage difference. Therefore, the percentage difference in content of the nutrient appropriately appears with the claim. Accordingly, new § 101.13(j)(2)(i) of the final regulation requires declaration of the identity of the reference food and the percentage difference in content of the nutrient to accompany the most prominent relative claim on the PDP.

However, FDA concludes that the declaration of the absolute amount of the nutrient in each of the two foods provides the type of quantitative information that generally appears on the information panel, and that, therefore, the absolute amount declaration need not directly accompany the claim. In fact, while the absolute amount declaration is a material fact under section 201(n) of the act, FDA finds that it is consistent with the scheme in section 403(r)(2) of the act to place this information on the information panel in conjunction with nutrition labeling. Specifically, if a food that bears a nutrient content claim contains another nutrient in an amount that exceeds the applicable disclosure level, section 403(r)(2)(B)(ii) of the act requires that that nutrient be highlighted in conjunction with the claim, and that the consumer be referred to the information panel for quantitative information about that nutrient. Here, analogously, the comparative percentage differences are to be set forth with the relative claim, and the referral statement will guide the consumer to the information panel for the relevant

quantitative comparison. Accordingly, FDA has revised new § 101.13(j)(2)(iv) to permit declaration of the absolute amount of the nutrient in each food on the information panel. Of course, a manufacturer is free to place this information in direct proximity with the claim.

FDA disagrees with comments that requested that all accompanying information be declared with the claim each time it is stated on the label. In the general principles proposal, the agency tentatively concluded that the consumer will likely read the most prominent claim at the point of purchase, and that if the essential information is declared near that claim, the consumer will receive adequate explanation of the meaning of the claim.

The comments did not explain why this presentation is inadequate. In addition, requiring that accompanying information appear with every claim would add considerably to label clutter. FDA agrees with the many comments that stressed that label clutter should be minimized to the extent possible. The agency concludes that requiring that the information accompany the claim each time it appears would reduce the readability of the label while providing no additional information. Therefore, the agency is not adopting such a requirement.

Finally, FDA concludes that requiring an asterisk on the PDP to guide the consumer to the amount of nutrient information on the information panel is not necessary. The referral statement required to accompany all nutrient content claims (new § 101.13(g)) will be on the label and will direct the consumer to the information panel. Additional referrals to the information panel would be redundant.

215. One comment stated that while the percentage the nutrient differs compared to the reference food and the referral statements were appropriate for single nutrient claims, this same information for multiple claims would clutter the PDP.

The agency recognizes that multiple claims would require more information on the PDP. However, because the absolute amount of the nutrient compared to the reference food will no longer be required to be on the PDP, and because § 101.13(g) requires that there be only a single referral statement when multiple claims are made on the same panel, the label information required to be on that panel is considerably lessened. In addition, although not required, a single reference food will likely be used when multiple claims are made on a particular product. Use of the same reference food will considerably reduce the amount of information on the label. In addition, in light of the changes that the agency is making in this final rule, the percentage that the nutrient has been changed will often be part of the claim, e.g., "25 percent reduced fat cheese cake." Therefore, the agency concludes that no additional changes in declaration requirements are necessary for multiple nutrient claims.

216. Several comments suggested that the percentage declaration that accompanies the claim be in the same type size, style, and color as the rest of the claim. However, many other comments suggested that the proposed type size requirement would make the declaration too large and would leave insufficient label space to effectively convey information about the product. To substantiate this contention, the comments provided mock ups of labels showing how the type size requirements would lead to label clutter. They requested that the type size be reduced.

The agency considered these comments and examined the label examples that were submitted. As a result, the agency has become convinced that the type size requirements for accompanying information may so crowd the PDP that manufacturers may not be able to effectively communicate needed information to the consumer. Therefore, the agency has determined that a different type size requirement is appropriate for this information. Because the accompanying information is adjacent to (although preceding) the referral statement and, like the referral statement, is used to clarify the claim, the agency concludes that the accompanying information should be subject to the same type size and style requirements that it has prescribed for the referral statement. Therefore, the agency in new § 101.13(j)(2)(ii) is cross-referencing the type size requirements in new § 101.13(g)(1) for referral statements. Thus, the accompanying information will be in the type size required by § 101.105(i) for net contents declaration or one-half the size of the claim, as appropriate, but in no case less than one-sixteenth inch.

217. A few comments suggested that the labeling disclaimers for substitute foods that do not have the same performance characteristics as the original food, e.g., "Not for use in cooking," be required on foods that bear "light" claims as well those that bear "reduced" claims.

The agency advises that the requirement for performance characteristic labeling for substitute foods applies to all foods that bear claims that they may be used interchangeably with another food. Therefore, the disclaimer requirement in § 101.13(d) will apply equally to any food in which a nutrient level has been changed and that bears a nutrient content claim including "free," "low," "reduced," "less" (or "fewer"), "light," "more," and "added."

6. Modified

218. Of those commenting on the term "modified," most agreed with the proposed use of the term. However, one comment stated that the term "modified" does not explain whether the nutrient has been reduced or augmented. Another comment suggested that the word "modified" used to compare dissimilar products would be misleading and recommended that foods bearing the term "modified" as part of the statement of identity not be allowed to use a dissimilar food as reference food. It said that a food labeled "modified" should be required to be actually changed as compared to other foods of its type. A few comments said that "modified" should be used only to distinguish chemical changes in a food or to refer to the nutrient character of the food (e.g., "modified fat" or "modified food starch"), not to a change in the amount of a nutrient. A comment suggested that "adjusted" should be used instead of "modified." Another comment suggested that the term "modified" was unattractive for marketing purposes.

The agency points out that the term "modified" is not meant to be used alone, nor was the term meant to be used to describe products that had not been altered. Therefore, as discussed in comment 204 of this document, the term will not be permitted based on a comparison to a dissimilar product.

Additionally, because the word "modified" reflects a change in the food, the reference food used for the "modified" would be one that was appropriate for a "reduced" or "added" claims. For example, a modified fat cheddar cheese would have as its reference a full fat version of cheddar cheese, not some other cheese.

The comment suggesting "adjusted" did not provide any basis to believe that this term is more useful as part of the statement of identity to reflect a change in a food than is the term "modified." In addition, the agency is not persuaded that the term "modified" is an inappropriate term to reflect nutrient changes in a food, or that it should be limited only to uses describing changes in the chemical nature of a food or in the character of the food, such as "modified food starch." Accordingly, the agency is not amending its provision

for the term "modified" and is retaining the criteria as proposed in § 101.13(k).

D. Implied Claims

In the general principles proposal (56 FR 60421 at 60423), FDA proposed to define an implied nutrient content claim as any claim that describes the food or an ingredient therein in such a manner that leads a consumer to assume that a nutrient is absent or present in a certain amount (e.g., "high in oat bran"), or that the food because of its nutrient content, may be useful in achieving a total diet that conforms to current dietary recommendations (e.g., "healthy"). The agency stated that, under the provisions of the statute, such implied claims are prohibited until they are defined by FDA by regulation.

However, the agency recognized that an argument could be made that statements such as "contains oat bran" are not intended to be nutrient content claims but are intended to advise consumers about the nature of certain ingredients. Likewise, the agency said that statements that a particular ingredient constitutes 100 percent of the food, e.g., "100 percent corn oil," should not be considered implied nutrient content claims when such statements are the statement of identity for the food. Moreover, the agency reasoned that claims such as "contains no preservatives" could not be characterized as nutrient content claims because they do not relate to nutrients of the type addressed in nutrition labeling.

The agency requested comments on how to draw an appropriate line between implied nutrient content claims and ingredient and other label claims. The agency did not propose regulations that authorized specific implied claims. However, it solicited comments concerning criteria for evaluating whether implied claims are appropriate and not misleading, as well as information on specific implied claims. The agency said that if it received sufficient information in comments, it would consider providing for specific implied claims in the final regulation. The agency said that, alternatively, it would defer action on implied claims until after the rulemaking required by the 1990 amendments is complete and would then consider individual implied claims through the petition process on a case-by-case basis.

1. General

219. The agency received a wide variety of comments on what should constitute an implied nutrient content claim, and on what steps the agency should take to regulate such claims. Some comments stated that FDA must maintain strict control of claims made on food labels in order to prevent misleading nutrient content claims and subsequent consumer confusion. Another comment stated that the agency should develop a list of acceptable implied nutrient content claims and accept others on a petition basis. Several comments asserted that the proposed regulations are too vague and will not allow manufacturers to determine whether or not an ingredient claim will be considered an implied nutrient content claim by the agency. Some of these comments stated that because of the vagueness of provisions that rely on interpreting consumer perception and the criminal nature of violations of the act, it is incumbent on the agency to define with specificity, and through rulemaking, the standards by which implied claims will be judged. Other comments provided a wide variety of suggestions, discussed in detail below, as to what should constitute an implied nutrient content claim, what should not constitute such a claim, and what, if any, implied nutrient content claims should be provided for in regulations.

Other comments suggested that factual statements, particularly ingredient statements, that constitute implied claims and that are found to be misleading should be regulated under the general misbranding provision of section 403(a) of the act. One of these comments asserted that whether a label statement is an implied nutrient content claim can only be determined on a case-by-case basis in which the context of the entire label is considered. The comment stated that it is highly implausible to identify specific words that will always constitute implied claims. Some comments supported such a case-by-case approach on the grounds that a blanket prohibition of ingredient claims that constitute implied nutrient content claims would prohibit the presentation of truthful labeling statements concerning the content of a food product. Another comment stated that affording manufacturers wide latitude in language would better serve to educate consumers about nutrition and the nutrient content of food, because they would not become bored with and disregard a limited number of repetitive descriptors.

The agency disagrees with those comments that said that implied claims should be prohibited and also with those that suggested that all implied claims should be regulated under section 403(a) instead of 403(r) of the act. The language of the statute and the legislative history make clear that implied nutrient content claims are subject to the nutrient content claims regime. Section 403(r)(1)(A) of the act provides that a food is misbranded if it bears a claim that "expressly or by implication characterizes the level" of a nutrient unless the claim is made in accordance with regulations established by FDA. Section 3(b)(1)(A)(i) of the 1990 amendments instructs the agency to establish regulations that identify claims described in section 403(r)(1)(A) of the act that comply with section 403(r)(2). The legislative history (H. Rept. 101-538, supra 19) includes reference to "high in oat bran" as an example of an implied nutrient content claim. This reference to an ingredient claim as an implied claim subject to section 403(r)(1)(A) of the act clearly demonstrates that Congress intended that at least some statements about ingredients be subject to regulation under section 403(r)(1)(A). Accordingly, FDA concludes that it must attempt to define implied nutrient content claims.

The agency examined the comments carefully in attempting to devise a scheme for determining when a label statement is an implied nutrient content claim. The agency agrees with the comment that stated that in many cases whether a label statement is an implied nutrient content claim can only be evaluated on a case-by-case basis, considering the entire label and the context within which the claim is made. However, FDA also agrees with the comments that the definition in proposed § 101.13(b)(2) is too vague. Accordingly, as discussed below, FDA has modified that definition. Moreover, FDA has identified groups of claims that it concludes can be defined and would not be misleading. The agency is providing in new § 101.65(c) definitions for these claims.

However, because of the large variety of statements that can be considered to be implied claims, because of resource constraints, and because of the strict timeframes under which this rulemaking has been accomplished, FDA is unable to adopt a comprehensive set of implied nutrient content claims. Interested persons may provide information to the agency with which it can develop additional definitions, or they may submit petitions requesting approval of specific definitions or brand names.

2. Statements that are not implied claims

The agency has attempted to define as many groups of implied claims as possible so as to permit as many appropriate, nonmisleading implied nutrient content claims as possible in

this final rule. In addition, FDA examined the comments carefully to identify groups of label statements about ingredients and other attributes of foods that are not implied nutrient content claims. The agency finds that it can distinguish several types of statements that can be excluded from the requirements for nutrient content claims. The agency is describing these claims in new § 101.65(b).

a. Statements that facilitate avoidance

220. Several comments stated that some statements of the absence of a substance or an ingredient provide valuable information to consumers who seek to avoid certain substances. The comments noted that statements such as "100 percent milk free" or "contains no milk or milk fat" serve primarily to assist those buyers who adhere to Kosher dietary laws, or those who suffer from lactose intolerance, and wish to avoid dairy products. Other comments noted that statements such as "contains no MSG" or "contains no wheat flour" provide useful, indeed, sometimes vital, information to consumers who are sensitive to these substances. The comment stated that it was not clear from the proposal whether these ingredient statements would be permitted.

The agency has considered these comments and agrees that such statements are not nutrient content claims. Statements of the absence of an allergen are regulated under § 105.62 (21 CFR 105.62), which provides for labeling of foods for special dietary use by reason of the absence of an allergenic property. Statements that declare the absence of other food components or ingredients that are not nutrients of the type required to be declared in nutrition labeling and that are intended to facilitate avoidance of the substance for such reasons as food intolerance, religious beliefs, or dietary practices (such as vegetarianism), e.g., "100 percent milk free," are also not nutrient content claims. FDA has included new § 101.65(b)(1) in its regulations to recognize this fact. However, the agency cautions that such a statement could be made in such a way as to connote a nutrient content claim. For example, a statement such as "contains no milkfat" made in context with other label information about the benefits of reducing fat intake, implies that the product is "fat free." In such a context, the statement would be a nutrient content claim subject to section 403(r)(1)(A) of the act. Also, for example, claims such as "no tropical oils" or "contains no animal fat" are usually made in a context that implies that the product has little or no saturated fat. Therefore, such claims would not be avoidance claims under the provisions of § 101.65(b)(1) but implied "saturated fat free" claims. Thus, they would have to meet the requirements for such claims.

b. Ingredients that do not serve nutritive purposes

221. Several comments stated that factual statements about ingredients, by their very nature, are not nutrient content claims and should be allowed on food labels (e.g., "no artificial colors" and "contains no preservatives"). One comment suggested that this criterion should also apply to nonnutritive or nutritionally insignificant sweeteners such as saccharin, aspartame, and acesulfame-K and to the brand name Nutra-Sweet. Such claims, the comment said, should be accompanied by "not a reduced calorie food" if appropriate, and the label should provide a statement referring specifically to the caloric and sugar declarations in nutrition labeling.

The agency continues to believe, as it stated in the proposal, that claims about the absence of certain substances that do not function as nutrients, such as preservatives and artificial colors, provide information important to certain consumers but are not nutrient content claims because they are not claims about the level of a nutrient. Consequently, such claims are subject to regulation under section 403(a) of the act, to ensure that they are truthful and not misleading, but not section 403(r). Accordingly, the agency is listing in new § 101.65(b)(2) as a second class of claims that are not nutrient content claims, those that are about substances that do not have a nutritive function and do not substitute for nutritive substances, e.g., "contains no preservatives" or "no artificial colors."

However, FDA does not agree with the comment's suggestion that this policy should also apply to label statements referring to the presence of nonnutritive or nutritionally insignificant sweeteners. In the past the agency has regulated statements like "artificially sweetened" and "sweetened with nonnutritive sweetener" as claims of special dietary usefulness (§ 105.66), which in some contexts imply that the food is "low calorie" or "reduced calorie." Elsewhere in this issue of the **Federal Register**, in a companion final rule on revisions to § 105.66 related to the nutrient content claims regulations in this final rule, FDA has discussed its policy on label statements that refer to the presence of a nutritionally insignificant sweetener in a food. In that document the agency reiterated its position that such claims are subject to either new § 105.66(a) and (b), or (e).

c. Ingredients that provide added value

222. A few comments stated that claims about ingredients that provide added value to products convey important information about the quality of the products and should not be considered implied nutrient content claims. The comments suggested that claims such as "made with butter," "contains buttermilk," "made with whole wheat flour," "contains real fruit," or "made with natural, not processed, cheese" would be examples of added value claims.

The agency agrees that some of these claims would be useful as tools for the manufacturer to communicate to the consumer that the product is of high quality because premium or otherwise preferred ingredients have been used. In most instances, statements such as "made with butter," "made with whole fruit," or "contains honey" would not be considered to be a statement about the product's nutrient content. Accordingly, in new § 101.65(b)(3) the agency is listing claims about the presence of an ingredient that is perceived to add value to the product, such as "made with butter," "made with whole fruit," or "contains honey," as statements that are not nutrient content claims. However, there would be cases, such as "made with whole wheat flour," where the added value statement is made in such a context that it could imply not only that a preferred ingredient was used, but also that the product contained a certain level of a nutrient (e.g., fiber). Such statements would be subject to section 403(r) of the act.

d. Statements of identity

223. Some comments agreed with FDA's discussion in the proposal that factual statements that a particular ingredient constitutes 100 percent of the food (e.g., 100 percent corn oil or 100 percent Columbian coffee) are statements of identity and not implied nutrient content claims. In addition, one comment specifically requested that FDA clarify that the names of dietary supplements (e.g., Vitamin C supplements) will not be considered implied nutrient content claims.

The agency concludes that when an ingredient constitutes essentially 100 percent of the food, so that the name of the ingredient is the statement of identity, the name of the ingredient does not constitute an implied nutrient content claim. In such circumstances, the name of the ingredient constitutes

the common or usual name of the product as described in § 101.5 or the identity of the commodity as described in § 101.3. As such it must provide an adequate description of the food.

When the ingredient is not associated with a nutritional benefit (e.g., Colombian coffee), it is clear that the statement of identity does not imply that a nutrient is present or absent in a certain amount. When the ingredient is associated with a particular nutritional benefit (e.g., corn oil), declaring its presence could imply the presence or absence of a nutrient. However, when used as the statement of identity, the name of the ingredient does not imply that the nutrient is present in a certain amount. Rather, it describes the nature of the product and does not specifically characterize the level of the nutrient. Hence, it would not be considered a nutrient content claim. As for the comment that the names of dietary supplements (e.g., vitamin C supplements) are usually not nutrient content claims, FDA intends to deal with this issue in the rulemaking that it will conduct under the Dietary Supplement Act of 1992.

Accordingly, FDA is providing in new § 101.65(b)(4) that the name of an ingredient is not a nutrient content claim when the ingredient constitutes essentially 100 percent of a food, so that the name of the ingredient is the statement of identity of the food. The agency notes, however, that a statement of identity may include an express nutrient content claim (see e.g., the final rule on requirements for foods named by use of a nutrient content claim and a standardized term, published elsewhere in this issue of the **Federal Register**). Such nutrient content claims are fully subject to new § 101.13 and the regulations in part 101, subpart D.

224. Several comments suggested that common names or statements of identity of foods that include terms that relate directly or indirectly to the nutrient content of a food (e.g., "oat bran muffins") should be considered implied nutrient content claims. Other comments suggested that such statements are merely statements of the characterizing ingredient and should not be considered implied nutrient content claims. They suggested that "oat bran muffin" is not different from "carrot spice muffin." One comment stated that truthful statements such as these should be assumed to be nonmisleading unless there is evidence to the contrary and should be permitted as part of the statement of identity.

While FDA agrees that most statements of identity are statements about the character of a food, there are a limited number of statements of identity that contain the name of an ingredient that is associated with a nutrient or a nutritional benefit and that therefore may also be implied nutrient content claims, depending on what other statements are made on the label or in labeling. Examples of such statements of identity would be "corn oil margarine," "oat bran muffins," and "whole grain bread." The agency will evaluate such claims on a case-by-case basis in the context of the entire label and the labeling to determine whether they are nutrient content claims. For example, if the labeling of oat bran muffins includes a discussion of the importance of fiber in the diet, FDA believes that the "oat bran muffins" name is an implied claim that the muffins are high in fiber. If the labeling is devoid of such information, FDA is not likely to consider the name to be an implied nutrient content claim. Accordingly the agency is providing in new § 101.65(b)(5) that a statement of identity that names as a characterizing ingredient, an ingredient associated with a nutrient (e.g., "corn oil margarine," "oat bran muffins," or "whole wheat bagels") is not an implied nutrient content claim unless such claim is made in a context in which label or labeling statements, symbols, vignettes, or other forms of communication suggest that a nutrient is absent or present in a certain amount.

Statements of identity that are provided by a standard of identity subject to section 403(r)(5)(c) of the act are not subject to definition under section 403(r) of the act and are therefore not considered nutrient content claims.

e. Statements of special dietary usefulness

225. One comment requested that the agency clarify that FDA will not deem a statement of special dietary usefulness made on the label or in labeling of a food in accordance with part 105 of FDA's regulations to be an implied nutrient content claim solely because it represents the food to be for special dietary use.

The agency has considered this comment. As stated in the general principles proposal (56 FR 60421 at 60457), FDA views claims on a food relative to special dietary needs to be different from claims made on a food relative to the nutrient content of the food. The agency would not consider claims made solely to portray the usefulness of the food for supplying a particular dietary need that exists by reason of a physical, physiological, pathological, or other condition as described in part 105 to be a nutrient content claims subject to new § 101.13. A claim such as "use as part of a weight reduction program" in and of itself, would not be considered to be a nutrient content claim.

However, there are circumstances in which a claim that a food is useful in a special diet may be made in a context that portrays a nutritional aspect of the food relative to the general population. If, for example, in addition to including a claim that the food was part of a weight reduction program, the label said that the food was "low calorie," or the label contained other statements of specific nutritional information, then such statement would be subject to the requirements for nutrient content claims because the label contained information directed toward the general population. Accordingly, the agency is providing in new § 101.65(b)(6) that label statements made in compliance with part 105 solely to note that a food has special dietary usefulness relative to a physical, physiological, pathological, or other condition where the claim identifies the special diet of which the food is intended to be a part, is generally not a nutrient content claim.

3. Single nutrient implied claims

a. Ingredient statements

226. Many comments addressed how requirements for implied claims should be applied to ingredient statements like "contains oat bran" and "corn oil margarine." Some stated that ingredient statements should not be considered implied nutrient content claims. Other comments stated that even though there are good reasons for having ingredient statements on labels, the fact that a declaration is an ingredient statement does not preclude the possibility that it is also an implied claim. Some said that claims such as "contains no tropical oils" and "made with 100 percent vegetable oil" would be misleading to consumers who would be led to assume that such a product is low in or free from saturated fat, when that is often not the case. A few comments stated that to prevent ingredient claims from being misleading nutrient content claims, all ingredient statements should be subject to the provisions of section 403(r) of the act.

The agency disagrees both with the comments stating that no ingredient claims should be considered to be implied nutrient content claims, and with those that want all ingredient claims to be regulated under section 403(r) of the act. As discussed above, some ingredient statements clearly are not implied nutrient content claims, and

some clearly are, while other ingredient statements will have to be evaluated on a case-by-case basis to determine whether they are implied claims. The agency will evaluate ingredient statements in the context of the total label to determine whether they are implied claims and therefore subject to section 403(r)(1)(A) of the act. The agency's focus will be on whether the ingredient statement identifies a nutrient explicitly or by implication, and whether it states or implies that the nutrient is absent, or that it is present in a certain amount.

227. One comment disagreed with FDA's definition for single nutrient implied claims in proposed § 101.13(b)(2), stating that the phrase "leads a consumer to assume" should be changed to "consumers acting reasonably under the circumstances." This phrase is preferable, the comment said, because it requires that the label be interpreted reasonably, rather than in an arbitrary, unusual, or unreasonable fashion. The comment asserted that a standard that is based on the interpretations of a few credulous people is not legally sustainable. The comment stated that the phrase "consumers acting reasonably under the circumstances" correctly takes into account the context in which the statement is made.

The agency has considered the comment and disagrees that "consumers acting reasonably under the circumstances" is a more valid standard for implied nutrient content claims than the one proposed by the agency. The focus of FDA's definition of implied claims is on what the claim suggests. The definition is not intended to be a quantitative standard to determine the number of consumers who have a particular conception about an individual claim but is intended to focus on what the claim is saying. To clarify the intent of the definition, FDA is striking the phrase in question and replacing it with the word "suggests."

228. A few comments said that FDA should evaluate, on a case-by case basis, whether a manufacturer intends a particular label statement to make an implied nutrient content claim, and whether consumers perceive the statement to be that claim. The comments asserted that a similar approach has been supported by the courts in determining whether a product is sold as a food or a drug.

In making an evaluation of a label statement within the context of the labeling as a whole, FDA agrees that it should consider both the manufacturer's intent and consumer perception. However, it notes that intent means more than the manufacturer's subjective intent. See *National Nutritional Foods Association* v. *Mathews*, 557 F.2d 325, 334 (2d Cir. 1977). An article's intended use is established by its label, labeling, promotional materials, advertising, and "any other relevant source." Id.

FDA advises that it will evaluate ingredient label statements on a case-by-case basis using the definition of implied claims in new § 101.13(b)(2) and the other provisions of the regulations to determine whether a label statement is an implied nutrient content claim. As stated above, the agency's primary focus will be whether the statement identifies the nutrient explicitly or by implication, and whether it states or implies absence of that nutrient or its presence in a certain amount.

229. Several comments suggested that the agency should consult popular media, scientific articles, and consumer surveys to determine when an ingredient claim constitutes an implied nutrient content claim. Several of these comments suggested that implied claims should not be allowed on food labels unless there is scientific consensus as to what these terms mean. On the other hand, a few comments suggested that a statement about an ingredient is not an implied nutrient content claim, unless there is direct consumer survey evidence that a substantial number of consumers understand the statement to imply a specific nutrient claim. The comment contended that any other position would create chaos because manufacturers would continually be in doubt as to whether an ingredient claim would be interpreted by the agency to be an implied nutrient content claim.

Another comment asserted that claims must be interpreted in their historical context. The comment stated that "high in oat bran," implying "high in fiber," for example, is taken out of context. The comment stated that at the time the claim became widely used, consumers believed that they needed to eat oat bran, not soluble fiber, to lower cholesterol. The comment further stated that consumers wanted to know the amount of oat bran in a product in order to follow a diet high in oat bran. However, current scientific evidence may not substantiate this early finding, and the necessity for consuming large amounts of oat bran may not currently be supported by scientific data. Therefore, for an implied claim to be considered valid, the comments said, current scientific data must be considered.

The agency agrees that nutrient content claims should be defined so as to be meaningful to consumers. It has attempted to ensure through the definitions established in these regulations that permitted claims will assist consumers in maintaining healthy dietary practices. In addition, where possible, FDA has used information on consumer understanding of terms. However, the agency is not persuaded that direct consumer survey information is always needed for it to provide clear guidance to manufacturers on whether an ingredient statement is an implied nutrient content claim. As discussed above, FDA is describing in this document some label statements that clearly are nutrient content claims, and others that clearly are not. For those label statements not addressed in this document, manufacturers who wish guidance can submit a petition requesting approval of a claim. The minimum requirements for information needed to support such a request are described in new § 101.69. Petitioners are welcome to provide consumer survey information as well as other types of information in support of a petition.

230. Some comments asserted that FDA's definition of implied nutrient content claims should be limited to those statements that either expressly or by implication describe the level of a nutrient present in a food, as opposed to simply describing the food's composition. One comment stated that such an approach is consistent with Congressional intent as recorded in the House Report, which states:

> An example of an implied claim covered by this section would be the statement "lite", which implies that the product is low in some nutrient (typically calories or fat), but does not say so expressly, or "high oat bran" which conveys an implied high fiber message.

(H. Rept. 101–538, 101st Cong. 2d sess. (June 13, 1990).)

Another comment asserted that it would be inconsistent with the language of the 1990 amendments to regulate claims about an ingredient that do not characterize the level of that ingredient as implied nutrient content claims. The comment requested that FDA specifically exempt ingredient claims that do not directly or indirectly refer to the level of a nutrient (e.g., "contains oat bran" and "made with vegetable oil").

As already discussed, FDA agrees that statements that describe (expressly or by implication) the level of a nutrient present in a food are nutrient content claims. In addition, for ingredients with nutrient implications (e.g., "bran" implies fiber and "tropical oils" implies saturated fat), a claim that describes the

level as "high," "low," or "free" clearly constitutes a nutrient content claim.

The agency does not agree, however, that claims such as "made with oat bran" and "contains vegetable oil" should be exempt from the regulations. It is not clear to FDA that such claims describe the nature of the food and not the level of a nutrient. The agency notes that it is providing in new § 101.54 that a claim that a food is a "good source" of a nutrient can only be made if the nutrient is present at 10 percent or more of the RDI or the DRV per serving of the food. The agency is also providing for use of the terms "contains" and "provides" as synonyms for "good source." As a result, "contains fiber" is a defined expressed claim that must meet the 10 percent of the DRV criterion.

The question then becomes whether "contains oat bran" and "contains whole wheat" imply that the food is a "good source of fiber." Some comments state that such claims are implied nutrient content claims, while others argue that they are statements about an ingredient and not the level of a nutrient. The agency concludes that, in certain contexts, these statements would be nutrient content claims because they call attention to the fact that the product has been made with an ingredient that contains a valuable nutrient. For example, if a label declared "Joe's Oat Bran Muffins" or "Joe's Muffins, made with oat bran" the prominence of "oat bran" may not call attention to it is a way that proclaims its nutritional value. However, if "Joe's Muffins" bore a bright banner with "oat bran" in large, bright letters, the emphasis on "oat bran" would likely place it in the overall context of a nutrient content claim. However, FDA will evaluate these claims on a case-by-case basis, taking into account the entire label and the labeling, including the placement and prominence of the claim as well as the text of label statements.

231. Some comments asserted that FDA should narrow the definition of nutrient content claims to include only those claims specifically mentioning a nutrient of the type addressed in section 403(q) of the act and of the type appearing as part of the nutrition panel (e.g., fat or cholesterol). Similar comments asserted that any statement regarding an ingredient, as opposed to a nutrient, should not be considered an implied claim. One comment asserted that even those ingredient claims that imply that a nutrient is absent or present in a certain amount are not implied claims. Rather, according to these comments they are more appropriately considered statements of identity or parts of ingredient claims. Some comments specifically disagreed with the House report and FDA that the phrase "high in oat bran" should automatically constitute an implied fiber claim. These comments argued that this claim, as well as others that simply describe the ingredients present in a product in a truthful and nonmisleading manner, should be considered ingredient statements. One comment supported this position by stating that these claims do not automatically lead a consumer to assume that fiber is absent or present in any amount. The comment asserted that such a statement simply advises consumers that oat bran is used as a significant ingredient in the product. The comment went on to say that while oat bran does have some relationship to fiber, consumers will not automatically associate the two. A similar comment requested that FDA alter proposed § 101.13(b)(2) to read, "e.g., high in oat bran, which may imply that a food is also high in fiber."

The agency does not agree that nutrient content claims under section 403(r)(1)(A) of the act are limited to label statements that specifically identify a nutrient, e.g., fat or cholesterol. The legislative history identifies the term "high in oat bran" as an example of an implied nutrient content claim (H. Rept 101–538, 101st Cong. 2d sess. 19 (June 13, 1990)). This statement provides strong evidence that when Congress said that "a claim * * * which expressly or by implication—characterizes the level of a nutrient * * * must be made in accordance with section 403(r)(2)," it intended to include ingredient claims that imply that a nutrient is present at a particular level in, or is absent from, the food. Accordingly, FDA rejects the comment that objected to this interpretation.

The agency advises that there are long established relationships between ingredients and nutrients that are covered under the definition of implied nutrient content claims. Some of these ingredient-nutrient relationships have been regulated as claims for special dietary use. For example, terms like "sugar free" have been regulated by FDA as implying that the product is low or significantly reduced in calories (§ 105.66). In addition, FDA has issued warning letters regarding foods that contain tropical oils (which contain significant levels of saturated fat) when they bear label statements, like "100 percent vegetable oil," that imply that these ingredients have low levels of saturated fat.

Consequently, FDA is not granting the request to exempt from the nutrient content claim requirements ingredient claims that do not explicitly identify a nutrient. However, as discussed in the previous comment, the agency acknowledges that some statements that name ingredients that have nutritional relevance are not nutrient content claims. The agency will evaluate such claims on a case-by-case basis. In addition, where appropriate, manufacturers may submit petitions under new § 101.69 requesting approval of specific claims.

232. A few comments suggested that only those ingredient statements that meet the definition for a defined nutrient content claim should be considered implied nutrient content claims, and that all other ingredient claims should not be considered nutrient content claims. However, several other comments suggested that all ingredient claims that imply that a nutrient is either absent or present at a particular level, whether or not they met the definition of the expressed term, should be considered implied nutrient content claims.

Some of the latter comments said that only those implied claims that meet the requirement for an analogous expressed claim should be permitted on the label or in labeling. For example, several comments said that a statement that a product "contains oat bran" implies that the product is a good source of fiber and should, therefore, only be permitted on foods that meet the definition for "good source of fiber." The comments said that requiring that the expressed claim be met in order to make an implied claim would be effective in preventing manufacturers from using claims on food that may not meet appropriate nutritional standards. Another group of comments stated that any "no [ingredient]" claims (e.g., "contains no tropical oils") that imply that the product is free of a nutrient, but that disparage the absent ingredient, could be misleading if there is inadequate scientific support for health concerns about the ingredient and therefore should be prohibited. The comments presented various other examples to either support or oppose a requirement that an implied ingredient claim that meets the requirements for an explicit nutrient content claim should be permitted.

The agency agrees that ingredient claims that make implied representations about the level of a nutrient in a food, whether or not they meet the definition of the expressed claim, should be considered implied nutrient content claims. This conclusion is consistent with section 403(r)(1)(A) of the act, which states that a food can be misbranded by a statement that

expressly or by implication characterizes the level of a nutrient in a food. An ingredient claim that implies that a nutrient is present in the food at a particular level, but that fails to meet the requirements for the equivalent express claim, will misbrand the food under section 403(r)(1)(A) of the act.

The question of whether claims like "contains no tropical oil" should be prohibited as misleading because they disparage the ingredient will turn on what the scientific evidence shows about the ingredient. If it is commonly known that the ingredient for which absence is claimed is a source of a nutrient for which the current dietary guidelines recommend decreased or moderated intake, then there is no reason for the agency to refuse to permit the claim. The fact that FDA would permit such a claim, however, would in no way represent a disparagement of the ingredient. The claim provides a means by which a manufacturer could highlight the saturated fat content of its food. It does not imply that the ingredient in question is a "bad" food.

233. One comment suggested that FDA allow companies to use expressed or implied nutrient content claims (in brand names or otherwise) that have not been defined or specifically approved by the agency if the claim is not false and misleading and is consistent with, and explained by, an immediately adjacent term that is defined in the agency's regulations. Alternatively, the comment requested that FDA permit ingredient claims that did not meet the expressed nutrient content claims definition but require them to be followed by a factual statement clarifying the nutrient content implication (e.g., "no tropical oils—this product contains 2 g of saturated fat" or "contains oat bran—not a significant source of fiber"). The comment stated that, in effect, companies would be allowed to define certain ingredient claims as implied nutrient content claims. Such a process would be in addition to the petition process established by FDA, thus allowing a company to choose whether to determine its own definition of an expressed or implied nutrient content claim or to petition the agency for a codified definition. The inclusion of a self-definition procedure would, the comment contended, be more in keeping with Executive Order 12630. Also, according to the comment, under such a policy, companies would not be forced to abandon nonmisleading implied claims and brand names, as they would under FDA's proposed rule. Companies would also not be made to change labels repeatedly, or ce by the effective date of the regulations and again after each new implied nutrient content claim is approved. Finally, the comment stated that the rule proposed by FDA would lead to a proliferation of unexplained terms that have been defined by FDA in the regulations but which have little or no meaning to consumers, whereas the procedure suggested in the comment would require the use of a defined term on the label to explain the intended meaning of the implied claim, adding significantly to consumer understanding. The comment asserted that the alternative method is fully consistent with the language and the intent of the 1990 amendments.

The agency does not agree that allowing manufacturers to use undefined claims that do not meet the definition for an expressed claim to be accompanied by a defining statement is consistent with either the intent or the letter of the 1990 amendments. The act provides that claims that characterize the level of a nutrient either expressly or by implication "may be made only if the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary" (section 403(r)(2)(A)(i) of the act). Thus, Executive Order 12630 is not relevant to the approach that FDA is required by statute to take on this matter. To do as the comment requests and allow manufacturers to continue using any label statements they choose (provided they add a defining statement as explanation) would be inconsistent with the letter and spirit of the act. The agency points out that under section 403(r)(4)(A) of the act, any person may petition the agency for permission to use terms that are subject to section 403(r)(2)(A)(i). This section also provides timeframes in which the agency must act on these petitions. Thus, there should not be any undue delay in obtaining a determination as to whether the claims can be used. Because the act specifically provides a mechanism by which use of claims can be authorized, the agency concludes that it would be inappropriate for FDA to establish an alternate mechanism by which such claims can be used.

The agency disagrees that companies would be required to make frequent label changes because of the approval of each new term. The company could decide what term it wants to use, determine whether the use of the term has been authorized, and if it has not been, petition for such authorization. Once the use of a term is authorized, the firm would be free to use it. Any change in the company's labeling made after that point because FDA approved a new term would occur because the company wanted to take advantage of the term, not because FDA compelled a change.

The agency also disagrees that there would be a proliferation of unexplained terms defined by FDA that would have little meaning to consumers. The agency is establishing only a distinct group of terms and synonyms with well defined meanings that may be used as nutrient content claims. Any additional terms that are included in response to a request of a petitioner will have been shown to be as well supported as those terms originally defined.

The agency concludes that the approach to regulating implied nutrient content claims suggested by the comment is not consistent with the structure established by 1990 amendments and will not promote better consumer understanding of label claims. Accordingly, FDA is not permitting use of undefined nutrient content claims accompanied by an explanation.

234. Many comments asserted that factual declarations of the amount of an ingredient (e.g., "160 mg of sodium," or "contains less than 300 calories") do not constitute implied nutrient content claims. Other comments maintained that statements concerning the percent of a nutrient (e.g., "9 percent fat") should also not be considered implied nutrient content claim.

The agency advises that declarations of the amount of a nutrient or the percent of a nutrient are provided for in new § 101.13(i). That provision, pursuant to section 3(b)(1)(A)(iv) of the 1990 amendments, states that such statements must meet the definition for a defined term or must be accompanied by a statement that the food does not meet the appropriate definition. Comments 16 through 19 of this document contain a full discussion of such claims.

235. One comment suggested that "equivalent" be defined as a nutrient content claim so that comparisons could be made to indicate that a food had the amount of a nutrient equivalent to a reference food, e.g., "contains as much fiber as an apple." The comment stated that this type of claim was particularly appropriate for dietary supplements.

The agency advises that it considers the example given in the comment to be an implied claim about the fiber content of the food. "Contains as much dietary fiber as an apple" implies that one apple is a good source of fiber, and that by being equivalent in fiber to an apple, the labeled food is also a good source of fiber. Such a claim can be used to provide valid, valuable information to the consumer about the nature of a

product in terms of another product that the consumer already understands. However, the agency believes that such a statement would be misleading if the labeled food was compared to the level of nutrient in a food that was not consistent with dietary guidelines, namely the amount of nutrient in a food which is "free," "low," a "good source," or "high." Likewise such a claim would be misleading if comparisons between the foods were not made on a common basis. Because a serving of the product is the amount customarily consumed in one eating occasion (a value which is applicable to all foods), the agency concludes that comparisons using this type of claim should be made on a per serving basis.

Accordingly, the agency is providing in new § 101.65(c)(2) for the use of equivalence claims using the phrases "contains the same amount of [nutrient] as a [food]" and "as much [nutrient] as a [food]" to imply that the reference food is a good source of specified nutrient, and that on a per serving basis, the labeled food is an equivalent, good source of that nutrient (e.g., "as much fiber as an apple," "contains the same amount of Vitamin C as a glass of orange juice").

236. Several comments requested that the agency define specific implied claims so that their use would be permitted in labeling. Claims that were suggested included "high in oat bran," "contains no oil," "no tropical oils," and "contains canola oil." While the comments suggested definitions for the claims, they were not always in agreement on what the definitions should be.

The agency has carefully considered these terms and is providing its interpretation of the nutrient content implied by the label statement. Label statements about oils like corn, sunflower, safflower, and canola generally refer to the oils' fatty acid content. Accordingly, FDA considers a statement about a type of oil as an ingredient, such as "made with canola oil" or "contains corn oil," to generally imply that the oil in the product was low in saturated fatty acids. The statement "made only with vegetable oil" implies that because vegetable oil was used instead of animal fat, the oil component was low in saturated fat.

A claim that a product contains "no tropical oils," including a statement about the absence of a specific tropical oil, assumes that the consumer understands that tropical oils have a large amount of saturated fats. Such a claim would imply that another oil had been used that did not have a large amount of saturated fat. Consequently, a claim that a product "contains no tropical oils" would imply that the product is "low in saturated fat."

The agency considers that a statement that a product "contains no oil" implies that the product is not made with lipids (fat). Accordingly, such a claim would imply that the product was "fat free." Such a claim on a product that contained another source of lipids (e.g., animal fat) would be misleading.

Further, the agency considers that a claim that a product is made with or otherwise contains a whole grain, a bran, or any type of dietary fiber (such as soluble fiber), implies that the product is a good source of total dietary fiber. Such a claim would therefore be misleading if the product did not contain sufficient fiber derived largely from the sources of fiber mentioned such that the product met the definition for "good source of dietary fiber." However, a claim naming these ingredients that also used the term "high" or a synonym thereof would be misleading if the product was not "high in dietary fiber."

The agency would generally not consider ingredient claims that are consistent with the meanings that it has outlined above to be misleading under section 403(a) of the act. However, as with any implied claim, the agency will consider the appropriateness of the use of the claim in the context in which it is made.

The agency advises that it does not consider that the terms that it has mentioned provide an all-inclusive list of those ingredients that imply the level of a nutrient. Claims for other nutrients will be considered on a case-by-case basis.

In conclusion, a claim that states or implies a characteristic that distinguishes a particular nutritional attribute of an ingredient will generally be considered an implied nutrient content claim. Whether or not it is a nutrient content claim will depend on the context in which it is presented, taking the entire label into consideration. The level of the ingredient may be implicit or explicit. The agency has described generically in new § 101.65(c)(3) circumstances under which such implied claims can be made. The regulation states that claims may be made that a food contains or is made with an ingredient that is known to contain a particular nutrient, or is prepared in a way that affects the content of a particular nutrient in the food, if the finished food is either low in or a good source of the nutrient that is associated with the ingredient or type of preparation. If a more specific level is claimed (e.g., "high in ————"), that level of the nutrient must be present in the food. For example, a claim that a food contains oat bran is a claim that it is a good source of fiber; that a food is made only with vegetable oil is a claim that it is low in saturated fat; and that a food contains no oil is a claim that it is fat free.

The agency believes that the approach that it is taking in § 101.65(c)(3) strikes an appropriate balance between the interest of industry in making claims and the consumers' interest that claims that appear on the label accurately and fairly characterize the level in the food of the nutrient that, either explicitly or implicitly, is the subject of the claim.

b. Accompanying information

237. One comment suggested that implied nutrient content claims should be accompanied by appropriate referral statements that are consistent with the requirement for such statements to accompany nutrient content claims.

The agency advises that implied nutrient content claims that are defined in new § 101.65 (a)(2), must comply with all of the requirements for nutrient content claims described in new § 101.13. Among the requirements is the requirement for referral statements. In addition, FDA advises that as with other nutrient content claims, labels bearing such implied claims must also bear nutrition labeling in accordance with the requirements of new § 101.9 or, where applicable, new § 101.10. For clarity, the agency is listing the latter requirement in new § 101.65(a)(3).

4. General nutrition claims

In the general principles proposal (56 FR 60421 at 60423) FDA proposed to include in § 101.13(b)(2) a provision that label statements that imply that a product would be useful to consumers in selecting foods that are helpful in achieving a total diet that conforms to current dietary recommendations (e.g., "healthy") are implied nutrient content claims.

a. General comments

238. Many comments asserted that FDA's definition of implied nutrient content claims should not include claims that imply that a "food because of its nutrient content may be useful in achieving a total diet that conforms to current dietary recommendations (e.g., healthy)." Some of these comments stated that Congress showed no interest in regulating such claims but instead was concerned only with regulating those statements that characterize the level of a nutrient present in a food. One such comment noted that neither the act nor the legislative history contains any

language addressing general nutrition claims.

The agency does not agree with these comments. First, the reading of section 403(r)(1)(A) of the act suggested by these comments is clearly too narrow. A claim that a food, because of its nutrient content, may by useful in maintaining healthy dietary practices is clearly a claim that characterizes the level of nutrient in that food. The claim is essentially saying that the level of nutrients in the food is such that the food will contribute to good health.

Moreover, Congress was clearly concerned with such claims. The October 24, 1990, proceedings in the Senate show that one purpose of the 1990 amendments was to regulate the use of nutrient content claims that appear on food labels and labeling in order to help consumers make appropriate dietary choices (136 Congressional Record S16610 (October 24, 1990)). In addition, section 403(r) of the act itself, repeatedly uses the phrase "* * * will assist consumers in maintaining healthy dietary practices" to describe the information for which provision is being made (see e.g., section 403(r)(2)(A)(ii)(II) and (r)(2)(A)(iii)(I) of the act).

The agency is therefore not persuaded that this aspect of the proposed definition of implied nutrient content claims is inconsistent with the language of the act, the intent of Congress, or the goals of the 1990 amendments. However, FDA is modifying § 101.12(b)(2)(ii) to replace the phrase "* * * achieving a total diet that conforms to current dietary recommendations" with the statutory phrase "* * * maintaining healthy dietary practices."

239. Some comments objected to regulating terms such as "nutritious," "healthy," and "wholesome" under section 403(r) of the act because they have different meanings depending on their contextual use and would be difficult to define. These comments asserted that the agency should instead regulate the use of such terms on a case-by-case basis under section 403(a) of the act. The comments asked for assurance that these terms would not be regulated under section 403(r) of the act.

Other comments asserted that terms such as "wholesome," "nutritious," "eating right," "basic 4," "smart," and "good for you" are implied nutrient content claims and should be banned from food labels. A few of these comments suggested that such terms are more appropriately used to describe an overall diet and should not be used on the labels of individual foods. One of these comments cited a poll that was conducted for them in February 1992, in which 1,007 individuals were interviewed concerning their interpretations of the terms "wholesome" and "nutritious." The comment reported that, other than the 55 percent who responded that the term "wholesome" on a food label meant that the product was "good for you," none of the possible responses for the meaning of either term garnered more than 23 percent of the respondents. Some comments, however, suggested that terms such as "wholesome," "nutritious," "eating right," "basic 4," "smart," and "good for you" could be defined as synonyms for "healthy." Some of these comments supported such a definition only as a secondary option to banning the terms, while other comments stated that the terms should be allowed but controlled. One comment stated that if terms such as "healthy" are held to be implied nutrient content claims, then other suggestive words having to do with a product's quality, such as "beneficial" and "hearty," must similarly be defined or banned.

Some comments expressed concern about continued use of such terms in brand names grandfathered under section 403(r)(2)(C) of the act. One of these comments stated that leaving the terms undefined allows companies that used the claims before October 25, 1989, to continue to use them on foods that may not meet appropriate standards. The comment stated that if FDA chooses to define such terms, then the definition must include strict and comprehensive criteria.

One comment stated that the proposed definition for general nutrition claims could have an impact on many proprietary trademarks or slogans such as "Keeping Fit!", "Stay 'n Shape," "Product 19," "Breakfast of Champions," "Eat Right and Look It," and "Right Choice." Although the comment maintained that Congress did not intend these terms to be regulated, it acknowledged that these brand names serve as a beacon to consumers to indicate that there is something nutritionally desirable about the product.

FDA disagrees that terms such as those cited in the comments should be automatically excluded from regulation under section 403(r) of the act. The agency believes that these terms can be implied nutrient content claims when they appear in a nutritional context on a label or in labeling. FDA advises that it will consider these terms to be in a nutritional context when they appear in association with an explicit or implicit claim or statement about a nutrient. For example, in the statement "nutritious, contains 3 g of fiber," "nutritious" is an implied nutrient content claim because it suggests that the food may be useful in maintaining healthy dietary practices. Accordingly, the agency is providing in new § 101.65(d)(1) that such statements are implied nutrient content claims and are subject to the requirements of section 403(r) of the act.

However, the agency also believes that when a term such as "healthy," "wholesome," and "nutritious" appears on a food label in a context that does not render it an implied nutrient content claim, it is not subject to the requirements of section 403(r) of the act. Under such conditions, the use of the term is subject to section 403(a) of the act, and FDA will determine whether it is misleading on a case-by-case basis.

The agency further advises that, except for "healthy," it does not have enough information to decide if definitions for the terms mentioned in these comments are needed, and if so, what those definitions should be. In a tentative final rule published elsewhere in this issue of the **Federal Register**, the agency is providing its tentative position on an appropriate definition for "healthy" based on information received in the comments. In addition, because of the time constraints of this rulemaking, FDA has been unable to develop information with which to make such a decision. The agency solicits information on whether such definitions are appropriate, and if definitions are appropriate, what they should be. Interested persons may submit appropriate petitions under new § 101.69 with accompanying substantiating information to initiate this process.

E. Use of Nutrient Content Claims with Meal-type Products

1. Definition of meal-type products

In the general principles proposal (56 FR 60421 at 60455), FDA proposed a definition for a "meal-type product" for the purpose of regulating nutrient content claims for these products on a different basis than for individual foods. The proposal cited the many comments that the agency received in response to the ANPRM (54 FR 32610), and during the public hearings that followed, that requested that FDA define and allow for the use of nutrient content claims for meal-type products. FDA proposed in § 101.13(l), to define a "meal-type product" as a food that: (1) Makes a significant contribution to the diet either by providing at least 200 calories per serving (container) or by weighing at least 6 ounces per serving (container);

(2) contains ingredients from 2 or more of 4 food groups; and (3) is represented, or is in a form commonly understood to be, a breakfast, lunch, dinner, meal, main dish, entree, or pizza. The four food groups in § 101.13(i) were: (1) Bread, cereal, rice and pasta group; (2) fruits and vegetables group, (3) milk, yogurt, and cheese group; and (4) meat, poultry, fish, dry beans, eggs, and nuts group. The agency recognized that current guidelines for daily food intake specify five food groups, distinguishing between fruits and vegetables. However, FDA proposed to combine the fruits and vegetables groups for regulatory purposes.

FDA requested comments on the appropriateness of this definition of a "meal-type product" as well as on the appropriateness of specific amounts (e.g., 200 calories and 6 ounces) and specific product types (e.g., "main dish") used as a basis for this definition.

The agency received many comments on the need for separate criteria for meal-type products and the definition of meal-type products. After reviewing these comments, the agency continues to believe that separate criteria for meal-type products are needed but is revising the definition of a "meal-type product" to establish separate definitions for meal products and main dish products for the purpose of regulating claims (these products will still be referred to collectively as "meal-type products" in this preamble).

246. The majority of comments supported separate criteria for meal-type products as compared to individual foods. Two comments, however, stated that FDA should not create separate nutrient content claim definitions for these foods because meal-type products contain no more food or calories than ordinary foods. One of these comments also stated that FDA's proposal arbitrarily sets up a double standard for nutrient content claims in the marketplace. Alternatively, these comments recommended that the criteria for claims such as "low," "source," and "high" on all food products be based on specified nutrient levels per serving and per reference amount, or specified nutrient levels per 100 calories (or per 100 nonfat calories in the case of sodium and cholesterol). For example, for "low fat," one comment suggested that the criteria be no more than 3 g of fat per serving and per reference amount, or no more than 20 percent of calories from fat. For "low cholesterol," the comment suggested that the criteria be no more than 20 mg of cholesterol per serving and per reference amount, or no more than 15 mg per 100 nonfat calories. The comments stated that the alternative criteria would allow foods that are high in calories to make "low" claims for certain nutrients.

The agency acknowledges the complexity in defining a meal-type product for the purpose of regulating claims and agrees that, with any such definition, there is the potential for certain requirements that may result in similar food products having different bases for claims. The agency carefully considered the suggestion that it establish a single set of criteria for all types of food products but concluded that it was not appropriate to do so. This approach would generally result in the application of the per 100 calorie criterion rather than the per serving and per reference amount criterion to meal-type products, because the former would permit products to contain greater amounts of nutrients per serving. For example, a 400 calorie product could have as much as 9 g of fat if "low fat" was defined as not more than 20 percent of calories from fat. However, the agency concludes that the primary criterion for all "low" definitions for nutrients should be based on nutrient levels per 100 g as proposed, rather than on specified nutrient levels per 100 calories (or per 100 nonfat calories). The agency concludes that it is inappropriate to have as a primary basis for "low" claim a criterion that considers total fat levels in a food in addition to the levels of another nutrient that is the subject of the claim. For example, given the suggested criterion of no more than 15 mg of cholesterol per 100 nonfat calories, a 400 calorie dinner with 40 percent of the calories contributed by total fat could have only 36 mg of cholesterol, whereas another dinner with the same number of calories but only 20 percent of the calories contributed by total fat could have as much as 48 mg of cholesterol. The agency further believes that it would confuse consumers to have a criterion that links the amount of total fat in a product to the product's ability to make a "low" claim about another nutrient such as cholesterol or sodium. Accordingly, the agency is not persuaded to adopt this alternative set of criteria for meal-type products and individual foods.

However as discussed in comment 52 of this document, the agency has concluded that it is appropriate to have for "low" claims for fat and saturated fat, a second criterion that considers their caloric contribution to a meal-type product.

247. Some industry comments supported the proposed definition of a meal-type product, whereas others stated that the definition was too broad with respect to the minimum requirement of either 200 calories or 6 ounces and with respect to the inclusion of main dishes, entrees, and pizzas in this category.

One comment said that the 200 calorie level is an insufficient amount of food for a "meal-type product," even as part of a reducing diet, and that those who purchase such food could easily be misled that such foods will provide them with a filling, balanced meal. Other comments maintained that 200 calorie food items are meal segments, not meal replacers, for the vast majority of consumers and should not be included in a definition for a "meal-type product." Some comments recommended that a minimum of 500 calories be used. These comments maintained that a 500 calorie minimum would be a more accurate reflection of the calorie content of an individual's meal. They stated that foods that contain this higher calorie level still comprise less than one-third of the calories consumed by the segment of the population that consumes the fewest calories, and that this level would comprise about one-fourth of the typical consumer's daily caloric intake. One comment suggested that 350 calories be the minimum level, while another comment suggested that 300 calories be the minimum requirement.

These comments acknowledged, however, that a minimum calorie requirement, whether at 200 calories or 500 calories, could result in similar products slightly below or above these levels having very different outcomes with respect to claims. For example, it was stated that with FDA's proposal, a 200 calorie serving of soup could qualify for a "low fat" claim with 6 g of fat, whereas a 190 calorie soup that contained only 4 to 5 g of fat could not.

The agency acknowledges that the 200 calorie level is about equal to or less than one-tenth of the National Research Council's recommended energy allowances for adults (Ref. 28). The agency further agrees with the comments that a number of individual foods would meet this minimum caloric level. In addition, the agency has noted that, with this proposed minimum caloric level, it would be possible for meal-type products below the 300 calorie range that met the 3 g per 100-g criterion for "low fat" to contain more than 30 percent of calories from fat. This result would not occur if the agency adopted a higher minimum caloric level, such as 500 calories. However, this higher minimum caloric level would exclude a number of meal products that for some consumers are

appropriate for weight maintenance and for other consumers are appropriate for intended weight reduction.

The agency also considered whether to adopt the suggested levels of 350 or 500 calories. However, as pointed out in the comments, using a 350 or 500 calorie minimum requirement would not eliminate the problem of similar products having different outcomes for claims.

For these reasons, the agency is persuaded that a minimum calorie requirement is not an appropriate basis on which to define meal-type products, and that another product type category that would make the meal-type product category less broad is necessary. Accordingly, the agency has dropped a minimum calorie requirement from the definition of a "meal product" in § 101.13(l) and is not including one in the definition of a "main dish product" in § 101.13(m) (discussed below).

248. A few comments addressed the proposed requirement in the definition of a meal-type product that the food be represented as, or in a form commonly understood to be, a breakfast, lunch, dinner, meal, main dish, entree, or pizza. These comments stated that there needed to be a clear distinction in the regulations of the types of foods that are eligible to bear claims as "meal products." One comment raised the question of whether foods such as a danish, fruit sweetened yogurt, or a bowl of cereal could be a breakfast entree, or whether pasta, beans in tomato sauce, soup, or a baked potato with topping could be a lunch or dinner entree. Another comment suggested that entrees including pizza have a different basis for claims than meal products, and that this basis should be the reference amounts for mixed dishes.

These comments further demonstrate that the proposed category of a meal-type product is too broad for the purpose of regulating claims, and that an additional category needs to be established. The types of products that the agency intended to include in meal-type products, besides meal products, included foods that are often represented as main dish products and, thus, represent only a portion of the complete meal. Based on the comments, however, the agency is persuaded that it would be inappropriate to apply the same criteria to a product that represents a meal and to a product that represents a significant portion of a meal. Thus, the agency is persuaded that separate criteria for claims should be established for meal products and for main dish products. Accordingly, FDA is revising proposed § 101.13(l) to define a "meal product" and is defining a "main dish product" in § 101.13(m). The requirements in these definitions are discussed in comments 249, 251, and 252 of this document.

249. Some comments agreed with the 6-ounce minimum requirement, while other comments stated that this minimum requirement was too low. One of the latter comments stated that this minimum would be met by such products as canned soups, pastas, beverages, and most containers of yogurt, and that even the skimpiest meals or entrees weigh closer to 10 ounces. Another comment suggested that the minimum weight requirement should be at least 7 ounces per serving.

The agency acknowledges that the minimum 6-ounce weight is low for many meal products, even though it is within the range of main dish products that are now marketed. USDA has required that frozen products labeled as "dinner" or "supper" weigh at least 10 ounces (Ref. 29). Thus, FDA concludes that it is appropriate to require that products represented as meals weigh, at a minimum, 10 ounces to be consistent with USDA. Further, FDA believes that products weighing between 6 and 10 ounces which were defined as meal-type products in the proposal, generally are marketed as entrees and side dishes. Thus, the agency finds that because of their contribution to the overall diet and because of consumer expectations, it is appropriate to require that main dishes weigh at least 6 ounces.

Accordingly, for the purpose of making a claim, FDA is defining a "meal product" in § 101.13(l)(1) as a food that makes a major contribution to the total diet by weighing at least 10 ounces per labeled serving. Likewise, for the purpose of making a claim, FDA is defining a "main dish" in § 101.13(m)(1) as a food that makes a major contribution to a complete meal by weighing at least 6 ounces per labeled serving.

Consistent with these provisions, the agency is also revising proposed § 101.13(l)(3) (redesignated as new § 101.13(l)(2)) to provide that to qualify as a "meal product" the food be represented as or be in a form commonly understood to be, a breakfast, lunch, dinner, or meal. The agency is retaining the provision that such representations may be made either by statements, photographs, or vignettes. The agency is aware that some products currently available in the marketplace are represented as meals but weigh somewhat less that 10 ounces. Should these products make nutrient content claims, the agency advises that such claims should comply with the provisions established for main dish products in § 101.13(m)(2). This will ensure the application of appropriate disclosure levels for such products (see comment 273 of this document).

The agency is requiring in new § 101.13(m)(2) that to qualify as a "main dish" the food be represented as, or be in a form commonly understood to be, a main dish (e.g., not a beverage or a dessert). The agency has cited beverages and desserts in this provision because they are not commonly understood to be a main dish and thus are appropriately excluded. However, foods that may be marketed as main dishes in the future are not categorically excluded from being main dishes but will be considered by the agency on a case-by-case basis. 250. A few comments objected to use of the term "container" in the agency's proposed requirement that a meal-type product weigh at least 6 ounces per serving (container). The comments maintained that the term "container" effectively equates meal-type products with single-serving containers, whereas meal-type products are packaged in both single-serve and multiple-serve containers. One comment stated that it makes no sense to have a provision that would allow a product in a single-serve container to make a claim but not an identical product packaged differently.

The agency agrees with the comments that the term "container" may inappropriately equate meal-type products with single-serving containers. This was not the intent of the proposal. Therefore, the agency is deleting the term "container" from new § 101.13(l)(1)(i) and (m)(1)(i).

251. Some comments suggested revisions to FDA's proposed requirement that a meal-type product contain ingredients from two or more of four food groups. Several comments supported a requirement that the product contain at least 3 different foods. A few comments suggested that a specified number of food servings be required rather than ingredients, because, according to one comment, the requirement for two "ingredients," irrespective of their amount, was meaningless. Another comment suggested that a serving be at least one-half the reference amount.

Given the decision to provide separate criteria for meals and main dishes, the agency is persuaded that a meal product should contain at least three different foods from at least two of four food groups and is revising new § 101.13(l)(1)(ii) accordingly. Dietary guidance recommends that Americans assemble daily diets by selecting a variety of foods from the various food groups. Because meals are large

segments of the diet, it is appropriate to expect that meals would include at least three different foods from at least two food groups. Main dishes, on the other hand, are combined with other foods to create a meal and thus may contain as few as two foods from two food groups. Therefore, the agency is requiring in § 101.13(m)(1)(ii) that a main dish product contain at least two different foods from two of four food groups.

The agency also agrees that the requirement for a specified number of foods may be problematic without a minimum weight requirement. FDA considered whether there should be a requirement based on a minimum percentage of a reference amount such as 50 percent. The agency has concluded, however, that such a requirement would be difficult to implement and may not in the end be meaningful. Different reference amounts could be applied to a food in a meal-type product depending on how the food was prepared (e.g., with or without sauce), how it was used in a product (e.g., as a major component or a garnish), or whether the food is subject to a mixed dish reference amount.

Therefore, the agency has developed an alternative approach that derives from the comment that suggested that a serving be at least one-half of the reference amount, the aim of which would be to prevent an ingredient that is present in small amounts from counting toward the requirement that a meal product and a main dish product contain a minimum number of foods from at least two food groups. Thus, FDA has revised new § 101.13(l)(1)(ii) and (m)(1)(ii) to require that a meal product contain not less than 40 g each of the minimum number of different foods.

The 40 g minimum requirement is about one-half of the reference amount for fish, shellfish, or meat/poultry substitutes without sauce (reference amount is 85 g) and is about one-half of the reference amount for drained vegetables (reference amount is 85 g). The 40 g amount is also within the middle range when comparing one-half the reference amount of foods with large reference amounts (e.g., 140 g is the reference amount for pasta) to products with small reference amounts (e.g., 30 g is the reference amount for cheese); that is, 40 g is about midway between 15 g and 70 g. The 40 g amount should not be confused with the reference amounts for individual foods.

252. One comment stated that FDA's proposed requirement that a meal-type product contain ingredients from at least two food groups sets up an artificial distinction between foods. The comment asked, for example, would breaded fish, but not unbreaded fish, be considered as consisting of two food groups?

The agency finds that it is inappropriate to include certain types of foods when determining the number of foods from the four food groups because such foods cannot be considered to contribute a recommended serving of food. These type of foods are gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings, and garnishes. The agency also believes that it is inappropriate to count sauces toward this requirement because of their high water content. However, a food that is in a sauce and that belongs to one of the four food groups can be counted toward the requirement for the particular food group if the food weighs a minimum of 40 g (e.g., 40 g of tomatoes in tomato sauce). The agency believes that a requirement for a minimum amount of a food in a meal or main dish product should be determined by the weight of the food and not by the way in which the food is presented in the product (i.e., an ingredient in a sauce).

Accordingly, the agency is providing for a meal product in § 101.13(l)(1)(ii)(E) and main dish product in § 101.13(m)(1)(ii)(E) that gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings, and garnishes can not be counted as foods to meet the requirement for a specified number of foods from at least two food groups. This provision also excludes sauces except for foods in the four food groups that are in the sauces.

253. One comment suggested that there be separate food groups for fruits and for vegetables. It pointed out that such a separation would be consistent with the food groups recommended in current dietary guidelines.

FDA endorses the five food groups recommended in current dietary guidelines. For this particular regulatory application, however, the agency believes fruits and vegetables should not be treated as separate groups. While the agency acknowledges the important and distinct contributions each makes to the diet, FDA is concerned that a combination of a fruit and a vegetable could be classified as a main dish. The nutritional contribution of each, while not the same, is more similar than any other two food groups. These products would contribute only a limited number of calories and would fail to contribute as diverse a range of nutrients and food components as a combination of two other food groups.

2. Definition of "free" for meal-type products

In the general principles proposal (56 FR 60421 at 60473), FDA proposed definitions of the term "free" to describe the content of sugar and sodium in a food. The agency also proposed in the fat/cholesterol proposal (56 FR 60478) definitions of the term "free" to describe the content of fat and cholesterol in a food. These proposed definitions applied both to individual foods and to meal-type products, and for meal-type products, were based on specified nutrient levels per reference amount and per labeled serving. The rationale proposed for the definition of "free" was based on the finding that this nutrient content claim is an absolute term implying absence of a nutrient. The agency further stated that the definition considered the level of a nutrient that is at the reliable limit of detection and that is dietetically trivial or physiologically inconsequential.

254. One comment supported the use of the same criteria for "free" claims for individual foods and for meal-type products. Another comment suggested that all nutrient content claims for meal-type products should be based on nutrient levels per 100 g of food.

The agency continues to believe, as it stated in the general principles proposal (56 FR 60421 at 60433), that the term "free" is an absolute term implying absence of a nutrient in a serving of a food, whether it is an individual food or a meal-type product, not absence of a nutrient in a specified weight of food such as per 100 g. Therefore, the agency rejects the suggestion that it base "free" claims for meal-type products on nutrient levels per 100 g.

255. One comment stated that the proposed requirement of less than 2 mg per serving in the definition of "cholesterol free" for meal-type products is unreasonable. This comment stated that 2 mg of cholesterol in a 9-ounce serving is less than 0.008 percent, whereas in a small serving product such as crackers, the same amount of cholesterol represents 0.015 percent. This comment suggested raising the cholesterol free level for meal-type products to 5 mg per serving. The comment stated that at the 5 mg level, 60 servings of a meal-type product would be required to be consumed to meet the DRV and thus would result in ample protection for the consumer.

This comment has not convinced the agency to raise the level for "cholesterol free" for meals and main dishes. The agency acknowledges that 2 mg of cholesterol in a meal/main dish product will be a much smaller percentage by

weight than a small serving size product but points out that these percentage differences also occur with individual foods that vary considerably in serving size weight. The agency continues to believe that the same cholesterol level for the definition of "free" should be used for meal-type products as for individual foods, because it is defining "free" as an absolute term implying absence of a nutrient in a serving of food, irrespective of the serving size of the food in question. Accordingly, the agency has retained the proposed cholesterol levels in the final rule, including the disclosure statement allowed for ingredients commonly understood to contain the nutrient in question.

3. Definition of "low" and "very low" for meal-type products

a. Basis for claims

In the general principles proposal, FDA proposed that the definition of "low" and "very low," when describing the content of single nutrients in meal-type products, be based on nutrient levels per 100 g. The proposal stated that this approach would alleviate the need to accommodate the variations in serving size for the various types of meals. The agency proposed that the nutrient levels per 100 g, except for calories, be the same levels for meal-type products as for individual foods. As part of the rationale for proposing specific levels of nutrients for the "low" definition of individual foods (56 FR 60421 at 60440), the agency considered that the "low" definition should be sufficiently restrictive to allow consumers to select a variety of foods, including some that are "low" in a nutrient and some that are not "low," and still meet current dietary recommendations.

256. Many comments supported using amounts of nutrients per 100 g as the basis for regulating "low" and "very low" claims on meal-type products. One of these comments stated that this is the only workable approach because of the wide variety of products and the range in net weights encompassed within meal-type products. However, another comment stated that meal-type foods should have to meet the same criteria (i.e., a per serving rather than per 100 g basis for claims) as single item foods to qualify for nutrient content claim. An additional comment expressed the view that an approach based only on nutrient amounts per 100 g would allow many claims on meal-type products that would be prohibited on individual foods. This comment and two other comments suggested, for example, that FDA consider requiring that a meal-type product obtain no more than a certain percentage of its calories from fat (e.g., 20 percent) in order to qualify for a "low fat" claim. Two other comments supported upper limits for "low calorie" claims, with one comment recommending an upper limit of 300 calories and another recommending an upper limit of 350 calories.

FDA agrees with the majority of comments that support the use of per 100 g as the basis for regulating "low" and "very low" claims on meal-type products. FDA does not agree with the comment that meal-type products should have to meet the same criteria as single foods because meal/main dish products are generally a larger part of the total diet than single foods.

The agency has not been persuaded by these comments that there is a need or an appropriate basis for establishing upper limits for absolute amounts of calories or nutrients per serving when a claim for "low" is made. Rather, the agency believes that providing for the level of the nutrient per 100 g of food is generally sufficient to prevent misleading claims on meal-type products. While FDA has usually assumed that food consumption patterns generally reflect 3 meals per day and a snack (with about 25 percent of daily intake for each), the agency notes that even if a meal-type products weighs as much as 400 g, the absolute amount of a nutrient or calories consumed would be relatively low and thus consistent with the claim. For example, a 400 g meal could contain no more than 12 g of fat, which is only about one-fifth of the DRV.

Moreover, meal size will increase and decrease as a function of the number of servings of individual foods in the meal-type product. Larger persons in need of more calories and greater amounts of nutrients are expected to select a meal comprised of more servings of an individual food or of more servings of different foods (hence a larger meal) than would be expected to be selected by a smaller person. Thus, a basis for determining an absolute amount of a nutrient that would preclude the product from being considered "low" in a particular nutrient is problematic.

However, FDA is persuaded by comments that it is appropriate to require that meal-type products contain no more than a certain percentage of calories from fat. The agency recognizes that it is possible for certain meal-type products to contain no more than 3 g of fat per 100 g of product and still derive more than 30 percent of their calories from fat. FDA is concerned that claims be consistent with dietary guidance. Current recommendations are that 30 percent or less of calories from fat and less than 10 percent of calories from saturated fat. These recommendations are targeted toward the total diet, and the agency has stated in this document several times that they should not be applied to individual foods. However, the agency believes that a meal-type product makes a significant contribution to the diet and, thus, finds that it is appropriate to apply these total diet-oriented recommendations to meal-type products. By their nature, meal-type products are not single foods but combinations of foods intended to contribute a larger amount to the diet than a single food.

FDA has therefore concluded that "low fat" or "low saturated fat" claims on meal-type products that have more than 30 percent of calories from fat or 10 percent or more of calories from saturated fat are misleading to consumers and inconsistent with dietary guidance. Accordingly, the agency is providing in new § 101.62(b)(3)(i) that meal-type products that contain 3 g or less of fat per 100 g and derive 30 percent or fewer of their calories from fat may bear a "low fat" claim. Likewise, the agency is providing in new § 101.62(c)(3)(i) that meal-type products that contain 1 g or less of saturated fat per 100 g and derive less than 10 percent of their calories from saturated fat may bear a "low saturated fat" claim.

b. "Low calorie"

257. In the general principles proposal, FDA requested comments on whether the criterion of 105 calories per 100 g of product for "low calorie" meal-type products was too low. A few comments from industry recommended that the level be raised from 105 calories per 100 g to 120 calories per 100 g. One of these comments was submitted by the organization that had previously suggested the 105 calories that became the level in FDA's proposal. At least one comment suggested that FDA not establish an upper limit for calories in a serving. However, a foreign government suggested an upper limit of 300 calories, and a well-known health organization suggested 350 calories as the upper limit. Another comment maintained that the proposed criterion of 105 calories per 100 g was arbitrary and did not bear any relation to the definition of "low calorie" for individual foods. This comment further maintained that a weight-based criterion was not necessarily relevant, that a "low calorie meal" was a contradiction in terms, and that consumers did not need this provision because of the availability

of comparative claims. An additional comment recommended that the number of calories be disclosed next to the nutrient content claim for meal-type products.

First, FDA disagrees with the comment that the agency should not provide a separate definition for "low calorie" for meal-type products because of the availability of comparative claims. Obesity is a major public health concern and the agency has long acknowledged that the availability and marketing of low calorie food products helps to promote weight control among American consumers. The agency has made provisions for absolute claims (such as "low") as well as comparative claims (such as "reduced") on individual foods, and, given that meal-type products are combinations of individual foods, finds no reason why such claims on meal-type products would not be helpful to consumers.

Secondly, as discussed in response to the previous comment, the agency has established no upper limit for nutrient or calorie levels in meal-type products making nutrient content claims, but instead believes that the amount per 100 g of food provides sufficient control so that claims are not misleading to consumers and are consistent with current dietary recommendations.

The agency acknowledged in its general principles proposal (56 FR 60421 at 60455) that establishing a definition for "low calorie" meal-type products was problematic but accepted the suggestion put forth in a comment that 105 calories per 100 g of food was reasonable and consistent with market practices. FDA specifically asked for comments on this issue. Little support was expressed for this level, while several comments suggested that the level be raised from 105 calories to 120 calories per 100 g.

FDA finds that it is appropriate to increase the definition to this level. The agency notes that 120 calories per 100 g of food is low enough to allow consumers to select different types of meal-type products during the day, including some that are "low" in calories and some that are not "low," and still consume calories at a level consistent with weight control goals. For example, even if a meal product weighs 400 g it would be limited to no more than 480 calories. This calorie amount is less than one-fourth of the average recommended energy allowance for most adult age/sex groups (Ref. 28). Accordingly, FDA is revising new § 101.60(b)(3)(i) to provide that to qualify for a "low calorie" claim, a main dish or a meal product contain 120 calories or less per 100 g.

c. "Low sodium"

258. Several industry comments supported raising the level of sodium that would justify a "low sodium" claim on meal-type products to 200 mg per 100 g. One comment stated that the 140 mg per 100 g level is more appropriate for medically supervised therapeutic diets to manage serious health conditions than for the general population or for many individuals on restricted diets. The comment further stated that the 140 mg per 100 g level would inhibit, if not effectively preclude, the marketing of meal-type products to persons interested in restricting sodium intake. Another comment stated that they knew of no products that would qualify for "low sodium" at the 140 mg per 100 g level, while other comments maintained that products below the 140 mg per 100 g level would have an unacceptable flavor profile. Still another comment stated that for a 10 ounce product, the 200 mg per 100 g level would represent one-fourth of the sodium DRV. The comment further stated that this definition for "low sodium" is reasonable because it provides sufficient room for consumption of other sodium-containing foods during the day while remaining within the DRV. Additional comments stated that current USDA guidelines for low sodium meals require that sodium content be no more than 560 mg for a four component dinner (minimum weight 10 ounces), which is a level to which consumers have grown accustomed.

The agency is not persuaded that the 140 mg of sodium per 100 g level for meal-type products should be raised, or that the level is too restrictive for products marketed to the general population. This level is consistent with the level for individual foods. Further, FDA believes that meal products labeled "low" should be low enough in a nutrient to allow a consumer to eat several such products and still have a significant reduction in total daily intake in the particular nutrient when compared to the DRV for that particular nutrient. The agency notes that with the 140 mg/100 g level, a meal product that weighs as much as 400 g could have no more than 560 mg of sodium. However, with the higher suggested level of 200 mg/100 g, a meal product at this weight could have as much as 800 mg of sodium, which is one-third of the sodium DRV (i.e., 2,400 mg). This level would be too high for a low sodium claim on a meal product, given the assumption of a daily food consumption pattern that includes three meals and a snack (with about 25 percent of daily intake contributed by each).

The agency acknowledges that many products now on the market would not qualify for "low sodium" with the criterion of 140 mg per 100 g but does not believe that currently marketed foods should be the driving force for a "low" definition. Accordingly, FDA has retained the 140 mg per 100 g level in new § 101.61(b)(5)(i).

d. Other sodium claims

259. One comment recommended that in addition to "low sodium," "moderate sodium" be defined as a nutrient content claim on meal-type products for levels of sodium higher than "low." This term was recommended to allow consumers interested in modifying sodium intake a wider choice of products.

The agency believes that the existing nutrient content claims "low sodium" and "very low sodium" are adequate to provide information about sodium content to consumers wishing to limit their sodium intake. The comments did not provide any support for an additional term. The agency believes, for reasons discussed above, that the number of nutrient content claims should be limited. The additional term suggested in the comment is likely to confuse the consumer and possibly reduce the effectiveness of the other nutrient content claims for sodium. Furthermore, consumers interested in modifying their sodium intake will be able to refer to the nutrition label to determine if the product meets their personal dietary needs. Accordingly, the agency is not defining "moderate sodium" for meal-type products.

e. "Low fat"

260. Two industry comments supported defining "low fat" for meal-type products as no more than 3.5 g per 100 g instead of no more than 3 g per 100 g as FDA proposed. One of these comments stated that most meal-type products contain meat or poultry, and in order to use these ingredients, even lean cuts, the fat content will often be greater than 3 g per 100 g because of the meat requirements. The 3.5 g level, it was argued, would provide consumers with a greater number and variety of products available to them.

As it stated in the general principles proposal (56 FR 60421 at 60455), the agency believes that the fat level for meal products and main dish products should be consistent with the level for individual foods. Such consistency will minimize consumer confusion and assist consumers and health professionals in recalling and using

these definitions. The agency acknowledges that a number of meal-type products may not be able to make "low fat" claims. However, the term "lean" will be available to these products. FDA has retained the proposed level of 3 g or less per 100 g for a "low fat" claim in new § 101.62(b)(3)(i).

f. "Low saturated fat"

261. A few comments supported the proposed "low saturated fat" definition of no more than 1 g of saturated fat per 100 g for a meal-type product. Two comments, however, recommended that "low saturated fat" for all food products be defined as no more than 1 g of saturated fat per serving or no more than 7 percent calories from saturated fat.

As discussed in comment 256 of this document, the agency believes that nutrient amounts per 100 g should be the basis for regulating "low" claims on meal-type products. However, as discussed in comment 256 of this document, the agency is establishing an additional criterion in new § 101.62(c)(3)(i) that a meal-type product derive less than 10 percent of its calories from saturated fat in order to bear a "low saturated fat" claim.

g. "Low cholesterol"

262. Two comments recommended that FDA define "low cholesterol" for all meal-type products as no more than 20 mg of cholesterol per serving or no more than 15 mg cholesterol per 100 nonfat calories.

The agency is not persuaded to adopt this alternative criterion because, as previously stated, it believes that it is inappropriate and would confuse consumers to have a primary criterion for a "low" claim that links the amount of total fat in a food to the food's ability to make a "low" claim for another nutrient. However, the agency is including in the "low cholesterol" definition of meal-type products in new § 101.62(d)(3) a criterion that requires that a meal product contain no more than 2 g of saturated fat per 100 g. The agency has established this additional criterion under the authority in the 1990 amendments to establish a saturated fat limit with cholesterol claims. Section 403(r)(2)(A)(vi) of the act states that a nutrient content claim "may not be made if the Secretary by regulation prohibits the claim because the claim is misleading in light of the level of another nutrient in the food." As discussed above in response to comment 116 of this document, the agency believes that a saturated fat level that exceeds 2 g would make a cholesterol claim misleading because consumer expectations would not be met if such a food is not consistent with the recommendations of the health and dietary guidelines to lower blood cholesterol levels by limiting cholesterol and saturated fat intake. Thus, with respect to "low cholesterol" claims on meal-type products, the agency concludes that consumer expectations regarding blood cholesterol levels are met as long as the food contains 20 mg or less of cholesterol and 2 g or less of saturated fat per 100 g.

4. Definition of "percent fat free" for meal-type products

263. A few comments supported the proposed requirement that a meal-type product meet the "low fat" definition to make a "percent fat free" claim, whereas another comment stated that "percent fat free" claims can be particularly deceptive on meal-type products because many of these products, such as frozen dinners, have a high moisture content. The latter comment further stated that because moisture contributes significantly to a product's weight, foods with a high moisture content can make higher (more impressive) "percent fat free" claims than foods with lower moisture levels. The comment pointed out that a label on an 18 ounce frozen dinner containing 15 g of fat could make a "97 percent fat free" claim.

The agency is not persuaded by the latter comment that a "percent fat free" claim on an 18-ounce dinner that meets the "low fat" definition would be deceptive. Regardless of the total weight of the dinner, it still contains 3 g or less fat per 100 g, is a "low fat" meal-type product, and would assist consumers in limiting their fat intake. Thus, the agency finds that a percent fat free claim on meal-type products that meet the "low fat" definition, regardless of the serving size of the product, is not deceptive and can be useful in assisting consumers in meeting their dietary goals.

5. Definition of "high" and "good source"

In the general principles proposal (56 FR 60421 at 60457), FDA proposed that for meal-type products, the nutrient levels for "high" and "good source" be the same percentages of the DRV or RDI as for individual foods, but that the basis for these nutrient levels be per 100 g, not per serving. The agency proposed in § 101.54(b)(2) that "high" be defined as 20 percent or more of the DRV or RDI per 100 g of product, and in § 101.54(c)(2) that "good source" be defined as 10 to 19 percent of the RDI or DRV per 100 g of product.

While one comment supported the use of a per 100 g basis for the definitions of "high" and "good source," a few comments opposed this basis. For the reasons cited below, the latter comments have persuaded the agency to reconsider the basis for "high" and "good source" claims for meal products and for main dish products.

264. One comment recommended that FDA base its definition of "high" and "good source" for all foods including meal-type products on a criterion that considers the nutrient/caloric contribution of a food. This comment proposed that "good source" be defined as at least 10 percent of the DRV or RDI per serving and at least 10 percent of the DRV per 200 calories. Similarly, "high" would be defined as at least 20 percent of the DRV or RDI per serving and at least 20 percent of the DRV or RDI per 200 calories.

The agency rejects this alternative because it could result in plain vegetable products being able to make a claim for "high in vitamin C," but a similar product with these vegetables in a sauce not being able to make this claim. The additional calories contributed by the sauce would cause the product not to meet the minimum DRV level per 200 calories. Such an approach to defining these claims would create inconsistencies in the use of the claims and could cause consumer confusion.

265. Several comments stated that the per 100 g basis would result in inappropriately high nutrient levels for meal-type products eligible to make "high" or "good source" claims. For example, it was stated that to make a "high in fiber" or "high in vitamin C" claim, a 10-ounce frozen dinner would be required to contain over one-half of the DRV or RDI. The comments stated that products that contain a smaller percent of the DRV or RDI still may be considered excellent nutrient sources. Alternatively, one comment recommended that the basis for the definitions of "high" and "good source" for meal-type products be per labeled serving rather than per 100 g of food.

FDA is persuaded, for the reasons given in the comments, that the per 100 g basis would result in inappropriately high nutrient levels for meal-type products. The per 100 g basis would require that a 10-ounce meal-type product have at least 30 percent of the DRV to be labeled a "good source" of a nutrient, or at least 60 percent of the DRV or RDI to be labeled "high" in a nutrient. The agency acknowledges that some meal-type products on the market meet these definitions, but it is

concerned that the proposed levels may encourage increased fortification of these products, with little benefit to the consumer.

Furthermore, the agency is not persuaded to adopt the suggested alternative to define "good source" and "high" using the same percentage levels as individual foods per labeled serving because it would be misleading to state on a label that a three component meal is "high" in a nutrient, when each of the three components may only have 6 percent of the DRV or RDI.

Having considered the alternatives for defining "high" and "good source" claims for meal-type products and finding inadequacies in each, FDA now concludes that such claims should not be defined for meal-type products. FDA is, therefore, not providing definitions for "high" and "good source" claims for meal products and main dish products. The agency concludes that it would not be misleading, however, to state on a label that a specific individual food in a meal-type product is a "good source" of a nutrient or is "high" in a nutrient if that food meets the individual food criteria for these claims.

Accordingly, FDA is revising new § 101.54(b)(2) and (c)(2) to allow "high" and "good source" claims for a food contained in the meal product or main dish product provided that the food meets the individual food criteria for these claims and provided that this food is identified with the use of the nutrient content claim (e.g., "The serving of broccoli in this product is high in vitamin C;" "The serving of sweet potatoes in this product is a good source of dietary fiber").

6. Relative claims for meal-type products

FDA also proposed definitions for "less" and "fewer," "more," "reduced," and "light" for individual foods in the general principles proposal (56 FR 60421 at 60456). With the exception of the terms "reduced" and "light," FDA proposed that the provisions for individual foods apply to meal-type-products.

Some of the comments, as discussed below, have persuaded the agency to change the basis for "less," "fewer," and "more" claims and to provide for "reduced" and "light" claims on meal products and main dish products.

a. "Less," "fewer," and "more"

FDA proposed requirements for "less" and "fewer" claims on meal-type products that were consistent with the requirements for these claims on individual foods. The proposed provisions included a requirement that the product have a minimum percentage and absolute reduction of a nutrient per labeled serving size compared with the reference food that it resembles and for which it substitutes. For "more" claims, the proposed requirements included a provision that the product contain at least 10 percent more of the DRV or RDI for a nutrient per labeled serving than the reference food that it resembles and for which it substitutes.

However, information provided in comments has persuaded the agency to revise the proposed requirements for the percent nutrient reduction and absolute nutrient reduction for the use of the comparative claims "less" and "fewer" on meal-type products. The agency has also revised new § 101.13(j)(1) with regard to reference foods, as previously discussed in this document. This revision applies to meal products and main dish products as well as to individual foods.

266. One comment suggested that the criteria for comparative claims on meal-type products should be based on a percentage difference in a nutrient per 100 g of food compared with per 100 g of the reference food. This comment pointed out that meal-type products include a wide variety of types of foods and a range of serving sizes. It further stated that claims that compare dissimilar products, such as a two component product to a three component product or spaghetti and tomato sauce to macaroni and cheese, would only lead to consumer confusion and misinterpretation of the claim.

The agency agrees that both the meal and main dish categories include products that vary substantially in the number of foods, type of foods, and size of the labeled serving, and that claims that compare dissimilar products on a per labeled serving basis have the potential to confuse consumers. For example, the only difference between two products that may bear a comparative claim under the proposed criteria may be the amount of the food components. The agency has also considered that comparative claims based on FDA's proposed labeled serving size may encourage manufacturer manipulation of serving size to make these comparative claims, given the fact that the labeled serving size for many of these products is the single serve container rather that the reference amount.

Thus, the agency finds merit in the comment's suggestion to base a comparative claim for meal-type products on a per 100-g criterion rather than per labeled serving size. A per 100 g basis reflects the composition of the product based on an absolute amount and not a serving size that can vary from one product to another. Moreover, a per 100-g criterion is likely to not encourage manipulation of serving size because the serving size will have no bearing on whether the food qualifies to bear the claim. Thus, a claim will result in more meaningful comparisons of dissimilar products.

Accordingly, the agency is establishing a per 100 g basis for the use of these comparative terms on meal/main dish products in new §§ 101.54(e)(2)(i), 101.60(b)(5) and (c)(5), 101.61(b)(7), 101.62(b)(5), (c)(5), and (d)(5). Like other relative claims, a statement that identifies the reference food and the percentage change in the nutrient must be declared in immediate proximity to the most prominent claim (e.g., Contains 33 percent less fat per ounce than Brand Y meal product.). Moreover, quantitative information comparing the level of the nutrient that is the subject of the claim in the labeled food to the level of that nutrient in the reference food must be declared either adjacent to the most prominent claim or on the information panel (e.g., Fat content has been reduced from 2.5 g per ounce to 1.7 g per ounce.). In addition, consistent with the use of relative claims on individual foods, meal or main dish products may not bear comparative claims if the level of the nutrient that is the subject of the claim in the reference foods meets the definition for a "low" claim for such nutrient.

267. One comment contended that the agency's published correction (57 FR 8189, March 6, 1992) of the minimum absolute reduction criterion in the definition of "fewer calories" from "more than 40 calories" to "more than 105 calories" must be withdrawn from this rulemaking because it changes the substance of the proposal, and the agency is not permitted to make a substantive proposal in a notice of correction.

The agency disagrees with the comment. In proposing the absolute minimum reduction criterion for making comparative claims, the agency concluded that the amount of nutrient in the food bearing the claim should reflect a nutritionally significant reduction in the amount of that nutrient when compared to the reference food. The agency recognized, however, that no guidelines or definitions were available to determine the amount of reduction in a nutrient that would be nutritionally significant. Thus, the agency tentatively concluded that such a criterion should be based on the amount specified in the definition of "low" for the nutrient in question. The

agency applied this rationale to individual foods as well as to meal type products. The amount specified in the proposed definition of "low calorie" for meal-type products was 105 calories per serving. Thus, it was clear that the intent of the agency was to propose an absolute minimum reduction criterion for comparative claims for decreased levels of calories for meal-type products as "more than 105 calories." Therefore, the notice of correction did not make a substantive change in the proposal but only an editorial change.

b. "Reduced"

FDA proposed not to provide for the use of "reduced" claims on meal-type products because it was of the opinion that there was an insufficient basis on which to establish a reference criterion. In the general principles proposal (56 FR 60421 at 60456), the agency stated that meal-type products may have the same basic ingredient, e.g., fish, but may differ in their preparation and in added ingredients. Consequently, the agency expressed concern that such a provision could result in inappropriate comparisons of dissimilar products.

268. One comment agreed that FDA should not allow "reduced" as a nutrient content claim for meal-type products, whereas a few comments recommended that the term be permitted. One of the latter comments recommended that a single set of criteria for all comparative terms be applied to meal-type products. Thus, the same definitions would be used for "reduced," "less," "fewer," and "light." Another comment was specifically concerned that there was no definition for "reduced fat" and "reduced cholesterol" meal-type products. An additional comment stated that manufacturers should be permitted to make a "reduced" claim for a meal-type product if the recipe has been changed to effect a meaningful reduction in a nutrient from the previous recipe, and that to disallow "reduced" on these products would be a serious disincentive for manufacturers to improve their products' nutritional profiles and a disservice to consumers.

In response to these comments, the agency has reconsidered its proposal to disallow "reduced" claims on meal-type products. In another section of this document, the agency has concluded that comparisons using the term "reduced" are only appropriate for use in comparing similar foods, i.e., a reformulated version of a manufacturer's product to the original product (e.g., a lasagna meal-type product that uses low fat ricotta cheese and lean meat may bear the claim "reduced" when the original product uses regular ricotta cheese and meat, whereas a lasagna with low fat ricotta cheese that substitutes spinach for the meat portion could not bear a "reduced" claim but may bear a "less" claim with respect to the original product). This revised position of the agency is consistent with the comment that recommended that "reduced" be allowed on meal-type products that have been reformulated and addresses the agency's earlier concerns, as stated in the general principles proposal (56 FR 60421 at 60456), that "reduced" not be used to compare dissimilar products. Accordingly, the agency is establishing similar provisions for use of the term "reduced" on meal-type products in new §§ 101.60(b)(5) and (c)(5), 101.61(b)(7), 101.62(b)(5), (c)(5), and (d)(5). In addition, the agency advises that if the manufacturer should discontinue the original product used as the basis for the "reduced" claim, the use of the "reduced" claim is limited to a maximum of 6 months after the original product has been removed from the market. As with other comparative claims such as "less," these provisions will require that the comparisons be based on per 100 g of the product, so that "reduced" claims will not be subject to manipulation by reducing the label serving size (e.g., reduced fat—33 percent less fat than our former recipe. Fat content has been lowered from 1.7 to 1.1 g per ounce).

c. "Light"

FDA did not propose a definition for "light" for meal-type products in its general principles proposal because, similar to "reduced" claims, the agency could not identify appropriate reference foods to permit this use of the claim (56 FR 60421 at 60456). However, the agency tentatively concluded that the term "light" could be useful to consumers in selecting products that contain fewer calories than would be expected in a normal meal and asked for comments on the need for, and definition of, this term on meal-type products. The agency stated that it was considering allowing the term "light" to be used if a meal-type product met the criteria for a "low calorie" claim, provided that the product did not contain more than one-fourth of the DRV for fat, saturated fat, sodium, or cholesterol. The agency noted that the proposed "low calorie" level for a 10-ounce meal product (i.e., 105 calories per 100 g or 300 calories per 10 ounces) was nearly one fourth of the calorie intake in a calorie-restricted diet of 1,200 calories a day. FDA further stated that the requirement that these four nutrients not exceed one-fourth of the DRV would ensure that "light" meal-type products would not contribute amounts of these nutrients that would cause total daily intake to exceed recommended values.

269. One comment agreed with FDA's suggested definition of "light" for meal-type products (i.e., a "low calorie" meal-type product that contained no more than 25 percent of the DRV for fat, saturated fat, cholesterol, and sodium). Several comments, however, offered alternative definitions for the use of the term on meal-type products. A few comments suggested that comparative criteria be used to define "light" for meal-type products. One comment recommended that the definition for "light" for meal-type products be consistent with the definition of "light" for other foods. In addition, this comment stated that meal-type products should meet the per 100-g criterion. Other comments recommended that a "light" claim be permitted on meal-type products if a food product meets the definition for a "low nutrient" product, or if the product achieved a reduction of at least 25 percent of calories. One of these comments stated that there may be some instances when there will be an appropriate reference food to which a comparison could be made.

The agency's general approach in defining nutrient content claims is to try to define terms as consistently as possible for all types of food. Thus, if the agency were to adopt comparative criteria for "light" claims for meal-type products, it would be consistent with the criteria that it has established for use of this term on individual foods. However, the agency believes that in the case of meal-type products, there is only a limited group of appropriate reference foods for use with comparative claims. Meal-type products vary greatly in the number and type of ingredients as well as in labeled serving size, and as one comment stated, meal-type products, other than reformulated meal-type products do not truly "substitute" for a definable reference food as do individual foods. The agency is providing for the use of "reduced" on those meal-type products that are reformulated, and it considered whether the term "light" might also be appropriately used on these products. Limiting the use of "light" on meal-type products to only reformulated products would, however, greatly limit the number of such products that could bear this term. The agency has concluded that because of its widespread appeal and its potential usefulness in denoting foods that can assist consumers in maintaining healthy dietary practices,

the use of this term should not be so limited. Accordingly, the agency has rejected the suggestions to use criteria that compare a product with a reference food in defining "light" for meal-type products.

270. A few comments recommended that the term "light" not be permitted on meal-type products. Two of these comments stated that products meeting the criteria for a low calorie meal would already meet consumer expectations, and therefore a "light" claim is unnecessary. Comments further noted that eliminating unnecessary terms and different criteria for the same term would help reduce consumer confusion.

The agency does not agree with the comments that contended that the use of the term "light" is without value on meal-type products. As explained above in the section on "light" claims for individuals foods, the terms "light" and "light in sodium" in comment 185 are terms that have special usefulness as marketing tools for manufacturers to quickly and easily convey to consumers that the product to which the term is attached has been significantly reduced in fat, calories, or sodium. Furthermore, available data and comments show that products labeled as "light" are particularly useful in achieving a diet that is consistent with dietary guidelines.

Thus, the agency has concluded that provisions for the use of the terms "light" and "light in sodium" on meal products and main dish products that require (as discussed below in comment 272 of this document) that meal-type products bearing such claims meet the definition of "low calorie," "low fat," or "low sodium" will assist consumers in implementing dietary recommendations with respect to limiting caloric, fat, and sodium intake. Further, as reflected in the legislative history (136 Congressional Record 16609 (October 24, 1990)), Congress' intent was to permit the use of the comparative claim "light" for entrees, meals, dinners (i.e., meal-type products). Accordingly, the agency rejects the suggestion to not allow this term on meal-type products.

271. One comment contended that FDA's calorie criterion for "light" (i.e., no more than 105 calories per 100 g) was too restrictive. This comment recommended that "light" be allowed on products that contain no more than 450 to 550 calories (or about one-fifth to one-fourth of a 2,350 calorie diet).

FDA has made a number of changes that have had the effect of making this criterion not as restrictive as this comment contended. The agency has modified the criterion, as discussed above, to 120 calories per 100 g and is basing its dietary calculations on a 2,000 calorie diet, as discussed in the document on RDI's and DRV's, published elsewhere in this issue of the Federal Register. Thus, a "light" claim will be allowed on a 300 g (approximately 10 oz) meal if it contains no more that 360 calories.

272. Some of the comments also addressed what nutrients in addition to calories should be limited for a meal-type product to qualify for a "light" claim. One comment suggested that the term "light" as applied to meal-type products should focus on healthfulness rather than low calorie, while another comment stated that the conceptual basis of "light" should be different from "healthy." The latter comment stated that "light" claims should be allowed on meal-type products that are "low calorie," "low fat," or both, with the relevant expressed claim (e.g., "low in calories) appearing in close proximity to the "light" claim. This comment stated that the term has been widely used to enable consumers to select products that contain less fat or fewer calories than would be expected in a normal meal. However, this comment specifically objected to the proposal's suggestion of not allowing more than 25 percent of the DRV for fat, saturated fat, cholesterol, and sodium for a "light" claim to be made. Other comments agreed that there should be no restrictions on these four nutrients, whereas another comment stated that the restrictions should correspond to one-eighth of the DRV, rather than one-fourth, because the maximum permitted level of about 300 calories for a 10 ounce product would correspond to one-eighth of the reference caloric intake of 2,350 calories.

FDA has reconsidered what nutrients should be limited in a meal-type product for it to be permitted to bear a "light" claim. FDA is persuaded by the comment that an unqualified "light" claim on meal/main dish products may appropriately refer to fat, calories, or both. However, as discussed in comment 269, the agency has determined that for meal-type products, "light" should not be limited to reductions in the level of nutrients in existing foods. Rather, the agency is persuaded by the comments that the term should denote those meal-type products in which the level of the nutrients are particularly useful in constructing a diet that is consistent with dietary guidelines, that is, the term should be permitted on foods that are "low in calories," "low in fat," or both. The agency notes that a provision for "light" to refer either to calories or to fat is consistent with the definition of "light" for individual foods that have less than 50 percent of calories from fat. It is also consistent with consumer understanding of this term. FDA is also persuaded, however, that a statement that explains whether "light" is used to mean "low in fat," "low in calories," or both should appear on the principal display panel to clarify the nature of the claim for consumers who may be interested in limiting only calories, only fat, or both (§ 101.56(d)(2)(i)). Furthermore, to ensure that this explanatory statement is sufficiently prominent relative to the "light" claim, FDA concludes that it should be in no less than one-half the type size of the "light" claim (new § 101.56(d)(2)(ii)). This requirement is also consistent with the final rule on "light" claims on individual foods that requires that qualifying statements of sufficient type size must accompany the claim.

Accordingly, FDA is defining "light" for meal products and main dish products in new § 101.56(d). To meet this definition, a meal product or main dish product must meet the definition of "low" for calories, fat, or both (new § 101.56(d)(1)). Further, the agency believes that for consistency with individual foods, it should provide for use of the additional claim "light in sodium" on meal-type products. As with individual foods, the agency has determined that the words "light in sodium" or "lite in sodium" is a single descriptive term, presented in the manner described above, that should all be presented in the same type size, style, color, and prominence. Further, the agency believes that such a "light in sodium" claim for meal-type products should be based on the same criteria as the "light" claim for other nutrients for meal-type products, i.e., it should be based on the "low" definition for the specified nutrient. Accordingly, the agency is defining "light in sodium" for meal-type products in new § 10.56(d)(2). To qualify to make this claim, a meal product or a main dish product must meet the definition of "low" for sodium (new § 101.61(b)(5)(i)). However, because the nutrient that is the subject of the claim is identified as part of the claim i.e., the defined term is "light in sodium," the agency believes that the additional defining label statement (i.e., "low in sodium") that is required with other "light" claims on meal-type products would be redundant. Therefore, the agency is not requiring this additional information to be stated adjacent to the claim.

FDA has also reconsidered whether the definition of "light" should require that fat, saturated fat, cholesterol, and sodium not exceed specified levels in a

product. The agency has no evidence that would suggest that consumers who use "light"roducts expect these products to have restricted levels for all of these nutrients, especially if the "light" claim is clarified by a statement that identifies the nutrients that are the subject of the claim. Further, if the levels of any of these nutrients were sufficiently high in a product, the product will have to bear a disclosure statement referring the consumer to the nutrition information panel that discloses the amount of the nutrient (new § 101.13(h)(2) and (h)(3)). Accordingly, the agency is not including in the definition of "light" restrictions on the amount of saturated fat, cholesterol, or sodium.

7. Definition of "lean" and "extra lean" for meal-type products

As discussed elsewhere in this document, although FDA did not propose to define "lean" or "extra lean" in the general principles proposal, the comments have persuaded the agency to adopt the provisions that the FSIS is establishing for "lean" and "extra lean" for meat and poultry products, including meal-type products, regulated by USDA. FDA is providing for the use of the term "lean" and "extra lean" to describe FDA regulated products comparable to those covered by the FSIS regulation. The criteria that FDA is adopting for "lean" as used to describe meal and main dish products are provided in new § 101.62(e)(2) and "extra lean" as used to describe meal and main dish products are provided in new § 101.62(e)(4).

Accordingly, the provisions in new § 101.62(e)(2) require that for the term "lean"o be used on the label or in labeling of a meal product or main dish product that product must contain less than 10 g of fat, less than 4 g of saturated fat, and less than 95 mg of cholesterol per 100 g and per labeled serving. The provisions in new § 101.62(e)(4) require that for the term "extra lean" to be used on the label or in labeling of a meal product or a main dish product that product must contain less than 5 g of fat, less than 2 g of saturated fat, and less than 95 mg of cholesterol per 100 g and per labeled serving.

The agency recognizes that the definitions for "lean" and "extra lean" for main dish products allow for use of the claim when levels of cholesterol exceed FDA's disclosure levels for this nutrient in a main dish product (i.e., 90 mg). It considered whether to prohibit the claim on products that contained greater than 90 mg of cholesterol. However, the agency has concluded that it would be more beneficial to consumers to allow the claim on meal-type products whose cholesterol content exceeds the disclosure level because the claims identify foods relative to other foods in this broad category of foods that contain lower amounts of fat and saturated fat. Consequently, these changes will assist consumers in selecting such foods. Furthermore, when the level of cholesterol exceeds FDA's disclosure level, the food will be required to bear a disclosure statement that refers the consumer to the nutrition information panel for additional information about cholesterol content.

8. Disclosure statement

In the general principles proposal (56 FR 60421 at 60457), the agency applied the concept of disclosure levels for individual foods to meal-type products. However, the agency did not propose specific disclosure levels for meal-type products and solicited comment on whether the disclosure levels should be different for meal-type products than for individual foods, and if so, what the levels should be and why.

273. FDA received comments recommending that it provide separate disclosure criteria for meal-type products. Several comments argued that the single food disclosure levels were too stringent to be applied to large quantities of food such as meal-type products. Two comments suggested that a specified amount of the designated nutrient per 100 g of product was the most appropriate basis for a criterion.

The agency considered whether to retain the disclosure levels for individual foods as the disclosure levels for meal-type products but on a per 100 g basis rather than per serving (i.e, 13 g of total fat, 4 g of saturated fat, 60 mg cholesterol and 480 mg sodium). On this basis, a meal weighing 10 ounces (280 g) would be subject to the disclosure requirements if it contained approximately 36 g of fat or 55 percent of the DRV. A single meal product weighing 12 ounces (336 g) would be subject to the disclosure requirement if it contained about 44 g of fat or about 67 percent of the DRV for total fat. If it is assumed that a "meal constitutes one-fourth of a total day's nutrient/calorie intake, this criterion appears to be too high in that such a meal could contribute more than half of the total amount of the nutrient (i.e., fat, saturated fat, cholesterol, or sodium) generally recommended as a total daily intake, not be required to bear a disclosure, yet still be able to bear a health claim.

The comments received offered no alternatives to the per 100 g basis for disclosure levels for main dishes and meal products. FDA, therefore, has developed an approach that extends the rationale used for individual foods to main dishes and meal products. This approach allows a greater percentage of the DRV for main dish products and meal products than for individual foods.

In arriving at specific percentage levels for disclosure nutrients, FDA considered that the amount of a nutrient in the total daily diet that may increase the risk of a disease may be between 100 percent and 200 percent of the DRV for that nutrient. The agency then considered that if three meals and a snack were consumed during the day, and each contained 40 percent of the DRV for a particular disclosure nutrient, and if foods that sometimes accompany meals such as beverages, breads, and desserts were also consumed and contributed an additional 40 percent of the DRV for that nutrient, then the total daily intake of the nutrient would not exceed 200 percent of the DRV, the level the agency used to establish disclosure levels for individual foods (see the final rule on health claims that appears elsewhere in this issue of the Federal Register). Thus, the agency is adopting 40 percent of the DRV as the disclosure level for meal products in this final rule.

The agency further considered that the contribution of main dish products is generally between meal products and individual foods (for which a disclosure level of 20 percent of the DRV is established in this final rule). Thus, the agency chose 30 percent of the DRV, the mid-point between meals and individual foods, as the disclosure level for main dish products.

Based on the comments received, the agency has established separate disclosure criteria for meal/main dish products. For meal products, new § 101.13(h)(2) requires that a disclosure statement be made on a product that makes a nutrient content claim if the food contains more than 26 g of fat, 8.0 g of saturated fat, 120 mg of cholesterol, or 960 mg of sodium per labeled serving. These levels correspond to no more than 40 percent of the DRV per labeled serving. For main dish products, new § 101.13(h)(3) requires that a disclosure statement be made on a product that makes a nutrient content claim if the food contains more than 19.5 g of fat, 6.0 g of saturated fat, 90 mg cholesterol, or 720 mg of sodium per labeled serving. These levels correspond to no more than 30 percent of the DRV per labeled serving.

9. Other

275. The agency received a comment that recommended that the term "controlled" be defined as an implied

nutrient content claim for meal-type products. This comment asserted that this term would be very useful in describing carefully established levels of nutrients and has historically referred to established levels in a line of products designed to be used regularly within the context of a total diet that met dietary guidelines. The recommended criteria for the term "controlled" recommended by the comment were: (1) Less than 300 calories, (2) less than 30 percent of calories from fat, (3) no more than 65 mg cholesterol, and (4) less than 600 mg of sodium.

The term "controlled" has traditionally been used in the marketplace (especially on products marketed for special dietary use) to refer to designated size portions of foods and not to levels of nutrients. Thus, the agency has not defined the term "controlled" as suggested in the comment. However, the agency advises that individuals who believe that there is a need for additional terms for the use of implied claims on meal-type products may petition the agency under the provisions of § 101.69.

IV. Restaurant Foods

A. Nutrient Content Claims for Restaurant Foods

FDA received many comments regarding the proposed nutrient content claims criteria as they would apply to restaurant foods and to foods sold in other establishments in which food that is ready for human consumption is sold (e.g., institutional food service, delicatessens, catering). In this discussion, such foods will be referred to as "restaurant foods," firms selling such foods will be referred to as "restaurants," and responsible individuals in these firms will be referred to as "restaurateurs." However, the concepts and policies discussed are intended to apply broadly to the foods covered by section 403(q)(5)(A)(i) and (q)(5)(A)(ii) of the act. Issues with respect to menus are discussed separately below.

276. Several comments stated that because the 1990 amendments are silent with respect to requiring restaurant foods to comply with the requirements for nutrient content claims, FDA is not legally required to regulate such claims for restaurant foods in a manner identical to that proposed for packaged foods.

FDA disagrees with the comments that the 1990 amendments do not apply to nutrient content claims made for restaurant foods. As explained in the general principles proposal (56 FR 60421 at 60428), the 1990 amendments, fully support the agency's proposal in § 101.13(o)(5) (redesignated as new § 101.13(q)(5)) that a nutrient content claim may not be used for food that is served in restaurants or other establishments in which food is served for immediate human consumption, or for food that is sold for sale or use in such establishments, unless the claim is used in a manner that is authorized by a definition that FDA has adopted. However, FDA agrees that under section 403(r)(2) of the act, it is not required to regulate claims on restaurant foods in a manner identical to that for packaged foods. In fact, restaurants are exempt from the referral and disclosure requirements in section 402(r)(2)(B) of the act and certain of the requirements in section 402(r)(2)(A). FDA's regulations incorporate these exemptions. While the regulatory criteria governing claims for restaurant-type foods need not be identical to those governing other foods, if claims on foods are to be useful for consumers, the criteria for those claims must be consistent.

277. Several comments stated that restaurant foods should be required to comply with the proposed requirements for nutrient content claims. Some comments stated that many restaurant foods are centrally manufactured and conform to system-wide composition and quality standards. Therefore, many restaurants and restaurant chains, especially the larger ones, already have access to the nutrition information necessary to verify claims about their products. Finally, these comments stated that portion control of foods is practiced by many restaurants to control their food costs, and that this control will facilitate compliance by the industry.

Some comments stated that the proposed regulations governing nutrient content claims would be impracticable for the restaurant industry because packaged foods and restaurant foods differ markedly in the way they are prepared and sold. For example, variability in the nutrient level of individual foods sold in restaurants occurs as a result of: (1) Seasonal, regional, and market variations in ingredients; (2) differences in preparation methods of similar foods; and (3) consumer preferences in terms of how food is prepared. The comments pointed out that these variabilities would require repeated costly analyses to determine if each food meets the criteria for the content claim. The comment cited additional, complicating factors such as: performance of 100-g calculations for meal-type products; inadequacy of current data bases on nutrient levels in many foods for validating nutrient content claims; and variations in recipes for restaurant foods. One comment estimated the cost of compliance in terms of redoing printed materials in the commercial sector of the food-service industry to be more than $500 million. Additionally, the comments assert that costs associated with product development, testing, preparation, marketing, and staff training will be required. For these reasons, these comments requested that FDA exempt restaurant foods from the requirements for nutrient claims it is establishing in this final rule.

Several comments stated that the proposed regulation for nutrient content claims for restaurants is not the least restrictive alternative available to FDA, in accordance with Executive Order 12291, because it would essentially eliminate a foodservice operator's ability to communicate meaningful nutrition information to consumers and create a disincentive for foodservice operators to develop healthful foods. These comments said that substantial costs of compliance with the new regulations would be passed on to consumers, and the small business segment of the industry would be especially adversely affected. The alternatives suggested by the comments are: (1) Develop definitions for foodservice oriented nutrient content claims; (2) develop voluntary guidelines for foodservice that specify how foodservice operators should provide nutrition information, or (3) establish a standard set of criteria concerning a recommended daily diet so that foodservice operators could flexibly and reliably design meals that may be promoted as healthful.

Several comments specifically addressed the use of the term "light" on restaurant foods. One of these comments said that "light" used on a restaurant food or meal should have the same meaning as when placed on a packaged food. Another comment said that "light" should mean only a reduction in calories, and that it should be restricted to use on meal-type products, on salt substitutes, and for describing physical or organoleptic attributes. One comment said that "light" as used in a restaurant can mean a wide variety of things from lighter texture, color, or consistency to overall healthiness, and that the proposed definition was too restrictive. A comment from a restaurant chain recommended that the term "light" should be used to refer to total meal packages that have at least 25 percent less fat, cholesterol, sodium, or calories than the traditional menu selections. This comment contended that a

restaurant meal will take the place of at least three servings, and that a 25 percent reduction would be significant in terms of total diet.

Other comments were less specific in addressing the issue of restaurant foods or meals bearing relative claims. One of these comments said that relative claims should be permitted for total meal packages at restaurants. Another of these comments said that for relative claims, a restaurant should compare a product to the restaurant's own product.

Given that almost half of the American food dollar is spent on food consumed away from home, and that perhaps as much as 30 percent of the American diet is composed of foods prepared in food service operations, FDA believes that, from an overall public health perspective, this important segment of the diet cannot be ignored. Further, FDA believes that dietary information provided to consumers at point of purchase in restaurants and other food service operations can be useful in helping Americans in maintaining healthy dietary practices. FDA wants to encourage the provision of such dietary information. However, FDA firmly believes that consumers expect, and deserve, that the claims made at point of purchase are truthful and not misleading.

FDA advises that not all claims made for restaurant foods are necessarily the type of claims that are covered by the 1990 amendments. For the sake of clarification, the agency offers the following observations. Statements such as "lightly breaded," "light crust," or "in a light sauce" on a sign or placard are not nutrient content claims covered by the 1990 amendments. Moreover, because of the importance of context, statements such as "Light Fare," "Lite Bites," or "Light Entrees" will not be considered nutrient content claims if the sign or placard on which the statement appears offers an explanation of the basis for the terms that makes clear that they are not intended to characterize the level of a nutrient. For example, a term such as "Lite Fare," on a sign or placard followed by an asterisk referring to a note that makes clear that in this restaurant the term means dishes with smaller portion sizes than normal would not be considered a nutrient content claim under section 403(r) of the act. In most cases, a prominently displayed disclaimer or information that clearly explains the basis for the use of the term, and that does not characterize the level of a nutrient in the explanation, will be sufficient to remove that use of the term from the coverage of the 1990 amendments.

Similarly, a restaurant may be able to use symbols next to the listing of an item on a sign or placard where the symbols are clearly explained in terms that would not subject the claim implied by the symbol to the 1990 amendments. For example, the use of a star symbol next to the name of an entree, where the symbol is explained in a footnote stating that the item is broiled instead of fried, would not be subject to the 1990 amendments.

Also, a restaurant may use symbols or make reference on a sign or placard to the criteria of a health professional organization or accrediting group and explain that the entree or meal is consistent with the general dietary guidelines of that group and not be subject to the 1990 amendments. For example, use of a heart symbol with reference to a note that explains that this entree is consistent with the general dietary guidelines of the AHA will be considered dietary guidance and not a nutrient content or health claim subject to section 403(r) of the act, provided the explanation does not characterize the level of a nutrient.

Finally, a restaurant also may be able to devise foods or complete meals that are formulated in complete accordance with the Dietary Guidelines for Americans (e.g., moderate calories, less than 30 percent calories from fat, less than 10 percent calories from saturated fat, emphasis on vegetables, fruits, and grain products, moderate use of sugars and sodium). FDA encourages such actions because a meal, especially a restaurant meal, represents a significant portion of the day's consumption, as compared to an individual food product. A restaurateur may signal to customers by the use of a term or symbol on a sign or placard that the meal is formulated in accordance with dietary guidelines, and FDA will consider such indications to be dietary guidance and not nutrient content claims under the 1990 amendments.

FDA is including a provision in new § 101.13(q)(5)(iii) that describes when such indications will be considered to constitute dietary guidance and not nutrient content claims. The agency will evaluate the validity of such guidance on the basis of its being truthful and not misleading under section 403(a) of the act. However, if the restaurateur goes on to characterize the level of nutrients in the food, it would subject the food and the claims for the food to the nutrient content claim regime. When a restaurant uses a defined term such as "low calorie," uses the term "light" without further explanation, or uses a term or symbol that is explained in such a way that states or implies levels of nutrients in the food, it must comply with FDA's definitions of those terms.

How the restaurant demonstrates compliance with those definitions is a difficult matter. FDA recognizes that, as detailed in the comments, there are variations in the nutrient values for restaurant foods. Some of these variations are not unique to restaurants. Manufacturers of packaged foods also have to deal with differences in nutrient levels as a result of seasonal, regional, and supplier variations. FDA has been able to develop workable criteria that take into account these variations. However, the agency acknowledges that there are variations unique to restaurant foods (e.g., methods of preparation). Moreover, FDA recognizes that there are difficult questions, as demonstrated by the comments, as to how exactly to analyze restaurant foods in a reasonable and cost effective manner.

While there are difficulties associated with restaurant foods, FDA concludes that the difficulties are not so great as to preclude restaurants from making claims or to prevent the agency from being able to assure consumers that the nutrient content claims that appear on restaurant foods reasonably reflect the nutrient content of the food. Thus, FDA is providing in new § 101.13(q)(5)(ii) that, except if a claim is made on a menu, a restaurant food may bear a nutrient content claim if the restaurateur has a reasonable basis on which to believe that the food that bears the claim meets the definition for the claim that FDA has established under section 403(r)(2)(A)(i) of the act. Thus, if a restaurateur labels a fish dish as "low fat," on a sign or a placard he or she must have a reasonable basis for believing that the dish complies with FDA's definition for "low fat," that is it contains less than 3 g of fat per 100 g. The reasonable basis can be provided in a number of ways. The restaurateur can show, for example, that FDA's guideline on nutrient levels in seafood (56 FR 60880, Appendix B, November 27, 1991) shows that the fish contains less than 3 g of fat per 100 g, and that the method of cooking and other foods used in the dish would not add fat. In addition, the restaurateur could show that he or she relied on a reliable cookbook that gave values for fat in the finished food that were less than 3 g per 100 g. Certainly other methods are possible. If a restaurateur uses recognized data bases for raw and processed foods to compute nutrient levels in the foods or meals and then does not use methods of preparation that violate the appropriate use of data bases (e.g., uncontrolled addition of ingredients or inappropriate substitutions of ingredients), FDA will

find that there is a reasonable basis for believing that the food meets the criteria for a defined nutrient content claim.

Upon request, the restaurateur will be expected to present the basis on which he or she believes that the pertinent nutrient levels are present in the foods. In addition, the firm must be prepared to demonstrate that it adhered to the information that provides the basis for its belief, i.e., to the recipe, use of certain types and amounts of ingredients, or preparation methods in preparing the food. The agency will then determine whether the basis cited by the restaurant reasonably supports its use of a nutrient content claim such as "low calorie" or "low fat."

This reasonable basis for belief standard for restaurant nutrient content claims will provide regulatory officials, especially State and local authorities, with an effective standard for verifying that such claims are truthful and not misleading and in accordance with FDA regulations. FDA does not have resources to adequately enforce its regulations in restaurants. State and local authorities have traditionally carried out this responsibility. In addition, section 4 of the 1990 amendments provides that State and local authorities may enforce section 403(r) of the act in Federal court.

The agency notes, however, that while restaurants, and particularly small restaurants, have nominally been subject to FDA's existing nutrition labeling regulation (see § 101.10), they have, as a practical matter, not been required to comply with these regulations or with State or local regulations that focused on the nutrient content of the food. Thus, the efforts that will be necessary on the part of restaurants to show that they have a reasonable basis to believe that their food complies with the nutrient content claims requirements will be significant. These efforts will place particularly great demands on the resources of the small business segment of the industry, that is, restaurant firms that have ten or less individual restaurant establishments (Ref. 34). FDA will refer to this segment of the industry as "small restaurants."

Small restaurants generally do not have the established nutrition support component that larger restaurant chains have. Thus, it will be more difficult for small restaurants to determine how to adapt nutrient content information to their individual food selection and preparation methods. In addition, it is likely that they will not be as aware of available information sources, like nutrient content data bases, as large chains. Moreover, because of resource limitations, a small restaurant is not as likely as a large restaurant chain to be familiar with Federal requirements. Thus, small restaurants will have to become familiar with not only FDA's requirements, but with available FDA information, like the nutrient content information that FDA published in conjunction with its regulation on the voluntary labeling of raw fruits and vegetables (56 FR 60880, November 27, 1991).

Because of the great initial demands that small restaurants will find if they wish to make claims, FDA has decided that they should be given additional time to come into compliance with these regulations. Without additional time, for the reasons discussed above, small restaurants will be placed at a disadvantage with respect to their ability to make claims. As a result, they may decide not to even attempt to provide useful nutrition information to consumers about their foods. To provide for equitable implementation of these requirements for small restaurants, FDA has decided to not make § 101.13(q)(5) effective with respect to such establishments until February 14, 1995.

While the statute will be in effect during that period, FDA will not enforce the statute's nutrient content claim requirements in small restaurants until the regulations are effective. Although state action is not preempted under section 403A(a)(5) of the act until Federal regulations are effective, the agency expects that States will refrain from enforcing any nutrient content claim requirements in small restaurants until the Federal regulations are effective for those restaurants.

FDA believes that this action is fully consistent with the 1990 amendments and with the act. The 1990 amendments impose no date by which the agency's regulations must be effective, only when they must be promulgated (see sections 3 and 10 of the 1990 amendments). Moreover, FDA believes that this action will facilitate effective enforcement of the act. FDA believes that the agency's and State's resources can best be used during this initial period in educating small restaurants about the requirements of the law and by developing a better understanding of the unique practical circumstances of small restaurants in complying with nutrient content labeling requirements. Moreover, during this period, there will be an opportunity for interested persons to develop new data bases that will help facilitate the provision of nutrition information on foods sold in restaurants and particularly in small restaurants.

As an additional measure of flexibility, which will especially benefit small restaurants, it was decided not to include claims on menus within the coverage of these regulations. FDA has considerable discretion in regulating nutrient content claims in restaurants. As the comments have indicated, there are unique problems and concerns associated with regulating such claims. The 1990 amendments do not specify precisely how such claims are to be regulated. These regulations will apply to nutrient content claims made in restaurants except on menus. The agency's efforts will focus on signs, placards, and posters, which are increasingly used in fast food and other restaurants to bring nutrition information and claims about food to consumer's particular attention. The comments pointed out that menus are subject to frequent, even daily, change. This additional measure of flexibility for menus will help assure that restaurants, especially small restaurants, will not be deterred by the 1990 amendments from providing useful nutrition-related information to their customers. State's remain free, however, to ensure under their own consumer protection laws that menus do not provide false or misleading information.

Although it has arrived at an approach that will provide for nutrient content claims on restaurant foods, other than the exclusion of menus, FDA does not consider the problem of assuring the useful and reliable provision of nutrient related information in restaurants to be solved. It is possible that there are other definitional criteria that are more appropriate for restaurant foods than those that FDA has developed based largely on packaged foods. Also, it may be that consumers have completely different expectations for, and understanding of, terms used for restaurant foods as compared to the same terms used on packaged foods. If this is the case, a different glossary of terms for use in restaurants may be appropriate. However, at this time, the agency simply does not have the data or knowledge on which to base such determinations. FDA is working, and will continue to work, with the restaurant industry to determine how terms are used on restaurant foods and whether such terms are appropriate. For example, with FDA's cooperation, the National Restaurant Association is planning to undertake a survey of industry use of nutrition information and of consumer knowledge, practices, expectations, and understanding of various terms and symbols in restaurants. FDA is open to petitions for different criteria for nutrient content

claims for restaurant foods, and if data warrant, the agency will consider establishing regulations specifically for restaurant foods.

FDA also recognizes that there are a number of significant issues concerning the adequacy of existing data bases for use to compute nutrient levels in restaurant meals. However, the agency is working, and will continue to work, with the restaurant industry to assess the adequacy of these data bases and to encourage the development of additional or newer data where those data bases are found to be lacking.

In developing more specific policies, FDA will also consider whether restaurant foods should be afforded greater latitude in the compliance criteria than the criteria that are currently applied to nutrient variations in processed foods. FDA regulations state that for naturally occurring vitamins, minerals, and protein, the nutrient content must be at least 80 percent of the value declared, and that for calories, carbohydrate, fat, and sodium, the level must not exceed the declared value by more than 20 percent. The agency recognizes that all data bases have inherent variabilities, and that a computed nutrient level for a food with several ingredients may have an accumulated variability that exceeds the agency's criteria for packaged foods. FDA is concerned about the accuracy of nutrient level estimations, but pending the development of better data, the agency will accept, as a reasonable basis, claims based on nutrient levels drawn from recognized nutrient data bases, without regard to the computed variability or to differences between the computed nutrient levels and levels determined by laboratory analyses. The agency is open to comments and suggestions on how nutrient variability issues should be addressed for restaurant foods and will continue to work with the industry on this issue.

278. One comment stated that the use of the terms "healthy" or "healthful" on meal-type products is necessary for restaurants to assist the consumer in identifying the choices that fit an eating pattern consistent with reducing the risk of certain chronic diseases. This comment further stated that disqualifying levels for fat, saturated fat, sodium, and cholesterol should be set in order to prevent inappropriate foods from bearing this claim.

The agency is publishing a proposed rule concerning use of the term "healthy" as an implied nutrient content claim elsewhere in this issue of the Federal Register. Any comments and information with respect to whether the agency's tentative definition of "healthy" is appropriate for restaurant meals and main dishes will be considered in that rulemaking.

B. Nutrition Labeling of Restaurant Foods

279. Several comments agreed that FDA has authority to require nutrition labeling when nutrient content claims are made on restaurant foods and stated that nutrition labeling should be required on restaurant foods bearing claims. These comments generally contended that restaurants should be required to follow the same nutrition labeling requirements as food manufacturers when nutrient content claims are made.

Many comments expressed the opinion that FDA does not have authority to require nutrition labeling when nutrient content claims are made on restaurant foods and stated that nutrition labeling should not be required on restaurant foods bearing nutrient content claims. These comments generally contended that since the act exempts restaurant foods from nutrition labeling, FDA should allow for the nutrition labeling of restaurant foods on a voluntary basis.

FDA finds nothing in the comments to persuade the agency to adopt a position different from that stated in the general principles proposal (56 FR 60421 at 60427). The agency continues to believe that it has the authority to issue regulations requiring restaurants that make nutrient content claims to adhere to the requirements for such claims, including nutrition labeling.

280. A few comments stated that if nutrition labeling were required for restaurant foods bearing nutrient content claims, restaurants would not make such claims because restaurant foods are not standardized, and it would be too costly to provide accurate nutrition information for these foods. The comments also stated that mandatory nutrition labeling (when a claim is made) would inhibit restaurants from making frequent and more healthful changes in food.

Full nutrition labeling provides the consumer with a way of evaluating a claim within the nutrient context of the food or meal and, therefore, is advantageous in allowing more informed comparisons. However, in the general principles proposal (56 FR 60421 at 60427), the agency recognized the difficulty of providing nutrition labeling for restaurant foods and asked for comment. The comments have persuaded the agency that, at this time, a requirement for full nutrition labeling could be a significant barrier to the transfer of information about favorable nutritional characteristics of restaurant foods. Therefore, FDA is not requiring that full nutrition labeling be provided when a nutrient content claim is made for restaurant foods. It is adopting a somewhat different approach to the provision of nutrient information to the consumer, as explained in the response to the next comment. The agency does, however, encourage the voluntary provision of full nutrient information for restaurant foods, even when claims are not made.

281. Some comments stated that if nutrition labeling were required for restaurant foods bearing a claim, restaurants could utilize available nutrition software programs and recognized databases to provide the necessary information for the nutrition label. One comment stated that FDA should develop educational materials for restaurants that explain their obligation not to make nutrient or health claims without providing nutrition labeling. A few comments stated that before requiring mandatory nutrition labeling of restaurant foods bearing nutrient content claims, a pilot study should be done to determine the cost and feasibility of such labeling, and that more study is needed before the agency requires labeling on restaurant foods.

FDA believes that consumers should have access to information about the nutrient content of restaurant foods for which nutrient content claims or health claims are made. The agency is requiring in new § 101.10 that such information be available upon request by a consumer. However, because FDA recognizes the difficulty of providing nutrition labeling for restaurant foods, at this time it will allow such information to be conveyed either by nutrition labeling as described in new § 101.9 or by the provision of information to the consumer about the level of the nutrient for which the claim is made in a serving of the food upon request by the consumer. Under the latter alternative, for example, if a 333 g meal is characterized as being "low fat," the consumer could be informed that the meal contains less than 10 g of fat. Therefore, under this alternative the restaurateur need not state the actual amount of the nutrient present in a serving of the food but may simply state that the nutrient is present at "less than" or "greater than" the amount that would enable the serving of the food to make the claim. Thus, the agency is not requiring that the firm conduct an analysis of the food in order to provide this information. On the contrary, this information should be readily available to the firm from its determination that the food conforms to the criteria for the

claim. For the interim, the agency will consider that the provision of this limited amount of information to consumers will serve as the functional equivalent of nutrition labeling.

Further, the considerations discussed in the previous section concerning the effective date for small restaurants that make nutrient content claims also apply with respect to nutrition labeling when a nutrient content claim is made in those restaurants. Therefore, FDA is also deferring the effective date of § 101.10 for 1 year for small restaurants.

FDA agrees with the comments that educational programs and further study will be helpful. However, the statutory timeframes imposed on the agency by the 1990 amendments do not afford FDA the luxury of deferring until some future time all rulemaking on restaurant foods. The agency recognizes the limitations in the approach that it is taking and encourages the restaurant industry to continue to work with FDA to devise a program that will provide consumers with truthful and accurate nutrition information, without at the same time inhibiting the flow of such information or the development of healthier foods. The agency points out that the conduct of feasibility and consumer studies is more properly the responsibility of the regulated industry, and that FDA is currently working with the industry to do such studies.

282. One comment stated that § 101.10 should be deleted because it would be outdated if nutrition labeling requirements are imposed for restaurant foods bearing claims.

For the reasons discussed above, FDA is deleting current § 101.10. However, FDA is replacing it with a new provision that sets forth how nutrient information is to be provided when a claim that is subject to section 403(r) of the act is made for restaurant foods. The agency believes that information in § 101.10 was useful in advising firms about alternatives for declaring nutrition information when a claim is made, and as revised, § 101.10 will continue to serve this purpose.

283. Other comments addressed specific issues of nutrition labeling for restaurant foods, such as whether the requirement for nutrition labeling of restaurant foods should apply only to large restaurants with fixed items, and whether the content or format of nutrition labeling should be different for the foodservice industry than for packaged foods.

FDA will address these issues in its further deliberations and in its continued interactions with the regulated industries. The agency is likely to seek comment on a number of these issues in the future.

V. Petitions

In the general principles proposal (56 FR 60421 at 60458), FDA proposed to establish procedural regulations to govern the submission, content, and agency review of the three types of petitions authorized by section 403(r)(4) of the act (i.e., petitions for nutrient content claims, for synonymous terms, and for the use of an implied claim in a brand name). The agency also proposed to redelegate to the Director and Deputy Director of the Center for Food Safety and Applied Nutrition (CFSAN) all of the functions of the Commissioner of Food and Drugs relating to petitions for label claims under section 403(r) of the act involving noncontroversial issues. Further, the agency reiterated its interim policy on petitions submitted pursuant to the 1990 amendments that it announced in a notice published in the Federal Register of March 14, 1991 (56 FR 10906), i.e., that the agency intends to defer or deny action on all such petitions until it establishes the final procedural regulations for the submission, content, and review of these petitions.

284. One comment stated that the 1990 amendments do not require FDA to establish procedural regulations for petitions, and that the agency does not have the authority to defer or deny any petition submitted to the agency on the basis that the agency has not established regulations.

Although the 1990 amendments do not require FDA to establish procedural regulations for the petitions prescribed therein, FDA stated in a notice in the Federal Register of March 14, 1991, (56 FR 10906) that the most efficient way to manage a large influx of petitions likely under the 1990 amendments and to utilize agency resources is for FDA first to establish procedural regulations for handling petitions, and secondly to make them final at the same time as the other substantive regulations implementing the 1990 amendments. The agency continues to believe in the wisdom of this approach. Obviously, it will be more efficient for the agency to be able to simply review petitions to determine whether the petitioner has provided an appropriate basis to justify a claim, than to have to first determine whether a petition has provided the appropriate information and then to review it substantively. FDA believes that adopting new § 101.69 will greatly increase the likelihood that the petitions it receives are adequate.

Also, as explained in the general principles proposal (56 FR 60421 at 60458), the need to promulgate procedural regulations necessitates that the agency defer or deny petitions submitted before such regulations are finalized. Therefore, the agency concludes that the promulgation of procedural regulations for petitions submitted pursuant to the 1990 amendments, and its procedure for handling petitions before the final regulations are established, is appropriate.

285. Another comment urged that FDA not redelegate to the Director and Deputy Director of CFSAN all the functions of the Commissioner of Food and Drugs concerning petitions for label claims under section 403(r) of the act that do not involve controversial issues. The comment stated that all petitions that will be submitted to the agency concerning nutrient content claims and health claims will involve controversial issues that will require a response from the Commissioner of Food and Drugs.

FDA does not agree with this comment. Based on its experience with other types of petitions that have been submitted to FDA for consideration, it is not uncommon for a petition to contain major deficiencies that necessitate the denial of the petition or that result in the petition being put in a "not-filed" status until all deficiencies have been resolved. The agency believes that redelegating such functions to the Director and Deputy Director of CFSAN will permit the agency to take the required actions (e.g., denial of such a petition) in the most resource efficient manner.

Although the agency agrees that many petitions concerning label claims will indeed involve controversial issues, no basis was provided by the comment to support the contention that all such petitions will be controversial, and the agency does not believe that it should make this assumption. If a petition does not involve a controversial issue, the redelegation of the functions provision will enable the agency to take action in the most resource efficient manner. Therefore, the agency is retaining the redelegation provision in this final rule.

286. One comment stated that FDA should include a list of terms and synonyms in the final regulation so that the petition process would not be necessary.

This final rule is not intended to define by regulation all conceivable terms that may be used now or in the future to make nutrient content claims. The 1990 amendments included the petition process to enable FDA to amend the regulations to provide for

new terms and synonyms that may be presented to the agency with appropriate justification. Thus, this final rule does not render the petition process unnecessary.

287. Several comments were concerned that the requirements established for the petition process are ambiguous and should be streamlined. A few other comments suggested that the petition process would impose a significant burden on manufacturers.

The agency has reviewed these comments and has concluded that, in some cases, changes should be made to the requirements to clarify and simplify the petition process and eliminate unnecessary elements. The specific revisions in the final rule are discussed below.

288. One comment suggested that FDA should use the criteria established in section 403(a) and (r) of the act for determining when to deny or grant a petition. This comment also implied that no other requirements are necessary for the agency to use as a basis to determine whether to deny or grant a petition.

The agency does not agree with this comment. While it is true that section 403(a) and (r) of the act are the statutory provisions upon which the proposed procedural regulations are based, these statutory provisions do not provide petitioners with a clear description of the types of information and scientific data that would be necessary for a petition to be acceptable.

Given the large influx of petitions that the agency anticipates receiving, and the statutory time constraints placed on the agency regarding the review of these petitions, it is in the best interest of petitioners and of the agency for FDA to establish procedural regulations that clearly delineate the requirements that petitioners must satisfy when submitting a petition to FDA for consideration. This course will lead to the most efficient use of the petitioner's and the agency's resources because the data requirements for petitions will be clearly stated, and, as stated above, less agency resources will be expended in reviewing deficient petitions.

289. A number of comments expressed concern that the petition process will prevent manufacturers from developing innovative ways to convey nutrient levels in foods, retard product development, and serve as a disincentive for the development of new healthful foods. One comment suggested that the petition process will stifle product innovation because new marketing claims will need agency approval. This same comment also stated that one way to somewhat alleviate this problem would be for the petition that is under review to remain confidential until it is approved by the agency.

As stated above, FDA has in some cases made changes in the final rule to clarify, simplify, and eliminate unnecessary petition requirements. However, the agency's procedures must be consistent with the statutory requirement that all nutrient content claims used on food labels use terms that are defined in the regulations of the Secretary as provided in section 403(r)(2)(A)(i) of the act. Thus, the requirement of agency approval of a claim, and the petition process by which that approval is obtained, derive directly from the act itself.

Furthermore, section 403(r)(4)(A) of the act requires that nutrient content claim petitions that are filed for further action after 100 days and brand name petitions be made available to the public. Because of this requirement in the statute, FDA is retaining the provisions concerning the public availability of these petitions. However, the availability of information in these petitions will be determined in accordance with § 20.61 (21 CFR 20.61). This regulation provides that trade secrets and commercial or financial information that is confidential or privileged are not to be made available for public review.

290. A small number of comments stated that some specific requirements that the agency proposed for nutrient content claim petitions and synonym petitions (e.g., submission of consumer survey data and submission of data to demonstrate that consumers will understand the meaning of the proposed term) should not be included in the petition requirements. Most of these comments regarded the proposed petition requirements as unduly burdensome. Some of the comments stated that the proposed petition requirements command more information than FDA cited in issuing the proposed regulations for nutrient content claims.

FDA has reviewed the proposed requirements and has concluded that it is not necessary (as was proposed under format item B) for descriptor petitions and synonym petitions (proposed § 101.69(m)(1) and (n)(1)) to include data and information to demonstrate that consumers can be expected to understand the meaning of the proposed term under the proposed conditions of use. The agency believes that it can make a rational determination concerning the ability of consumers to understand a term without requiring such data and information, and, therefore, this requirement would impose an unnecessary burden on the petitioner. However, the inclusion of such information in a petition would, if it shows that consumers do correctly understand the term, enhance the persuasiveness of the petition.

The petitioner will still be required to address why the proposed use of the term will not be misleading (format item A). In this regard, if any concerns arise during the agency's review concerning the ability of consumers to understand the meaning of the proposed term, the agency is likely to deny the petition. Therefore, the agency is removing from new § 101.69(m)(1) and (n)(1) the provision stating "The petition shall include data and information, e.g., surveys to the extent necessary, to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use."

291. Some comments that addressed synonym and brand name petition requirements stated that the agency should delete the requirements in proposed format item C (proposed § 101.69(n)(1) and (o)(1)) that the petitioner provide a detailed analysis of the potential effects of the use of a proposed claim on food consumption and any corresponding changes in nutrient intake when requesting approval for a synonym or for a brand name containing an implied nutrient content claim. These comments stated that the burden imposed by this requirement guarantees that no petition will be successfully submitted. They also argued that such requirements treat synonyms as nutrient content claims rather than as alternative terms for claims that have already been approved by the agency.

The agency has considered this comment and agrees that synonym and brand name petitions need not include detailed analyses of food consumption and nutrient intake effects associated with use of the petitioned term. These matters will have been considered by the agency in approving the primary term with which the petitioned term is claimed to be consistent.

The agency is, therefore, deleting proposed format item C from the requirements for synonym and brand name petitions (new § 101.69(n)(1) and (o)(1)) in the final rule.

292. A comment stated that it is not necessary for FDA to publish a Federal Register notice informing the public of the agency's decision on whether to deny or to grant a synonym petition because it is not required by the statute.

FDA continues to believe that publishing a notice announcing the

agency's decision to either grant or deny a synonym petition will provide useful information to the public. Such decisions have relevance to persons interested in the outcome of the agency's review of the petition, because a synonym, if approved, may be used by any firm and, if denied, may not be used on labels or in labeling. Further, such action is appropriate because the granting of a synonym petition is an agency decision that has the force and effect of law. Public notice of the agency's action will notify all potentially affected parties of the legal status of the synonym. FDA is therefore retaining this provision in the final rule.

However, FDA is correcting an error in the proposed codified language. Proposed § 101.69(n)(4) should have stated that FDA will publish a notice in the Federal Register "As soon as practicable following the agency's decision to grant or deny the petition, * * *" as indicated by the preamble discussion. However, the proposed codified text only referred to the "granting" of the petition. FDA is making the appropriate revision in the final rule.

293. One comment stated that the petition process is unnecessary for the use of a nutrient content claim in a brand name if the term has been defined by the agency.

FDA agrees with this comment. In cases where a nutrient content claim has been defined by regulation or provided for under the regulations for implied nutrient content claims in new § 101.65, the term may be used in a brand name in accordance with the provisions of the applicable regulation. However, a brand name petition would be required for the use of a proposed term in a brand name that has not been defined by the agency by regulation or provided for under new § 101.65, but where the petition could establish that the proposed term is consistent with a defined term.

VI. Constitutional Issues

A. The First Amendment

294. A number of comments from trade associations and individual companies argued that truthful nutrient content claims are protected speech under the first amendment. Many comments contended that food labeling, including nutrient content claims, is commercial speech and argued that FDA's proposed regulations do not pass the Supreme Court's test for regulation of commercial speech. Comments asserted that any suggestion that consumers should be screened from truthful information for their own good is the kind of paternalism rejected by the Supreme Court in *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976), and that the idea that the public cannot be trusted to make judgments based on truthful information contravenes the basic principles of the first amendment. Comments maintained that the public has an interest in obtaining useful information, and that the Government's interest is best served by allowing the free flow of truthful information. FDA also received a comment expressing the opinion that the proposed rule does not violate the first amendment and urging the agency not to change its position on first amendment grounds.

FDA believes that its nutrient content claim regulations are consistent with the first amendment, and that the act, as amended by the 1990 amendments, does not violate the first amendment. The act has withstood numerous first amendment challenges. See, e.g., *United State* v. *General Nutrition, Inc.*, 638 F. Supp. 556, 562 (W.D.N.Y. 1986); *American Frozen Food Institute* v. *Mathews*, 413 F. Supp. 548, 555 (D.D.C. 1976), aff'd, 555 F.2d 1059 (D.C. Cir. 1977); *United States* v. *Articles of Food * * * Clover Club Potato Chips*, 67 F.R.D. 419, 424 (D. Idaho 1975); *United States v. 8 Cartons, Containing Plantation The Original etc. Molasses*, 103 F. Supp. 626, 628 (W.D.N.Y. 1951).

Parts of the 1990 amendments and these regulations have an incidental effect on speech in a narrowly defined area, food labeling. See *NAACP* v. *Claiborne Hardware* Co., 458 U.S. 886, 912 (1982). The Supreme Court, however, "has recognized the strong governmental interest in certain forms of economic regulation, even though such regulation may have an incidental effect on rights of speech and association." Id. The Government may regulate in areas of economic activity such as securities, antitrust, and labor in ways that affect speech. *SEC* v. *Wall Street Publishing Institute*, 851 F.2d 365, 372-73 (D.C. Cir. 1988), cert. denied, 489 U.S. 1066 (1989); see also *SEC* v. *Suter*, 732 F.2d 1294, 1299 (7th Cir. 1984) (the first amendment does not remove a business engaged in the communication of information from general laws regulating business practices). The Government "does not lose its power to regulate commercial activity deemed harmful to the public whenever speech is a component of the activity." *Ohralik* v. *Ohio State Bar Association*, 436 U.S. 447, 456 (1978); see also *Home Box Office, Inc.* v. *FCC*, 567 F.2d 9, 46 (D.C. Cir.) ("[R]ules restricting speech do not necessarily abridge freedom of speech."), cert. denied, 434 U.S. 829 (1977).

As with securities, labor, and antitrust regulation, the Government exerts extensive regulatory authority over the economic activity surrounding food and its labeling. Yet the regulation of food and food labeling clearly encompasses more than mere economic activity: It protects consumer health and safety in an area where harm to the public can be direct and immediate. See *Ohrali*, 436 U.S. at 456. FDA's crucial role in ensuring that food labels are informative, are not misleading, and do not otherwise misbrand products under the act has long been recognized. See 79 Congressional Record 4734 (1935), reprinted in Dunn, Federal Food, Drug, and Cosmetic Act 280 (1938) (statement of Sen. Copeland) ("No one disputes that the [FDA] should determine the quality of the product; no one disputes that it should determine what is on the label."). In such an area of extensive Federal regulation, the Government may place restrictions on speech by a regulated party where the speech relates directly to the Government's objectives. *SEC* v. *Wall Street Publishing Institute*, 851 F.2d at 372. Indeed, regulation of food labeling would be impossible if the Government could not restrict speech. See id. at 373.

Thus, when FDA seeks to ensure that food is not misbranded, it may place restrictions on label contents. "Freedom of [s]peech does not include the freedom to violate the labeling provisions of the Federal Food, Drug, and Cosmetic Act." *United States* v. *Articles of Food * * * Clover Club Potato Chips*, 67 F.R.D. 419, 424 (D. Idaho 1975). "[C]ertain speech in a certain limited context" becomes part of the labeling of a product and may serve as evidence of a violation of the act. *United States* v. *General Nutrition, Inc.*, 638 F. Supp. 556, 562 (W.D.N.Y. 1986). Thus, the seizure and condemnation of a book that misbrands a product is not a violation of the first amendment, even though in another context the book might be protected. See *United States* v. *8 Cartons, Containing Plantation The Original etc. Molasses*, 103 F. Supp. 626, 628 (W.D.N.Y. 1951); *United States* v. *Articles of Drug*, 32 F.R.D. 32, 35 (S.D. Ill. 1963). "It is the product and the manner in which the product is marketed which is said to be illegal," rather than the speech itself. *General Nutrition*, 638 F. Supp. at 562. A prohibition on selling a misbranded product restrains the violative act of selling, not speech itself. *Kellogg Co.* v. *Mattox*, 763 F. Supp. 1369, 1381 (N.D. Tex. 1991) (construing Texas food and drug law), aff'd without opinion, 940

F.2d 1530 (5th Cir. 1991). "The substantial government interest in the goals of the Act justif[ies] this extremely narrow encroachment" on speech. *General Nutrition*, 638 F. Supp. at 562. Indeed, where certain claims misbrand a product, "[a] requirement that the claims be removed, in order to sell the product, is certainly less restrictive than a flat prohibition of the sale of the product." *Kellogg*, 763 F. Supp. at 1381.

With the provisions of the 1990 amendments that govern nutrient content claims, Congress sought to put an end to the proliferation of confusing and contradictory nutrient content claims. 136 Congressional Record S16610 (Oct. 24, 1990) (statement of Sen. Hatch); 136 Congressional Record H5840 (July 30, 1990) (statement of Rep. Waxman). In order to assist consumers in improving their eating habits, Congress devised a scheme to ensure that nutrient content claims in food labeling will help consumers to make good nutrition choices, not mislead them. 136 Congressional Record H12954 (Oct. 26, 1990) (statement of Rep. Moakley); 136 Congressional Record S16609 (Oct. 24, 1990) (statement of Sen. Mitchell). Under this scheme, only those claims that FDA has defined by regulation, see section 343(r)(2)(A)(i) of the act, or approved pursuant to a petition, see section 343(r)(4)(A), are permitted, and a food that bears an unapproved nutrient content claim is misbranded. Since FDA case law makes clear that a label statement that misbrands a food product is not subject to first amendment protection, an unapproved nutrient content claim on a food label would not be protected speech. See *United States* v. *General Nutrition, Inc.*, 638 F. Supp. 556, 562 (W.D.N.Y. 1986); *United States* v. *Articles of Food * * * Clover Club Potato Chips*, 67 F.R.D. 419, 424 (D. Idaho 1975); *United States* v. *8 Cartons, Containing Plantation The Original etc. Molasses*, 103 F. Supp. 626, 628 (W.D.N.Y. 1951); *United States* v. *Articles of Drug*, 32 F.R.D. 32, 35 (S.D. Ill. 1963).

Congress considered existing labeling practices to be harmful to the public because of the "confusing" and "misleading" nutrient content claims made by many manufacturers. 136 Congressional Record H12954 (Oct. 26, 1990) (statement of Rep. Moakley); see also 136 Congressional Record H5843 (July 30, 1990) (statement of Rep. Madigan); cf. *Ohralik*, 436 U.S. at 456 ("[T]he State does not lose its power to regulate commercial activity deemed harmful to the public whenever speech is a component of that activity."). Congress dealt with this problem by crafting a system to permit certain useful information to appear on the food label, while ensuring that the information is not misleading. 136 Congressional Record H12954 (Oct. 26, 1990) (statement of Rep. Moakley); 136 Congressional Record S16609 (Oct. 24, 1990) (statement of Sen. Mitchell). Congress considered these restrictions on speech necessary to further the government's interest in ensuring that nutrient content claims on food labeling would not mislead consumers. The government's action in regulating the food label does not offend the first amendment simply because speech is involved. *Ohralik*, 436 U.S. at 456. The case law establishes that FDA's power to regulate the food label derives from its broad regulatory powers over food, and these regulations are valid under the limited scrutiny that has been afforded restrictions on speech under extensive regulatory schemes involving areas of economic activity. See *SEC* v. *Wall Street Publishing Institute*, 851 F.2d at 372–73; see also *Dun & Bradstreet, Inc.* v. *Greenmoss Builders*, 472 U.S. 749, 758 n.5 (1985); *Ohralik* v. *Ohio State Bar Association*, 436 U.S. 447, 456 (1978).

295. Many comments argued that labeling is commercial speech, and that restrictions placed on it must pass the tests enunciated by the Supreme Court in cases involving commercial speech. Unlike "advertising pure and simple," *Zauderer* v. *Office of Disciplinary Counsel*, 471 U.S. 626, 637 (1985), labeling does not fall clearly within the bounds of commercial speech. The agency does not consider it necessary for first amendment analysis, however, to determine whether or not food labeling fits the definition of commercial speech. See *SEC* v. *Wall Street Publishing Institute*, 851 F.2d at 372. Rather, the agency considers labeling on foods to form "a distinct category of communications in which the Government's power to regulate is at least as broad as with respect to the general rubric of commercial speech." *SEC* v. *Wall Street Publishing Institute*, 851 F.2d at 373. Nonetheless, recognizing that at least one court has categorized labeling as commercial speech, General Nutrition, 638 F. Supp. at 562, FDA agrees that labeling should certainly be considered closer to commercial speech than to "pure" speech.

Even if labeling is analyzed as commercial speech, these regulations do not violate the first amendment. First, speech that is misleading is not protected and may be prohibited. *Central Hudson Gas & Electric Corp.* v. *Public Service Commission*, 447 U.S. 557, 563–564 (1980). Secondly, speech that is only potentially misleading may be restricted, so long as the restrictions directly advance a substantial governmental interest and are no more extensive than necessary to serve that interest. *Central Hudson*, 447 U.S. at 566. These regulations govern a kind of speech that is inherently misleading and that, in Congress' judgment, has been used to mislead the American public for years: Unregulated, nonstandardized nutrient content claims on the food label. However, even if such claims are considered only potentially misleading, the regulations pass the test enunciated in *Central Hudson*.

Commercial speech receives only limited protection under the first amendment. See, e.g., *Bolger* v. *Youngs Drug Products Corp.*, 463 U.S. 60, 64–65 (1983). For commercial speech to be protected, it must concern lawful activity and not be misleading. *Central Hudson*, 447 U.S. at 563–64. The Supreme Court has recognized that restrictions on commercial speech may be appropriate to prevent deception. *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council*, 425 U.S. 748, 771 n.24 (1976). These regulations will have the effect of ensuring that the nutrition claims that appear in food labeling are not misleading. See *American Frozen Food Institute* v. *Mathews*, 413 F. Supp. 548, 555 (D.D.C. 1976), aff'd, 555 F.2d 1059 (D.C. Cir. 1977) (because FDA regulation was based on the agency's conclusion that "labeling which fails to meet the requirements of the regulation is misleading or otherwise not in compliance with the act," the regulation did not violate the first amendment).

The Supreme Court has labeled as misleading—and thus not protected—both speech that is inherently likely to deceive and that which "experience has proved * * * is subject to abuse." In re *R.M.J.*, 455 U.S. 191, 203 (1982). For example, in *Friedman* v. *Rogers*, 440 U.S. 1, 14–15 (1979), the Court held that Texas could prohibit the use of trade names by optometrists where there was a history of deception and abuse of the public. See also *Ohralik* v. *Ohio State Bar Association*, 436 U.S. 447, 468 (1978) (upholding State bar's rules against in-person solicitation where there was an inherent potential for abuse and prophylactic regulation was needed).

By enacting the 1990 amendments, Congress sought to ensure that food labeling, including express and implied nutrient content claims, would be accurate, uniform, and "based on science." 136 Congressional Record S16610 (Oct. 24, 1990) (statement of

Sen. Hatch). With respect to nutrient content claims, the principal problem that Congress sought to correct was the use of ambiguous, undefined claims like "light" and "low." See, e.g., 136 Congressional Record H5840 (July 30, 1990) (statement of Rep. Waxman). Experience had shown that consumers were being misled because these terms were being used differently by different manufacturers. Id.; 136 Congressional Record H12, 953–954 (Oct. 26, 1990) (statement of Rep. Madigan). Congress recognized that consumers were being hampered in their attempts to achieve a healthy diet by confusing implied nutrient content claims like "light." 136 Congressional Record H12954 (Oct. 26, 1990) (statement of Rep. Moakley).

Because of the misleading character of unregulated, nonstandardized nutrient content claims, Congress legislated that any claim that is not consistent with FDA regulations misbrands a food. Section 403(r)(2)(A)(i) of the act states that a food is misbranded if its label or labeling contains a claim that "expressly or by implication * * * characterizes the level of any nutrient * * * of the food *unless* the claim" complies with regulations promulgated by FDA (emphasis added). Section 403(r)(1)(A) of the act. By taking this approach, Congress chose to permit only those nutrient content claims that FDA defines or approves, effectively recognizing that unregulated claims mislead the public.

Particular attributes of unregulated nutrition claims on the food label make them inherently misleading. Because nutrition claims are of great importance to the public, they have a greater potential to be deceptive: Representations relating a product to an issue of public concern as a means to induce purchases may take on exaggerated importance in the public mind and thus be more likely to mislead. *FTC* v. *Pharmtech Research, Inc.*, 576 F. Supp. 294, 301 (D.D.C. 1983) (advertisements for food supplement were misleading where they "played on the average consumer's well-founded fear of cancer"). In addition, nutrient content claims on food labeling are difficult for consumers to verify independently. See *American Home Products* v. *FTC*, 695 F.2d 681, 698 (3d Cir. 1982); cf. *Peel* v. *Attorney Reg. & Disciplinary Commission*, 496 U.S. 91, 110 S. Ct. 2281, 2288 (1990) (a lawyer's certification is a "verifiable fact"). Finally, consumers place great reliance on the portions of the food label that they believe to be regulated by the Government. FDA's 1990 Health and Diet Survey, Division of Consumer Studies, CFSAN. Unapproved nutrient content claims that consumers assume to be consistent with government regulations are therefore more likely to be misleading. "Pervasive Government regulation * * * and consumer expectations about such regulation, create a climate in which questionable claims * * * have all the more power to mislead." *American Home Products* v. *FTC*, 695 F.2d at 697.

296. Many comments argued that nutrient content claims are only potentially misleading, pointing out that the Government may not absolutely prohibit potentially misleading speech if it can also be presented in a nondeceptive way. *Peel* v. *Attorney Registration & Disciplinary Comm'n*, 110 S. Ct. 2281, 2287 (1990); In re R.M.J., 455 U.S. 191, 203 (1982). The preferred remedy for potentially misleading speech, these comments stress, is not a prohibition but a requirement of disclaimers or explanation. In re *R.M.J.*, 455 U.S. at 203 (citing *Bates* v. *State Bar of Arizona*, 433 U.S. 350, 375 (1977)); see also *Peel*, 110 S. Ct. at 2292 (referring to "[t]he presumption favoring disclosure over concealment"). Comments argued that given the constitutionally based preference for more speech, rather than less, FDA should require disclaimers or explanations rather than prohibiting unapproved claims.

Even if unregulated nutrition claims are considered only potentially misleading, rather than actually or inherently misleading, these regulations are constitutional. The government may place restrictions on commercial speech that is merely potentially misleading. Such restrictions must directly advance a substantial governmental interest and be no more extensive than necessary to serve that interest. *Central Hudson Gas & Electric Corp.* v. *Public Service Commission*, 447 U.S. 557, 566 (1980). These regulations pass that test.

First, the government's interest is clearly substantial. The 1990 amendments and these regulations seek to ensure that consumers have access to nutrition information that is truthful, reliable, understandable, scientifically valid, and not misleading. This information will enable consumers to make more healthful food choices. The Supreme Court has recognized "the health, safety, and welfare of * * * citizens" as a substantial government interest. *Posadas de Puerto Rico Associates* v. *Tourism Co.*, 478 U.S. 328, 341 (1986). Moreover, consumers have a first amendment interest in obtaining information on which to base a decision whether to buy a product, and this interest is "served by insuring that the information is not false or deceptive." *National Commission on Egg Nutrition* v. *FTC*, 570 F.2d 157, 162 (7th Cir. 1977), cert. denied, 439 U.S. 821 (1978) "The fact that health is involved enhances the interests of both consumers and the public in being assured 'that the stream of commercial information flow[s] cleanly as well as freely.'" Id. (quoting *Virginia State Board of Pharmacy*, 425 U.S. at 772); *American Home Products*, 695 F.2d 681, 714. Moreover, FDA is implementing legislation whose purpose is "essential if the consumer is to obtain reasonable information regarding * * * the foods he buys." *American Frozen Food Institute* v. *Mathews*, 413 F. Supp. 548, 553 (D.D.C. 1976), aff'd, 555 F.2d 1059 (D.C. Cir. 1977).

Secondly, the regulations directly advance the government interest. Under the 1990 amendments and these regulations, FDA will define a nutrient content claim by regulation or make an administrative determination that a suggested claim is synonymous with a previously defined claim before permitting the claim to be used. In this way, the regulations will ensure that such claims are consistent, understandable, and do not confuse or mislead consumers. The regulatory scheme will also encourage companies to provide consumers with information that will enable them to improve their diets. There is an "immediate connection," *Central Hudson*, 447 U.S. at 569, between nutrient content claims on food labels and consumers' food choices.

Finally, these regulations are no more extensive than necessary to serve the Government's interest. Under *Board of Trustees* v. *Fox*, regulations that are narrowly tailored to serve the Government's interest will meet this prong of the *Central Hudson* test. 109 S. Ct. 3028, 3032–35 (1989). Narrow tailoring requires a reasonable fit between regulatory ends and means: "Not necessarily the single best disposition but one whose scope is 'in proportion to the interest served.'" Id. at 3035; see also *Ward* v. *Rock Against Racism*, 109 S. Ct. 2746, 2758 (1989) (a regulation is narrowly tailored if Government interest would be achieved less effectively without the regulation). These regulations reasonably and effectively ensure that nutrient content claims on food labels will be informative, consistent, and not misleading. Thus, they meet the third prong of the *Central Hudson* test and do not violate the first amendment.

FDA recognizes that the Government may not absolutely prohibit potentially misleading information if the information can also be presented in a

nondeceptive way. See In re *R.M.J.*, 455 U.S. 191, 203 (1982). The agency further acknowledges that the preferred remedy for potentially misleading speech is a disclaimer or explanation rather than a prohibition. Consequently, these regulations impose only those restrictions that are necessary to ensure that nutrient content claims are presented in a nondeceptive way. Conceding for the sake of argument that some unapproved claims are only potentially misleading, FDA has not outlawed the information conveyed by such claims; instead, the agency has prescribed that the information be presented in standardized form, using uniform, terms defined by the agency, so that consumers will not be misled.

297. Some comments argued that nutrient content claims, which help consumers to achieve healthy eating habits, convey information of general interest about nutrition and health. Thus, the comments argued, nutrient content claims are "pure" speech, not commercial speech, and as such are entitled to full first amendment protection.

FDA disagrees with these comments. As discussed above, FDA believes nutrient content claims belong to a distinct category of communications in which the government's power to regulate is broad. Under the comprehensive Federal scheme for the regulation of food and drugs, the Government has authority to impose incidental restrictions on food labeling, including nutrient content claims. As between commercial speech and "pure" speech, however, FDA believes nutrient content claims should be categorized as commercial speech. Labeling statements on food products intended for sale would clearly appear in the context of a commercial transaction and would "propose" such a transaction. See *Bolger* v. *Youngs Drug Products*, 463 U.S. 60, 66, 103 S. Ct. 2875, 2880 (1983); *Central Hudson Gas* v. *Public Service Commission*, 447 U.S. 557, 562 n.5, 100 S. Ct. 2343, 2349 n.5 (1980). A label is not entitled to the protection due noncommercial speech simply because it relates to an issue of broad public interest. See *Board of Trustees* v. *Fox*, 109 S. Ct. 3028, 3032 (1989); *Bolger*, 463 U.S. at 68, 103 S. Ct. at 2881; *Central Hudson*, 447 U.S. at 562 n.5, 100 S. Ct. at 2349 n.5. In determining whether the statements on a label are pure speech, it is irrelevant that they might be considered protected in other contexts. See *Zauderer* v. *Office of Disciplinary Counsel*, 471 U.S. 626, 637 n.7, 105 S. Ct. 2265, 2274 n.7 (1985). Just as informational pamphlets were considered commercial speech in *Bolger*, so too nutrient content claims on food labels, as between pure speech and commercial speech, should be considered commercial speech. See *Bolger*, 463 U.S. at 66–68, 103 S. Ct. at 288–81.

298. Several comments argued that the requirement that nutrient content claims be approved by FDA before they may be used places an unconstitutional prior restraint on expression. The agency, the comments reasoned, would be banning speech not previously determined to be false or misleading. The speech would remain banned until the agency defined the term at issue. Some comments further complained that the petition process is too burdensome. Citing *Space Age Products* v. *Gilliam*, 488 F. Supp. 775 (D. Del. 1980), one comment argued that "the public has an interest in minimizing the frequency and duration of erroneously imposed prior restraints on commercial speech." Id. at 784. This interest, according to *Gilliam*, mandates narrow tailoring of prior restraints on commercial speech and "such traditional safeguards with respect to these restraints as are not inconsistent with its ability to achieve its important and legitimate objectives." Id.

The Supreme Court has said that because commercial speech is not easily chilled, the heavy presumption against prior restraints may not apply to commercial speech. *Virginia State Board of Pharmacy*, 425 U.S. at 772 n.24. The Court has repeated its position on this subject since *Space Age Products* was decided. In Central Hudson, the Court remarked that the State could have required that ads for electricity be approved by the state before being used and reiterated that traditional prior restraint doctrine may not apply to commercial speech. *Central Hudson*, 447 U.S. at 571 n. 13.

Even assuming for the sake of argument that the presumption against prior restraints does apply to commercial expression, the agency believes that its regulations are constitutional because, as discussed more fully above, they limit only speech Congress has already determined to be misleading. This speech is therefore unprotected. See *American Frozen Food Institute v. Mathews*, 413 F. Supp. 548, 555 (D.D.C. 1976), aff'd, 555 F.2d 1059 (D.C. Cir. 1977) (FDA regulation based on agency's conclusion that labeling that fails to meet the requirements of the regulation is misleading or otherwise not in compliance with the act was not unconstitutional prior restraint). In addition, the regulatory scheme incorporates procedural safeguards that provide for a prompt determination of whether a particular claim is permissible. The agency is required to act on nutrient content claim petitions expeditiously. See section 403(r)(4)(A) of the act.

299. Some comments argued that the requirement that the proponent of an undefined claim submit a petition for its approval unconstitutionally shifts the burden of distinguishing misleading and nonmisleading speech from the Government to the speaker. See *Zauderer* v. *Office of Disciplinary Counsel*, 471 U.S. 626, 646 (1985). Even a showing that the speech has the potential to mislead does not allow the Government to shift that burden, one comment contended, citing *Peel* v. *Attorney Registration & Disciplinary Comm'n*, 110 S. Ct. 2281, 2292 (1990).

As discussed above, the Government has met its burden of showing that the speech being restricted is misleading. Congress made specific findings that both nutrient content claims in general and particular terms, such as "light," have misled the public. See, e.g., 136 Congressional Record H5840 (July 30, 1990) (statement of Rep. Waxman); id. at H5843 (statement of Rep. Cooper); 136 Cong. Rec. S16609 (Oct. 24, 1990) (statement of Sen. DeConcini). In addition, the comment misconstrues *Peel*. In that case, the Supreme Court said that a mere potential to mislead did not justify prohibition of the speech at issue. The Court did not say that the Government could not, based on a showing that a particular kind of speech had the potential to mislead the public, require preapproval of the speech.

300. Some comments suggested that the nutrient content claims regulations are unconstitutionally overbroad because, according to the comments, they reach a substantial amount of protected speech.

FDA disagrees. As discussed in detail elsewhere in this document, these regulations are narrowly tailored to meet a substantial government interest and do not "sweep[] within [their] prohibitions what may not be punished under the First * * * Amendment[]." *Grayned* v. *City of Rockford*, 408 U.S. 104, 115 (1972). In any event, it is doubtful that the overbreadth doctrine would apply to these regulations, particularly if they were considered to regulate commercial speech, because the overbreadth doctrine does not apply to commercial speech. *Village of Hoffman Estates* v. *Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 497 (1982); *Central Hudson*, 447 U.S. at 565 n.8.

301. One comment cited several lower court decisions involving food labeling and the first amendment to support its argument that these regulations are

unconstitutional. *Lever Bros.* v. *Maurer*, 712 F. Supp. 645 (S.D. Ohio 1989); *Taylor Wine Co.* v. *Department of the Treasury*, 509 F. Supp. 792 (D.D.C. 1981); *American Meat Inst.* v. *Ball*, 424 F. Supp. 758 (W.D. Mich. 1976); *Anderson, Clayton & Co.* v. *Washington State Dep't of Agric.*, 402 F. Supp. 1253 (W.D. Wash. 1975).

FDA disagrees with the comment's interpretation of these cases. *Anderson*, which predated *Virginia Pharmacy* and the Supreme Court's other commercial speech cases, struck down a State law prohibiting use of dairy terms in the advertising of margarine. The court mistakenly applied strict scrutiny to the statute, holding that the State must show a *compelling* government interest to justify restrictions on speech. 402 F. Supp. at 1257 (emphasis added). As discussed above, under current Supreme Court jurisprudence the Government need only demonstrate a substantial interest in regulating potentially misleading speech. *Central Hudson*, 447 U.S. at 564. If the speech is actually or inherently misleading, it may be prohibited or restricted on that basis alone. See *Peel*, 110 S. Ct. at 2292–93; In re *R.M.J.*, 455 U.S. at 203.

In *Lever Bros.* v. *Maurer*, which involved a similar statute prohibiting the use of "butter" in advertising for products intended as imitations of or substitutes for butter, the court held that prohibition of the term "butter" without regard for whether the term was used in a misleading way violated the first amendment. 712 F. Supp. at 652–653. Here, Congress has already found the labeling practices at issue to be misleading. In addition, here the Government's interest is not merely in accuracy, but also in uniformity. Standardizing the nutrition information that appears in food labeling, including nutrient content claims, will make it easier for consumers to find, understand, and compare the information they need to make healthy eating choices. No such government interest was present in *Lever Bros.*

Taylor Wine is also inapposite. That case involved a regulatory scheme that required preapproval of wine labeling. The challenge was not to the preapproval requirement itself, as here, but to the agency's refusal to approve a claim that it had conceded would not confuse or mislead consumers of the plaintiffs' wines. 509 F. Supp. at 795. In addition, the agency had conceded that the claim, which used the term "light," met the requirements established by the agency for use of that term. Id. at 793. Under the regulatory scheme at issue here, FDA will allow use of terms defined by FDA in nutrient content claims without preapproval.

Finally, in *American Meat Institute*, there was no first amendment challenge to the legislation at issue; rather, the first amendment was used to uphold the legislation against a preemption argument. The challenged legislation required meat producers whose products did not meet Michigan standards to notify Michigan consumers of that fact. The court upheld the law in part on the basis of the consumers' first amendment right to receive information. 424 F. Supp. at 769. The court further found that the State had a strong interest in consumer education and protection and suggested that striking down the statute might limit the State's communications with its citizens in violation of the first amendment. Id. at 767. The court said that the first amendment question that would arise if the Michigan law were preempted provided additional support for its holding that the notices required by the State were not "labeling" as defined in the Federal Wholesome Meat Act (21 U.S.C. 678). Id. at 769. Thus, far from serving to undermine the nutrient content claim regulations, *American Meat Institute*, if anything, supports them, since it recognizes consumers' strong interest in receiving accurate, useful information about food and the government's strong interest in ensuring that such information will be provided.

302. A number of comments argued that the rule prohibits certain nonmisleading uses of particular terms ("fresh" or "light") and types of claims (comparative statements or amount statements), and that such nonmisleading uses cannot constitutionally be prohibited.

FDA disagrees with the premise of these comments. As explained more fully above, Congress found that the unregulated use of undefined nutrient content claims is inherently and actually misleading. This final rule allows use of the referenced terms and types of claims, but only in ways that will inform the public rather than mislead it. The agency's response to the comments' suggestions concerning particular terms and types of claims can be found elsewhere in this document.

303. Two comments contended that with respect to certain types of nutrient content claims, FDA should use its authority under section 403(a)(1) of the act to regulate false and misleading claims on a case-by-case basis, rather than issuing regulations under the 1990 amendments. Specifically, the comments argued that statements of the amount or percentage of nutrients in foods (e.g., "contains 160 mg sodium") and certain ingredient claims that FDA has classified as implied nutrient content claims (e.g., "high in oat bran") should be regulated under section 403(a)(1) of the act rather than under the 1990 amendments.

FDA disagrees. Congress enacted the 1990 amendments because it found that existing law was insufficient to protect consumers from misleading food labeling practices. While FDA could have regulated deceptive nutrient content claims, including ingredient and amount claims, under section 403(a)(1) of the act, Congress considered FDA's authority to do so unclear and in need of strengthening. H. Rept. 101–538, 101st Cong., 2d sess. 7 (1990). Consequently, Congress passed new legislation directing FDA to issue new regulations that would curb deceptive food labeling. Congress specifically authorized FDA to issue regulations governing amount claims, see section 3(b)(1)(A)(iv) of the 1990 amendments, and also provided more generally for the issuance of regulations limiting the use of claims that expressly or by implication characterize the level of a nutrient required to be on the food label. See section 403(r)(1)(A) of the act. A claim that a food contains an ingredient associated with a particular nutrient by implication characterizes the level of that nutrient.

It is entirely appropriate for FDA to regulate ingredient and amount claims under the new regulations, which specifically target these claims, rather than under section 403(a)(1) of the act; indeed, FDA had no choice but to do so, given the congressional mandate. Moreover, the regulations themselves are narrowly tailored and do not prohibit nondeceptive speech.

304. Some comments asserted that FDA should not prohibit the use of undefined terms and should allow synonyms of FDA-defined terms as long as the synonyms meet the standard for the defined term.

Section 403(r)(2)(A)(i) of the act states that nutrient content claims may be made only if the characterization of the level made in the claim uses terms which are defined in regulations by the Secretary (and FDA, by delegation). This rule also applies to synonyms. See section 3(b)(1)(A) of the 1990 amendments. As discussed above, Congress was concerned about the proliferation of confusing and conflicting nutrient content claims; hence, it sought uniformity on the food label. Allowing unapproved terms and synonyms would undermine that goal. The petition process provided for in new § 101.69 allows anyone who wishes to suggest both new terms and

synonyms of already-defined terms. In light of Congress' findings and the availability of the petition process to expand the vocabulary of nutrient content claims, FDA does not believe its regulations unduly burden expression.

305. One comment proposed that FDA permit the use of unapproved nutrient content claims if they are consistent with and explained by an immediately adjacent term that is defined by regulation. The comment argued that this solution would cure the first amendment infirmity caused by the prohibition of unapproved claims yet would fulfill the goals of the 1990 amendments.

The agency rejects this suggestion because it would lead to the same kind of inconsistent use of terms that Congress wanted to eradicate. For example, one company might use "lean" as a synonym for "light," while another might use it as a synonym for "low fat." Thus, "lean" would be used in contradictory ways on different products. Such a result is not permissible under the act. As discussed above, the agency does not believe that its approach is constitutionally infirm.

306. In response to FDA's request for comments as to whether it should define "natural" or ban such claims entirely on the ground that they are false or misleading, one company argued that prohibition of "natural" would be an unconstitutional restriction on free speech. FDA has decided not to define the term "natural" or to prohibit its use. Therefore, this comment is moot.

307. One comment asserted that because those who violate the act are subject to criminal prosecution, FDA must define clearly which nutrient content claims are allowable. The comment further argued that a manufacturer who uses a term not intended as a nutrient content claim may learn, too late, that FDA so interprets it as such.

The comment seems to be invoking the vagueness doctrine, which, in the first amendment context, is generally applied to strike down prohibitions on speech that leave individuals without clear guidance on the type of speech that is prohibited. See, e.g., *Village of Hoffman Estates* v. *Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498—99 (1982); *Grayned* v. *City of Rockford*, 408 U.S. 104, 108 (1972). That is not the case here. Only approved nutrient content claims will be permitted on the food label, and all other nutrient content claims will misbrand a food. It should thus be clear which type of speech is prohibited and which permitted. Manufacturers will be on notice that the use of an unapproved nutrient content claim is prohibited conduct.

As to the comment's second point, FDA agrees that it is important to consider intent when determining whether an implied nutrient content claim has been made. However, the agency notes that intent means more than the manufacturer's subjective intent. "FDA is not bound by the manufacturer's subjective claims of intent * * *." *National Nutritional Foods Ass'n* v. *Mathews*, 557 F.2d 325, 334 (2d Cir. 1977). An article's intended use is established by its labeling, promotional material, advertising, and "any other relevant source." Id.; *United States* v. *An Article * * * Consisting of 216 Individually Cartoned Bottles * * * "Sudden Change,"* 409 F.2d 734, 739 (2d Cir. 1969). If a phrase on a food label meets the definition of an implied nutrient content claim, it is such a claim regardless of the manufacturer's subjective intent. The definition of an implied nutrient content claim is clear from the statute as interpreted by the regulations. See section 403(r)(1)(A) of the act; new § 101.13(b). Manufacturers are required to keep abreast of changes in the law and are responsible for scrutinizing their labeling to determine whether it makes nutrient content claims.

B. The Fifth Amendment

These regulations will affect some companies' use of brand names, including names subject to trademarks. A brand name that includes an FDA-defined nutrient content claim, such as "light," will be permitted to appear only on products that meet the regulations' definition of "light." Brand names that include nutrient content claims that FDA has not defined will not be permitted unless they were in use before October 25, 1989, the date the 1990 amendments were reported out of committee, or unless a petition for their use is submitted and approved.

308. Some comments contended that outlawing a brand name could violate the fifth amendment. Because brand names are property, banning their use could constitute a taking without just compensation, these comments argued. The comments suggested that in keeping with Executive Order No. 12630, FDA should conduct a takings analysis to assess whether compensation to owners of affected brand names would be appropriate.

In its November 27, 1991, regulatory impact analysis (RIA), 56 FR 60856 at 60865, FDA stated that any alteration of trade names required by the new regulations would not constitute a taking, and that, as a result, no takings analysis was necessary. In view of the comments and concerns raised about the takings issue, however, the agency reconsidered and decided that it was appropriate to conduct a formal takings analysis pursuant to Executive Order No. 12630. The agency has completed the takings analysis and still believes that there is no regulatory taking under the fifth amendment if a manufacturer is required to alter its brand name when that brand name asserts, expressly or by implication, a nutrient content claim that has not been approved by FDA. The basis for this conclusion is set forth in response to the comment that follows.

309. Comments from industry argued that the regulations' effect on companies' ability to use brand names constitutes a taking without compensation in violation of the fifth amendment of the U.S. Constitution. They point foremost to the financial consequences of losing the use of a valuable brand name. Standing alone, however, diminution in property value does not establish a taking. *Penn Central Transp. Co.* v. *City of New York*, 438 U.S. 104, 131 (1978). Indeed, "[g]overnment hardly could go on if to some extent values incident to property could not be diminished without paying for every such change in the general law." *Pennsylvania Coal Co.* v. *Mahon*, 260 U.S. 393, 413 (1922).

The Supreme Court has identified three factors for courts to consider in assessing whether a regulatory taking has occurred: (1) The character of the governmental action; (2) the extent to which a regulation interferes with reasonable investment-backed expectations; and (3) the regulation's economic impact. *Ruckelshaus* v. *Monsanto Co.*, 467 U.S. 986, 1005 (1984); *Penn Central*, 438 U.S. at 124. When examined in light of these three factors, it is clear that FDA's regulations do not effect a taking in violation of the Constitution.

With respect to the first factor, courts are more likely to find a taking when the interference with property can be characterized as a physical invasion by the Government than when the interference is caused by a regulatory program that "adjust[s] the benefits and burdens of economic life to promote the common good." *Penn Central*, 438 U.S. at 124. Courts have accorded particular deference to governmental action taken in order to protect the public interest in health, safety, and welfare. See *Keystone Bituminous Coal Ass'n* v. *DeBenedictis*, 480 U.S. 470, 488 (1987); *Penn Central*, 438 U.S. at 125; *Atlas Corp.* v. *United States*, 895 F.2d 745, 757 (Fed. Cir.), cert. denied, 111 S. Ct. 46 (1990);

Calvert Invs. v. *Metro. Sewer Dist.*, 847 F.2d 304, 309 (6th Cir. 1988).

With the 1990 amendments and these regulations, Congress and FDA seek to protect the public interest in health by ensuring that consumers who wish to maintain healthy dietary practices may be assisted in doing so by the information on food labels. This action constitutes a reasonable effort by the Government to promote the common good. By defining nutrient content claims, the regulations will "bring a sense of order to the understanding of terms used when describing characterizations of food products." 136 Congressional Record S16610 (Oct. 24, 1990) (statement of Sen. Hatch). By permitting approved nutrient content claims, the regulations seek to provide useful information to consumers while ensuring that the information is not confusing or misleading. 136 Congressional Record H12954 (Oct. 26, 1990) (statement of Rep. Moakley). These regulations substantially advance and are rationally related to FDA's legitimate interest in promoting the public health through the food label. See *Keystone*, 480 U.S. at 485; *Monsanto*, 467 U.S. at 1007; see also *Pace Resources, Inc.* v. *Shrewsbury Township*, 808 F.2d 1023, 1030 (3d Cir.) ("[T]he governmental action is entitled to a presumption that it does advance the public interest."), cert. denied, 482 U.S. 906 (1987).

Although these regulations will restrict the use of certain defined terms, including terms that appear in some trade names, this restriction does not rise to the level of a taking. Governmental restrictions on the uses individuals can make of their property are "properly treated as part of the burden of common citizenship." *Keystone*, 480 U.S. at 491 (citation omitted). These burdens are "borne to secure 'the advantage of living and doing business in a civilized community.'" *Andrus* v. *Allard*, 444 U.S. 51, 67 (1979) (quoting *Pennsylvania Coal Co.* v. *Mahon*, 260 U.S. 393, 422 (1922) (Brandeis, J., dissenting)). Moreover, these regulations are not without benefit to manufacturers. See *Keystone*, 480 U.S. at 4[illegible] ("While each of us is burdened somewhat by such restrictions, we, in turn, benefit greatly from the restrictions that are placed on others."); see also *Penn Central*, 438 U.S. at 134 ("preservation of landmarks benefits all * * * citizens and all structures"). By defining certain terms, the regulations will increase the reliability of the food label and thus will bolster consumer confidence in label statements. They will also level the commercial playing field: No manufacturer will be able to use a defined term unless its use is consistent with the definition.

The second factor that courts consider is whether a company has a reasonable investment-backed expectation in continuing to use its brand name. To be reasonable, expectations must take into account the power of the State to regulate in the public interest. *Pace Resources*, 808 F.2d at 1033. Reasonable expectations must also take into account the regulatory environment, including the foreseeability of changes in the regulatory scheme. "In an industry that long has been the focus of great public concern and significant government regulation," *Monsanto*, 467 U.S. at 1008, the possibility is substantial that there will be modifications of the regulatory requirements. "Those who do business in the regulated field cannot object if the legislative scheme is buttressed by subsequent amendments to achieve the legislative end." *Connolly* v. *Pension Benefit Guar. Corp.*, 475 U.S. 211, 227 (1986) (citation omitted); cf. *Lucas v. South Carolina Coastal Council*, 112 S. Ct. 2886, 2899 (1992) ("[I]n the case of personal property, by reason of the State's traditionally high degree of control over commercial dealings, [the property owner] ought to be aware of the possibility that new regulation might even render his property economically worthless * * * ."). Participants in a highly regulated industry are "on notice that [they] might be subjected to different regulatory burdens over time." *California Housing Secs., Inc.* v. *United States*, 959 F.2d 955, 959 (Fed. Cir. 1992), petition for cert. filed, 61 U.S.L.W. 3083 (U.S. July 22, 1992). In contrast, a regulatory scheme that appears suddenly may interfere with a company's reasonable expectations. Id.

It is not reasonable for a company to expect to be able to continue indefinitely to use a brand name that contains a defined nutrient content claim. Such an expectation would ignore FDA's power to regulate the food label, the regulatory environment of the food industry, and the foreseeability that FDA would regulate health and content claims on the food label.

FDA's authority to regulate the food label is broad and longstanding. Governmental authority to regulate the food label has long been recognized. For example, the Supreme Court stated in 1919 that "it is too plain for argument that a manufacturer or vendor has no constitutional right to sell goods without giving to the purchaser fair information of what it is that is being sold." *Corn Products Refining Co.* v. *Eddy*, 249 U.S. 427, 431 (1919). With the 1990 amendments, Congress did not suddenly grant the agency new authority of the sort that interfered with a company's reasonable expectations about the way the food label would be regulated, see *California Housing Secs.*, 959 F.2d at 959, but rather clarified FDA's authority to define nutrient content claims. The authority granted by the 1990 amendments was consistent with FDA's existing power over the food label. For example, FDA already had authority to define common or usual names for food and to set standards of identity. See, e.g., *American Frozen Food Inst.* v. *Mathews*, 413 F. Supp. 548 (D.D.C. 1976), aff'd, 555 F.2d 1059 (D.C. Cir. 1977). Moreover, under preexisting authority—e.g., sections 201(f) and (n) and 403(a) and (j)—the agency had regulated or taken steps to regulate nutrient content claims on the food label. Although FDA had earlier regulated the use of certain nutrient content claims, the 1990 amendments gave the agency specific authority to define terms such as "light" and "low" consistently across product categories. See, e.g., 136 Congressional Record H12953–54 (Oct. 26, 1990) (statement of Rep. Madigan).

Moreover, the food industry is highly regulated. Companies are well aware that they operate subject to the restrictions of the act. Like other regulatory schemes, the act has not been static, see *California Housing Secs.*, 959 F.2d at 959, and companies that are subject to the act should understand the possibility that its requirements will evolve over time. The food industry has long been "the focus of great public concern and significant government regulation," and "the possibility was substantial" that the government would, "upon focusing on the issue," decide that the actions now being undertaken are in the public interest. *Monsanto*, 467 U.S. at 1009.

Not only was the industry on notice that the regulatory scheme under which it operated might be amended, but it also had specific notice of the type of action FDA might take with respect to the food label. FDA promulgated regulations on the use of certain nutrient content claims years before the 1990 amendments were passed. The terms "sodium free," "very low sodium," "low sodium," and "reduced sodium" are defined in current § 101.13. Current § 101.25 governs information that may appear on food labels regarding fat, fatty acid, and cholesterol content. Current § 105.66 controls the use of the claims "low calorie," "reduced calorie," and "sugarfree." It would be unreasonable for a company to expect that the agency would forever

refrain from further regulation of nutrient content claims.

Thus, companies that use brand names that contain express or implied nutrient content claims lack a reasonable investment-backed expectation that they will be able to continue to use those names. Only with the passage of the 1990 amendments and the publication of these final rules does the possibility arise that a company might have a reasonable investment-backed expectation in continuing to use an approved claim. See *Ruckelshaus* v. *Monsanto Co.*, 467 U.S. at 1010–1013.

The final factor that courts consider is the economic impact of the governmental action. "There is no fixed formula to determine how much diminution in market value is allowable without the Fifth amendment coming into play." *Florida Rock Industries, Inc.* v. *United States*, 791 F.2d 893, 901 (Fed. Cir. 1986), cert. denied, 479 U.S. 1053 (1987). It is clear, however, that a regulation's economic impact may be great without rising to the level of a taking. See *Pace Resources*, 808 F.2d at 1031 (citing *Hadacheck* v. *Sebastian*, 239 U.S. 394 (1915) (reduction in value from $800,000 to $60,000); *Euclid* v. *Ambler Realty Co.*, 272 U.S. 365 (1926) (75 percent diminution in value)). Mere denial of the most profitable or beneficial use of a property does not require a finding that a taking has occurred. *Tirolerland, Inc.* v. *Lake Placid 1980 Olympic Games, Inc.*, 592 F. Supp. 304, 313 (N.D.N.Y. 1984); see also *Andrus* v. *Allard*, 444 U.S. 51, 66 (1979); *Florida Rock*, 791 F.2d at 901. Rather, courts look for extensive or drastic interference with a property's possible uses. See *Pace Resources*, 808 F.2d at 1031.

In assessing whether a regulation effects a taking, the Supreme Court has considered whether the regulation denies an owner the "economically viable" use of its property. See, e.g., *Keystone*, 480 U.S. at 499. This analysis involves looking not just at what has been lost, but at the whole "bundle" of property rights. *Andrus* v. *Allard*, 444 U.S. at 65–66. Courts focus on the remaining uses permitted and the residual value of the property. *Pace Resources*, 808 F.2d at 1031. Although it is undeniable that compliance with these regulations will cost money and may mean that certain product names must be altered, companies will not be denied the economically viable use of their property.

Many firms will be able to minimize the regulations' impact by reformulating those products that do not meet the regulations' definitions. These reformulated products could continue to bear the original brand name. Reformulation may be costly, but it is not the kind of economic impact that leads to a taking. "Requiring money to be spent is not a taking of property." *Atlas Corp.*, 895 F.2d at 756. Nor may companies argue, as one comment did, that their legal and other costs of seeking compensation for losses from these regulations should be included in the assessment of economic impact. These costs are not included in calculating just compensation under the fifth amendment. *United States* v. *Bodcaw Co.*, 440 U.S. 202, 203 (1979); *United States* v. *101.80 Acres*, 716 F.2d 714, 717 n.5 (9th Cir. 1983).

Other companies may be able to continue using their brand names with some, but not all, of their products. These companies will retain a residual economically viable use of their brand names. These companies will retain the ability to use their brand names on some of their products. Those with trademarks will also retain the important right to prevent other companies from marketing under the protected name. See *PruneYard Shopping Center* v. *Robins*, 447 U.S. 74, 82 (1980) ("[O]ne of the essential sticks in the bundle of property rights is the right to exclude others."). They would, moreover, be able to market new products that meet the applicable definition under the brand name. And finally, those foods that could not be marketed under the original brand name may continue to be sold under another name that does not violate the regulations.

It is unlikely that these regulations will force any company to stop using a brand name entirely. However, even if these regulations do have such an effect, the economic impact of this loss, without more, would not establish a taking: It is also critical to consider the character of the Government's action and its interference with reasonable investment-backed expectations. In addition, a company in this position lacks a property right to continue marketing a product under a defined term that its food does not meet. See 56 FR 60856 at 60865, November 27, 1991. For example, a food that bears a "light" claim but does not meet the definition of "light" and cannot be reformulated as a "light" product is not light and should not be called "light." Such a product is misbranded not only under section 403(r) of the act but also under section 403(a)—that is, even before the passage of the 1990 amendments, its labeling was false or misleading and in violation of the act. See *Lucas* v. *South Carolina Coastal Council*, 112 S. Ct. 2886, 2901 (1992) ("The use of these properties for what are now expressly prohibited purposes was always unlawful * * *.").

310. One comment inquired why, if so many misbranded products were on the market before the 1990 amendments, FDA did not take action to stop the misbranding.

In fact, FDA did send warning letters to a number of manufacturers who were making misleading claims. In virtually all of these cases, the manufacturer removed the misleading claim from the product. The agency would have done more but for lack of resources. In addition, consumer confusion resulted as much from the lack of any defined standards for claims as from individual claims that were objectionable. To solve the problem, it was necessary to address it globally by developing a regulatory scheme designed specifically for nutrient content claims.

311. One comment argued that to avoid an unnecessary taking, the agency should interpret section 403(r)(2)(C) of the act (the grandfather clause) to apply to product line extensions. The comment asserts that section 403(r)(2)(C) of the act is ambiguous and reads FDA's proposed implementing regulation (proposed § 101.13(o)(1)) to extend grandfathering to new products introduced under an existing brand name.

FDA does not believe the grandfather clause is ambiguous but has revised its regulation (new § 101.13(p)(1)) to clarify that the grandfather clause does not apply to product line extensions. The grandfather clause provides that unapproved nutrient content claims that are part of the brand name of a food are permitted if the brand name was in use *on the food* before October 25, 1989—not if the brand name was being used on some other food before that date (emphasis added). Therefore, new products introduced under the same brand name are not covered. Any company that started using a preexisting brand name on a new product after the grandfather date did not have a reasonable expectation of being able to use the name on that product. Therefore, the regulation does not effect a taking.

312. Another comment contended that the wording of the grandfather clause demonstrates that a product whose brand name includes an undefined nutrient content claim is not necessarily misbranded under section 403(a) of the act, which proscribes false and misleading labeling. The comment reasoned that, where there are two brand names that contain the same undefined claim—one grandfathered, one not—it would be absurd to say that

the nongrandfathered brand name is misleading, but that the grandfathered brand name is not.

The agency agrees that a grandfathered brand name is not necessarily false or misleading under section 403(a) of the act, nor is a nongrandfathered brand name that makes the same claim. A product with a nongrandfathered brand name that makes an unapproved nutrient content claim is misbranded under the 1990 amendments, however, because they prohibit the use of undefined claims. See section 403(r)(1)(A) of the act. Moreover, after the claim has been defined, both the grandfathered and nongrandfathered product will be misbranded under both section 403(a) of the act and the 1990 amendments if they do not conform to the definition. (See section 403(r)(2)(C).)

It should be noted that Congress did not make a judgment as to whether grandfathered brand names are misleading or nonmisleading; rather, it decided not to disrupt the market until FDA had a chance to define the terms used in grandfathered brand names. There is no taking of an undefined, nongrandfathered brand name because companies had no reasonable investment-backed expectation of being able to use undefined claims after the 1990 amendments were reported out of committee.

It should be pointed out that it is the statute, not FDA's regulations, that forbids the use of undefined terms in nutrient content claims.

313. The same comment argued that because the Patent Office considers the comment's trademark nondeceptive, the company has a reasonable, investment-backed expectation of being able to use the trademark.

The agency disagrees. FDA, not the Patent Office, has primary expertise in food labeling, and FDA does not consider itself bound by the Patent Office's decision as to whether a trademark is misleading.

314. Two comments argued, citing FTC case law, that the policy of the law to preserve trade names protects them from destruction if less drastic means would prevent deception. See *Jacob Siegel Co.* v. *FTC*, 327 U.S. 608, 612 (1946); *FTC* v. *Royal Milling Co.*, 288 U.S. 212, 217 (1932). The comments argued that prohibiting certain brand names is inappropriate because deception can be prevented by adding disclaimers or explanations to the brand names. One comment said the cited cases are rooted in takings doctrine. The other asserted that these cases are based on first amendment principles. See *Beneficial Corp.* v. *FTC*, 542 F.2d 611, 620 (3d Cir. 1976), cert. denied, 430 U.S. 983 (1977).

FDA disagrees with these comments. According to *Jacob Siegel Co.*, whether prohibition of a trade name is necessary "is a question initially and primarily for the [agency] * * * [which] is the expert body to determine what remedy is necessary to eliminate the unfair or deceptive trade practices which have been disclosed." 327 U.S. at 612. In another case, the Supreme Court upheld the prohibition of a trade name when, in the agency's judgment, the prohibition was necessary to prevent deception. *FTC* v. *Algoma Lumber Co.*, 291 U.S. 67, 81–82 (1934). With respect to food labeling, no disclaimer or explanation could eliminate the deceptive effect of a brand name that incorporates an FDA-defined term if the food on which the brand name appears does not meet the definition of that term.

The Supreme Court recently acknowledged the protection given to trade names in *Jacob Siegel* and *Royal Milling*, which were decided under section 5 of the Federal Trade Commission Act (15 U.S.C. 45) (the FTC act), but also recognized that those decisions rested on statutory—not constitutional—grounds. The court made clear that the holdings of those decisions do not carry over to cases decided on first amendment principles alone:

> [T]here is no First Amendment rule, comparable to the limitation on § 5, requiring a State to allow deceptive or misleading commercial speech whenever the publication of additional information can clarify or offset the effects of the spurious communication.

Friedman v. *Rogers*, 440 U.S. 1, 12 n.11 (1979). Like the first amendment, the act contains no limitation comparable to section 5 of the FTC act.

Finally, FDA is not bound to follow FTC case law. Although cases involving FTC may sometimes be relevant, it is important to note that fundamental differences exist between the regulatory schemes administered by the two agencies. See *Bristol-Myers Co.* v. *FTC*, 738 F.2d 554, 559 (2d Cir. 1984), cert. denied, 469 U.S. 1189 (1985). Congress has long recognized the division of roles between the two agencies. See 79 Congressional Record 4749 (1935), reprinted in "Federal Food, Drug, and Cosmetic Act: A Statement of its Legislative Record" 280–81 (Charles W. Dunn ed., 1938) (statements of Senators Copeland and Austin) (FTC concentrates on the interests of commerce and economic needs, whereas the objective of FDA is "the health of the people"). The FTC regulates unfair competition and trade practices, including food advertising. See, e.g., 15 U.S.C. 45 and 52. In contrast, FDA is a scientific agency empowered to regulate the food label, among other things. Thus, FTC case law does not govern FDA regulation.

VII. Other Issues

315. One comment stated that because of the range of meanings already attached to terms such as "light," "low," "free," "source of," and "reduced," FDA's attempt to define such terms will not be completely successful at eliminating confusion. The comment suggested that a better approach would have been for FDA to create a set of terms, either chosen from words not currently used in relationship to food or completely made up, to attach to their definitions instead of attempting to define terms already in vogue.

In response to this comment addressing the agency's basic approach to defining terms used to make nutrient content claims, the agency advises that many of the terms that it is defining are those that the 1990 amendments require the agency to define. Section 3(b)(1)(A)(iii) of the 1990 amendments directs the agency to define the terms "free," "low," "light" or "lite," "reduced," "less," and "high" when these terms are used to characterize the level of any nutrient in food, unless it finds that the use of such terms would be misleading. The agency has not found that any of these terms are misleading per se, although some consumer confusion as to their meanings may exist as a result of the variety of ways in which they have been used in the marketplace. Providing regulatory definitions for these terms that must be used by any manufacturers that use these terms in their labeling should alleviate or eliminate confusion. Therefore, the agency does not have the prerogative of creating a set of terms for nutrient content claims that have not previously been associated with claims for food as the comment suggested.

316. One comment stated that nutrient content claims such as "free," "low," and "reduced" should be defined for modified lactose levels in foods.

The agency does not agree with this comment. These regulations are intended to define nutrient content claims for categories of nutrients or individual nutrients that are required for maintaining a diet that meets current dietary guidelines (e.g., fiber, cholesterol, and fat). Lactose, a sugar that occurs in milk, is not a nutrient addressed in current dietary guidelines. However, labeling in regard to the lactose content of a food does have

significance for individuals who cannot tolerate this nutrient. FDA advises that provisions for the labeling of hypoallergenic foods are in § 105.62.

317. A comment stated that someone will still have to "educate" consumers about the meaning of the terms that FDA is defining. Another comment recommended that since terms are meaningless without the definitions to help distinguish among them, glossaries of allowed nutrient content claims should be available at points of purchase in the form of posters and free pamphlets. An alternative suggested in the comments was to abandon the effort to simplify nutrition information for consumers, to disallow claims on labels, and to educate consumers to interpret nutrition labels.

FDA does not agree that it should disallow claims on labels and instead only educate consumers to interpret nutrition labels. FDA believes that claims serve to highlight important nutritional aspects of foods, and as a result, they assist consumers in the identification and selection of foods that are useful for meeting dietary goals.

FDA agrees that educational programs will be necessary to develop consumer and industry understanding of the regulatory definitions. Section 2(c) of the 1990 amendments calls for activities that educate consumers about nutrition information on the food label and the importance of that information in maintaining healthy dietary practices. To achieve this purpose, FDA and USDA have jointly initiated a multi-year food labeling education campaign. The major goals of this campaign are to: (1) Increase consumers' knowledge and effective use of the new food label and to assist them in making accurate and sound dietary choices; (2) to integrate food labeling education into existing and new nutrition and health education programs; and (3) to build extensive partnerships capable of developing and evaluating labeling education targeted to the dietary needs of diverse populations, such as low literacy consumers, minorities, older Americans, children, and people with dietary restrictions.

As part of this effort, the agencies have established the National Exchange on Food Labeling Education which includes an information center housed in the Food and Nutrition Information Center at the National Agricultural Library. It provides the general public and professionals with access to information about food labeling research and educational activities (projects, programs, and materials) from both the public and private sector. Together, the agencies will facilitate cooperative projects with diverse organizations and the communication of information that targets various subpopulations as well as the general public. Thus, the agencies are developing an extensive food label education network that includes consumers; health professionals and organizations; educators; trade associations; Federal, State, and local governments and many others, to assist in the dissemination and development of information and activities.

To ensure that consumers have accurate and adequate resource materials and information, the agencies have begun, and will continue to: (1) Conduct and report on existing and planned food labeling research; (2) develop education initiatives at the national and local levels; (3) hold regularly-scheduled meetings to build labeling education exchanges; (4) produce video news releases and longer videos; and (5) produce an array of public education materials, including a special edition of *FDA Consumer* magazine that summarizes the final food labeling regulations, and brochures (in English and other languages) on the new label and how to use it to meet the Dietary Guidelines for Americans. These materials will be targeted to the general public, nutritionists, such special groups as ethnic minorities, and others. Organizations will also be able to use these resource materials to develop educational materials of their own.

318. Several comments stated that the proposed rules define claims so narrowly and require such burdensome disclosure requirements that manufacturers would have little or no incentive to develop new nutritionally improved products to qualify for nutrient content claims, to make substantial investments in research and development, or to develop the supporting manufacturing marketing capabilities.

The agency agrees that new products that are truly nutritionally improved can make positive contributions to public health. Thus, FDA is sensitive to the concerns raised by the comments that the proposed definitions could inhibit innovation. In response, FDA has attempted in the final regulations to make the definitions more flexible, while at the same time ensuring that the terms will be useful in maintaining healthy dietary practices and will be used in a manner that is truthful and not misleading. FDA believes that the final regulations, as revised, will stimulate innovation in food product research and the development of new versions of foods and food formulations that will meet the definitions, because nutrient content claims are an important aspect of a product's marketability.

319. Several industry comments stated that because these regulations depart significantly from the European Community (EC) nutrition labeling directive and from the Food Agricultural Organization/World Health Organization (FAO/WHO) Codex International recommendations, they will impede the resolution of differences under the General Agreement on Tariff and Trade.

The agency recognizes that the 1990 amendments and substantive provisions of these regulations are not in complete accord with the FAO/WHO Codex food labeling regulations or with regulations or directives of the EC or other countries. The agency also recognizes that this is an area that the FAO/WHO Codex has not yet addressed. Therefore, the regulations may have an impact on the resolution of issues related to international trade. However, these regulations are fully responsive to the 1990 amendments. The agency believes that these regulations will provide U.S. consumers with accurate and reliable information, information that consumers in other countries could use and may demand of their food regulators. The agency believes that the principles of these regulations may be adopted by other countries and serve as a basis for harmonization. This agency is committed to working with representatives of other nations and international organizations to achieve the greatest degree of harmonization possible.

VIII. Terms that Describe Other Aspects of Food

A. "Fresh" and Related Terms

The 1990 amendments do not require that FDA define labeling terms such as "fresh" that do not make nutrient content claims. However, the continued misuse of "fresh" and related terms in the marketplace, and the consumer confusion that has resulted, led the agency to propose definitions in the general principles proposal that establish labeling regulations to govern the use of "fresh," "freshly——" (e.g., "freshly baked"), and "fresh frozen" as they appear on the label or in the labeling of foods, including the use of these terms in brand names and as sensory modifiers (fresh tasting) (56 FR 60421 at 60462).

FDA also identified several questions in the general principles proposal regarding the use of the term "fresh" and solicited comments on whether these should be addressed in the final rule. The agency asked whether: (1) It

should allow the use of the term "fresh" to describe certain raw foods that have been treated with ionizing radiation in accordance with § 179.26 (21 CFR 179.26), specifically, those foods where irradiation at a maximum dose of 1 kiloGray (100 kilorads) is permitted; (2) it is appropriate to limit use of the term "freshly —— " to foods that are available for sale within 24 hours of preparation as the agency proposed, or whether other approaches to defining this term should be considered and incorporated into the final rule; (3) it would be misleading to allow the use of the term "freshly prepared" to describe recently prepared foods that contain processed ingredients; (4) it is important to the consumer to be able to distinguish between processed products made with fresh, as opposed to processed ingredients, and whether FDA should permit the use of a factual statement such as "spaghetti sauce—made with fresh mushrooms" on processed foods made from fresh as opposed to processed fruits and vegetables. Related to this issue, FDA requested comments on whether the inclusion of blanching as part of a continuous process at a facility should preclude labeling the ingredient as fresh; (5) the use of remanufactured ingredients affects the attributes of a finished product, such as a tomato product, to such a degree that the consumer is misled about the product if its labeling does not specifically declare the remanufactured nature of the ingredient. The agency asked whether it should require the use of a term such as "reconstituted," "remanufactured," or "made from concentrate" on the PDP of processed products made from remanufactured ingredients; and (6) extended shelf life foods merit the use of the term "freshly prepared," and if so, what factors should be considered to ensure that the term is not used in a misleading manner.

320. Several comments objected to the agency issuing a regulation that would define "fresh" and related terms while it is implementing the mandatory requirements of the 1990 amendments. These comments argued that a regulation governing the use of the term "fresh" is not mandated by the 1990 amendments and does not meet the President's reform directive of January 28, 1992. Some of these comments urged FDA to defer rulemaking on use of the term "fresh" until after it completes the mandatory rulemaking required by the 1990 amendments.

The agency does not agree that it should defer rulemaking to define "fresh." Although the 1990 amendments do not require the agency to define the term "fresh," FDA believes that a definition for certain uses of the term "fresh" is necessary because the term has been continuously misused in certain contexts. FDA concludes that a regulatory definition will discourage such misuse and will allow the agency to efficiently enforce the misbranding provisions of the act, particularly section 403(a) of the act, when the term is misused.

In issuing regulations concerning use of the term "fresh," the agency has also taken into account the requirements outlined in the President's reform directive regarding burdensome government regulations. Having concluded that it is necessary to promulgate regulations concerning use of the term "fresh," the agency considers that taking such action at this time is the most cost effective option because any required labeling changes that result from this action can be accomplished simultaneously with the label changes required by the 1990 amendments.

321. Comments addressing the proposed definition for the term "fresh" expressed widely diverse views on this subject. The agency received comments that supported the proposed definition, suggested alternatives to it, opposed the provision as proposed, or opposed FDA defining the term altogether.

Comments suggested that "fresh" should be defined as recently made, produced, or harvested foods that are not stale, spoiled, or withered. Numerous comments suggested that in addition to defining "fresh" as meaning raw and unprocessed, the term can also be associated with product quality, and therefore, a case-by-case determination may have to be made to determine where misleading uses of "fresh" have occurred rather than establishing one definition for the term. Some other comments contended that "fresh" has various meanings, and that the context in which it is used should ultimately dictate its meaning. One comment argued that the term "fresh" should be defined in such a way to distinguish between "garden fresh" and "market fresh."

Some comments that favored a regulation to govern the use of "fresh" suggested that the term should not refer to products prepared from concentrates, to commercially packed pasteurized products, or to products that are stored in cold storage warehouses until they are marketed. Some of these comments also stated that raw produce that has been trimmed or cut into smaller pieces should not be precluded from being described as fresh.

Some comments suggested that the proposed definition was too restrictive and did not consider the many ways consumers use and understand "fresh" because, as defined in the proposal, the term could only be used to describe raw, unprocessed foods. For example, these comments pointed out that, as proposed, the term "fresh" could not be used to describe some foods that are generally accepted by consumers as "fresh," such as fresh bread and pasteurized milk.

Some comments argued that there are numerous consumer perceptions associated with the term, and therefore, it is impossible to derive one definition that is universally acceptable. Another comment suggested that FDA should not permit the use of the term "fresh" on food labels because it is too difficult to define the term in a manner that would encompass all of the ways consumers use and understand it.

The volume of comments that expressed significantly different conceptions about the term "fresh," and that expressed reservations about the proposed definition of "fresh," has led FDA to reconsider this provision. FDA has been persuaded that the proposal was too restrictive, because it did not allow for various contexts in which "fresh" is appropriately used and would have disallowed uses of this term that are not misleading and are widely accepted by consumers ("fresh bread"). After considering all of the comments, FDA concludes that it is not necessary to establish a definition for "fresh" that would address all uses of this term as the proposal would have done.

However, FDA concludes that a definition for "fresh" is necessary to preclude the types of misuses of the term that the agency most frequently encounters, i.e., use of the term to imply that a product is unprocessed, when in fact it has been processed. The definition has particular applicability where there are processed and unprocessed forms of the food available. The use of the term "fresh" would imply that the food is the unprocessed form. If this is not the case, the food is misbranded. Therefore, FDA has revised the definition of "fresh" in § 101.95(a) so that it retains the same criteria that were in the proposal, but it only applies the criteria when the term "fresh" is used in a manner that suggests or implies that the food is unprocessed.

FDA is providing some examples of how certain foods relate to the definition of "fresh." These examples are intended to be illustrative. Except in a few cases where FDA believes clarification is necessary, FDA is not providing specific guidance in this final

rule on the many types of foods for which comments stated an opinion concerning the appropriateness of the use of the descriptive term "fresh." Under the definition of "fresh" that the agency is establishing, foods such as cut raw vegetables and expressed juices from raw produce could bear the term "fresh" on the label because these foods meet the requirements of the definition. However, if the term "fresh" were used to describe a pasteurized orange juice, that term would misbrand the product because when used in this context, the term implies that the food is unprocessed (e.g., fresh squeezed orange juice), when in fact it is a pasteurized food.

By contrast, in the case of pasteurized milk that is labeled as "fresh," such a food would not be subject to new § 101.95(a) because this term does not imply that milk is unprocessed inasmuch as consumers recognize that milk is nearly always pasteurized, and that unpasteurized milk (in states where it is permitted to be sold) would be labeled as "raw" milk. Also, the term "fresh" as used on bread would not be subject to new § 101.95(a) because bread is not a food that exists in a raw state, and the term "fresh bread" does not imply that the food is unprocessed and in its raw state. For clarity, FDA is including milk in § 101.95 as an example of a use of the term "fresh" that is not subject to this regulation, and pasta sauce as an example of a food that is subject to this regulation.

The agency advises that uses of the term "fresh" to describe foods that do not suggest or imply that a food is unprocessed will not be subject to the definition established for "fresh." However, all uses of this term in food labeling are subject to the requirements of 403(a) of the act, the act's prohibition of false or misleading labeling. Therefore, the agency has the authority to take action on a case-by-case basis against foods that use the term "fresh" on the label in a manner that is false or misleading, even though the food may not be subject to new § 101.95(a).

322. One comment stated that the agency should adopt FSIS' policy memo 022C that outlines conditions in which the term "fresh" can be used on approved labeling of meat and poultry products. FSIS' policy memo 022C states that the term "fresh" may not be used as part of a name on any product that is canned, cured, dried, chemically preserved, or hermetically sealed. In addition, FSIS' policy memo 022C states that "fresh" may not be used on any poultry or poultry part that has been frozen or previously frozen at or below zero degrees Fahrenheit.

FDA does not find it appropriate to adopt FSIS' policy memo O22C that addresses use of the term "fresh" on the labeling of meat and poultry products. Although the memo has provided FDA with useful information in formulating its "fresh" policy, the reference of the policy memo is limited in that it specifically addresses meat and poultry products and the conditions under which they are sold. Therefore, the agency does not find merit in the suggestion that it adopt the provisions set forth in that policy memo.

323. Several comments addressed the use of "fresh" as it relates to crabmeat. Comments on this issue urged FDA to reconsider its definition for "fresh" because as proposed, it would prohibit the use of this descriptor to describe crabmeat. These comments argued that it is not feasible for consumers to purchase raw crabmeat, and, furthermore, use of the term "fresh" has been traditionally associated with crabmeat that has been cooked and picked but not subjected to any other processing procedures. Other comments stated that some consumers look for the term "fresh crabmeat" as a way of distinguishing it from pasteurized crabmeat that is a lower price and that requires special handling.

FDA finds that the terms "fresh" or "fresh picked" as used to distinguish picked crabmeat from pasteurized crabmeat is not a use of the term "fresh" that implies that the food is unprocessed (as it is understood to mean that the food has been cooked and is not raw), nor is it misleading to consumers who are accustomed to this usage. Therefore, such use of the term is not subject to new § 101.95(a), and FDA will not object to such usage of the term.

324. One comment disagreed with some of the proposed exemptions that allowed for use of the term "fresh," i.e., (1) If an approved wax or coating has been applied to raw produce, (2) if a mild chlorine or mild acid wash has been applied to raw produce, or (3) if raw produce has been treated with approved pesticides after harvest. The comment stated that it is misleading to use the term "fresh" to describe raw produce that has been washed with a chlorine or mild acid wash, waxed, or treated with an approved pesticide. However, another comment suggested that the agency should permit use of the term "fresh" on foods whose surface is treated with ascorbic acid, calcium chloride, citric acid, potassium chloride, or sodium bisulfite, provided that these treatments are used at levels allowed by FDA regulations. The comment argued that these treatments affect a food's surface, and that they do not appreciably affect the body or alter the state of the food.

The agency does not agree that surface treatments such as waxing, washing with a mild chlorine or a mild acid wash, or the use of an approved pesticide should preclude describing the food as "fresh." As stated in the proposal, these applications are recognized as routine practices in the distribution and handling of raw produce. However, the agency does not agree that the use of the term "fresh" is appropriate if a food has been subjected to chemical treatments, including but not limited to antioxidants, antimicrobial agents, or preservatives, that introduce chemically active substances that remain in or on the food to preserve or otherwise affect the food. Thus, FDA is not providing for the use of the term "fresh" on foods that have been treated with the substances listed in the second comment. FDA is, however, retaining the exempting provisions in the final rule and is redesignating them as § 101.95(c)(1).

325. A number of the comments stated that use of low dose ionizing radiation has little effect on the attributes of a food in its raw state, and that "fresh" labeling should be permitted for foods that have been treated with low dose ionizing radiation. Other comments that supported the use of the term "fresh" on some irradiated foods suggested that irradiation enables a product to remain wholesome.

A small number of comments argued that use of the term "fresh" to describe certain irradiated raw foods would be misleading because irradiation is considered to be a form of processing that results in a loss of vitamins in foods. The comments also stated that safety procedures have not been established for irradiated foods, and that irradiation may affect the food in some unhealthful way. None of the comments that opposed the use of ionizing radiation on raw unprocessed foods provided the agency with supporting data to substantiate these claims. A few comments suggested that the labeling information associated with irradiated foods should state whether the food has been exposed to gamma or ionizing radiation from man-made sources. The majority of the comments agreed that the agency should require comprehensive and informative labeling on any raw unprocessed food that has been irradiated.

After reviewing the comments pertaining to the use of "fresh" to describe foods that have been exposed to ionizing radiation, the agency notes

that the concerns expressed relate primarily to safety and to the use of appropriate labeling to identify foods that have been irradiated. These comments appear to confuse safety and proper identification of foods that have been irradiated with perceptions related to the state of freshness of these foods. None of the comments, however, provided information to support the contention that use of currently approved low doses of irradiation on raw foods (not exceeding 1 kiloGray (100 kilorads)) would degrade the characteristics of a food associated with a food's raw state.

Under the provisions of § 179.26(b), irradiation of fresh foods is limited to the use of low dose irradiation (not to exceed 1 kiloGray) for the purpose of disinfestation of arthropod pests in food, for growth and maturation inhibition of some fresh foods, and for control of Trichina spiralis in pork carcasses. In approving these uses of irradiation, the agency concluded that foods treated with the approved levels of ionizing irradiation are safe. FDA requires that retail packages and bulk containers of such food bear a unique logo that distinguishes irradiated from nonirradiated foods and the statement "treated with radiation" or "treated by irradiation" (§ 179.26(c)). Therefore, FDA concludes that the safety and proper identification of any food that has been treated with low dose ionizing irradiation is not relevant in determining whether food that is "fresh" under § 101.95 before irradiation can continue to be described as "fresh" after such treatment.

The test for determining the appropriateness of applying the term "fresh" to foods treated with post harvest applications, including treatment with low dose irradiation, is the effect that the process has on a food. The low doses of irradiation approved for fresh foods (less than 1 kiloGray) are used to prevent maturation (sprouting) and to kill insects (§ 179.26(b)). Exposure of raw food to low dose irradiation typically causes insignificant changes in their appearance and nutrient content. While it is true that certain vitamins are sensitive to irradiation, the available literature indicates that foods irradiated at levels below 1 kiloGray are not nutritionally inferior to unirradiated foods (51 FR 13376, 13381, April 18, 1986).

The agency is not aware of any information that suggests that low dose (up to 1 kiloGray) irradiation of raw foods causes adverse changes in their physical or sensory qualities that would affect consumer's perceptions as to whether they are raw. Therefore, in the absence of meaningful differences in the appearance and quality between pre- and post- irradiated foods, and in light of the requirement that irradiated foods must be clearly labeled as such, the agency believes that it is appropriate to provide that the term "fresh" may be used to describe foods that have been treated with ionizing radiation at a maximum dose of 1 kiloGray (100 kilorads) in accordance with § 179.26(b) and that otherwise meet the requirements of new § 101.95(a). Accordingly the agency is adding an exemption for treatment with irradiation to new § 101.95(c)(iv).

326. None of the comments objected to the agency's position that use of the term "fresh" is appropriate to describe raw, unprocessed foods that are refrigerated and that otherwise meet the definition of "fresh."

Although refrigeration is a means of preserving food, consumers apparently generally regard raw unprocessed foods that are refrigerated as "fresh" (e.g., "fresh" produce). The agency also believes that consumers are not misled when the term "fresh" is used to describe raw unprocessed foods that are refrigerated. Accordingly, the agency is retaining in new § 101.95(c)(2) the provision that states that a food that meets the definition for "fresh," and that is refrigerated, is not precluded from the use of the term "fresh" under this regulation.

327. Many comments objected to the agency's proposed definition for the term "freshly prepared." Some of these comments pointed out that one of the major limitations associated with the proposed definition of "freshly prepared" is that bakery products (including bread) would not merit use of the term "fresh baked" because, in most cases, it is a common practice for the baking industry to utilize mold inhibitors. Other comments stated that consumers recognize baked bread containing mold inhibitors as "fresh baked" and are not misled by the use of this terminology. Numerous related comments suggested that bread and other bakery products (regardless of whether they contain mold inhibitors), should be permitted to use the term "freshly prepared."

Several comments objected to the provision in the proposal limiting the use of "freshly prepared" to foods available for sale within 24 hours after their preparation or production. Comments stated that the agency has no factual or scientific basis on which to impose a 24-hour restriction for prepared foods to qualify to be labeled "freshly prepared." Comments also stated that the 24-hour timeframe is applied inconsistently across the food industry, is unrealistic, and is impossible for most foods to achieve.

A few comments recommended that as an alternative to the 24-hour timeframe associated with "freshly prepared," the agency should consider timeframes such as 12 hours, 72 hours, 10 days from preparation, or 3 to 7 days, with "freshly baked" meaning those products that are baked within a 24-hour timeframe. A small percentage of comments suggested that any time restriction associated with "freshly prepared" should be based on a product's normal shelf life.

A review of the comments has persuaded the agency to reconsider its proposed definition of "freshly prepared." FDA now recognizes several problems with this proposed definition. First, the comments have persuaded the agency that the 24-hour timeframe proposed for the term "freshly prepared" is impractical and impossible to apply to foods across the board because of the diversity of foods in the marketplace that could be described as "freshly prepared." Additionally, no practical alternatives for defining "freshly prepared" were presented to the agency. To the contrary, because of the wide variety of contexts in which the term could be used to describe foods, FDA doubts that a practical definition for "freshly prepared" that would address all uses of the term is achievable.

FDA has thus reconsidered whether a need exists for a regulatory definition for the term "freshly prepared." First, FDA believes that systematic misuse of terms such as "freshly prepared" is not a significant problem in the marketplace. FDA is not aware of widespread misuse of this term. Further, as stated above, any use of terms such as "freshly prepared" are subject to the requirements of section 403(a) of the act, which prohibits false or misleading labeling. Therefore, the agency has the authority to take action on a case-by-case basis against foods that use the term "freshly prepared" on the label in a manner that is false or misleading. Given these factors, FDA believes that a definition of this term is not necessary to enable the agency to effectively enforce the provisions of the act that forbid false or misleading labeling on foods, and accordingly, FDA is withdrawing the proposed definition for "freshly prepared."

328. Several comments agreed with the agency's longstanding policy that use of the term "fresh frozen" is appropriate to describe a food that is quickly frozen while still "fresh." One comment requested that FDA extend the

proposed definition for "fresh frozen" to include foods such as "fresh" vegetables that are blanched before blast-freezing.

The agency agrees with the comment that foods blanched before blast-freezing merit use of the term "fresh frozen." Upon review of the literature, FDA finds that the blanching of vegetables before freezing is essential to prohibit the development of off-colors, off-flavors, and other kinds of enzymatic spoilage that are known to develop over a period of time in the frozen product (Ref. 30). Therefore, FDA is including a provision in new § 101.95(b) that provides for use of the term "fresh frozen" on raw foods that are blanched before blast-freezing.

329. Several comments requested that FDA reconsider the provision in the proposal that a food must comply with the definition of "fresh" for the term to be used in its labeling as part of a brand name. Some of these comments expressed the concern that prohibiting the use of "fresh" in brand names would mean banning the use of many brand names and trade names (some that are registered trademarks) that have been used for years in a nonmisleading manner.

The agency has reviewed the comments regarding the use of "fresh" in brand names. FDA is aware that situations exist where "fresh" is employed as an integral part of some brand names. In addition, the agency recognizes that some brand names are registered trademarks, and it is not uncommon for these brand names to be used as part of a company logo or on company promotional material.

The use of the term "fresh" on a food label in any manner, including its use in a brand name, is misleading if the use implies that the food is unprocessed when in fact it has been processed. Further, some of the instances where the term "fresh" has been misused in this regard have involved the use of this term as part of a brand name. For these reasons, FDA concludes that the use of "fresh" as part of a brand name should be subject to the definition it is establishing and is thus retaining reference to the use of "fresh" in a brand name in the introductory paragraph of new § 101.95. If, however, a use of the term "fresh" as part of a brand name does not imply or suggest that the food is unprocessed, and the use is not otherwise false and misleading, there is nothing in this final rule that would prevent this use of the term.

330. A few comments on the use of "fresh" in brand names suggested that FDA should continue to permit the term "fresh pack" on the label of pickles to refer to uncured, unfermented cucumbers packed in a vinegar solution and preserved by either pasteurization or refrigeration. These comments contended that consumers and USDA officials use the term "fresh pack" to distinguish these pickles from brine-cured pickles.

FDA has reviewed these comments. FDA is aware that the term "Fresh Pack" is recognized by USDA to distinguish a certain type of pickles. USDA regulations in 7 CFR 52.1684 specifically state that pickles of fresh-pack type are prepared from uncured, unfermented cucumbers that are packed in a vinegar solution with other ingredients to give the characteristics of the particular type of pickle. They are sufficiently processed by heat for preservation of the product in hermetically-sealed containers. That regulation also identifies characteristics for fresh-pack dill pickles, fresh-pack sweetened dill pickles, fresh-pack sweetened dill relish, fresh-pack sweet pickles, fresh-pack mild sweet pickles, fresh-pack sweet relish, and fresh-pack mild sweet relish, respectively. In recognition of USDA's standards, FDA will not take action against the term "Fresh Pack" when it refers to pickles that are graded according to those standards.

331. Some comments requested that FDA reconsider the provision in the proposal that a food must comply with the definition of "fresh" for the term to be used on its labeling as part of a sensory modifier. Other comments argued that as long as the term "fresh" is not misleading, the agency should permit its use as a sensory modifier, especially in those cases where the term refers to the sensory attributes of a food (i.e., "fresh flavor," "fresh-tasting," "tastes-fresh," "taste as good as fresh,"). However, a small percentage of comments asserted that the use of "fresh" as a sensory modifier is misleading to consumers and should not be allowed in any product.

FDA has considered these comments concerning the use of "fresh" as a sensory modifier. The use of "fresh" on the label of a food, including its use as a sensory modifier, is misleading if it implies that the food is unprocessed when in fact it has been processed. For this reason, FDA concludes that the use of "fresh" as a sensory modifier should be subject to the definition that it is establishing, and therefore the agency is retaining reference to the use of the term "fresh" as sensory modifier in the introductory paragraph of new § 101.95.

332. Several comments stated that a factual statement such as "spaghetti sauce-made with fresh mushrooms" provides useful information about a food product and should be permitted on the label of a processed food made with a fresh ingredient. One comment suggested that such factual statements should be allowed on frozen foods as well. A few comments contended that an ingredient that has undergone processing is no longer "fresh," and that, therefore, the use of such a statement on a processed food made with a fresh ingredient should be prohibited. The comment said that such a statement would be confusing, meaningless, and misleading to consumers. One comment stated that if "fresh" were defined to mean unprocessed as the agency proposed, it would be inconsistent to allow the term to be used to define an ingredient that had been added to the food before processing.

In the general principles proposal, FDA asked for comments regarding the use of these statements on a processed food because it intended to comprehensively regulate the use of the term "fresh" on food labels. Because the agency is taking a more limited approach in this final rule, it does not believe that it is necessary to specifically address the use of the term "fresh" to describe ingredients used in a processed food in its regulation. The agency concludes that this use of the term can be effectively regulated on a case-by-case basis.

FDA believes, however, that consumers generally are not misled when such statements are made about ingredients used in processed foods, provided that the statements clearly refer to the ingredient and do not imply that the food itself is unprocessed. The agency has not received complaints from consumers about this practice, and most of the comments that mentioned this use of the term said that such statements provide useful information. FDA advises that should specific situations arise where such statements are used in a manner that is misleading, the agency will take regulatory action under section 403(a) of the act.

333. Numerous comments expressed the opinion that the inclusion of blanching as part of a continuous process should not preclude labeling an ingredient as "fresh." These comments stated that blanching does not significantly damage the cellular structure of an ingredient and does not affect the taste of a product. A small number of comments argued that blanched ingredients should not be labeled as "fresh," especially if the entire product is heat-treated after the blanched ingredients have been added to the product.

FDA notes that blanching, as addressed here, is a common and sometimes required process that is accomplished by subjecting a food to a set temperature for a specific period of time. This practice is used in many food industries to arrest changes in the flavor profile of the food, to expel air and gases to inactivate food enzymes, and to destroy some microorganisms before the food is processed (Ref. 31). FDA believes that when the blanching operation is part of a continuous process, it is not misleading if the label of the processed product contains a statement such as "made from fresh ——" because the statement functions to inform the consumer of a noteworthy characteristic of the ingredient (i.e., that the ingredient was fresh, not canned, frozen, or dried at the time the food was processed).

334. Many comments both from industry and from consumers, stated that processed products (particularly tomato products) that are made from remanufactured ingredients should include a statement such as "remanufactured," "reconstituted," or "made from concentrate" on the product's PDP to avoid consumer deception and economic fraud in the marketplace. Other comments expressed the view that organoleptic, quality, and structural differences exist between remanufactured ingredients and fresh ingredients, resulting in significant differences in products made from them. Some comments provided data on these differences.

However, numerous comments opposed requiring a declaration on the PDP that a processed product is made from remanufactured ingredients. Some of these comments stated that FDA lacked legal authority and sufficient analytical and scientific data to promulgate a regulation requiring PDP declaration of the use of remanufactured ingredients, and that before the agency suggests that there is a quality difference between remanufactured tomatoes and raw unprocessed tomatoes, this issue would require further investigation. Some of these comments stated that some existing food standards allow for the use of processed ingredients in processed foods without requiring a declaration about the processed ingredient on the PDP. Therefore, these comments asserted, FDA could not require a declaration on the PDP for remanufactured ingredients without proposing to revise some existing food standards. Some of these comments argued that there was no indication in the rulemaking proceedings for the above food standards that consumers are misled by the lack of PDP labeling.

Some comments urged FDA to separate this issue from this rulemaking and to address the labeling of remanufactured ingredients in a separate proceeding after the agency completes implementing the mandatory requirements of the 1990 amendments. Other comments on this issue argued that, if the agency were to mandate this requirement, it would impose substantial costs on industry. Another comment implied that use of remanufactured ingredients is necessary because it is impossible for manufacturers to meet the demand of tomato-based products using only fresh tomatoes.

The agency has reviewed these comments and concludes that the issue of labeling for remanufactured ingredients involves matters that go well beyond those that the agency raised in the proposal. There is a large amount of information to be evaluated, and any decision on the issue will have a far reaching impact. Because this rulemaking has been conducted under the very tight time constraints of the 1990 amendments, the agency has not been able to fully evaluate all the information that it has received in comments or to develop appropriate provisions for a regulation. In addition, before FDA published the general principles proposal, the California Tomato Packers had submitted a petition (Docket No. 90P–0430) concerning, among other things, declaration of remanufactured ingredients in finished tomato products. This petition includes data and other information and is undergoing agency review.

However, the 1990 amendments do not require that FDA address this issue, and the time constraints in those provisions therefore are not applicable. The agency is persuaded that some of the issues discussed in the proposal concerning remanufactured ingredients warrant further consideration to determine whether labels should be required to inform consumers that processed products have been made with remanufactured ingredients. Accordingly, FDA has not established provisions in this final rule to address these products. The agency will complete its evaluation of all available information and will take appropriate action separately from this rulemaking. The agency solicits information on differences in finished products made with remanufactured ingredients from those made with unprocessed ingredients. In particular, FDA requests information on whether such differences occur in finished products other than tomato products, and, if so, whether the differences are significant. Information should be identified with Docket No. 90P–0430 and sent to the Dockets Management Branch (address above). If the agency determines that differences in finished products because of the use of processed ingredients are significant, such differences would form the basis for subsequent rulemaking.

In the interim, FDA advises that it has already established labeling provisions that apply to some foods made from processed ingredients. This final rule, in § 101.95, precludes processed products such as tomato products made using remanufactured ingredients from being described as "fresh." In addition, as discussed in comment 334 of this document, processed products made with fresh ingredients may bear label statements stating that fact. The agency will evaluate labels that are not subject to these provisions on a case-by-case basis to determine if they are false or misleading under section 403(a) of the act because they misrepresent a finished product made with a processed ingredient.

335. Several comments stated that extended shelf life foods do not merit use of the terms "fresh" or "freshly prepared." The comments suggested that extended shelf life foods are preserved using modern preservation techniques and should not be given special consideration over other methods of preservation. A small number of comments expressed the view that pasta products that are packaged in modified atmosphere packaging should be able to utilize the term "fresh" as a way to distinguish these pasta products from dried pasta.

FDA notes that "extended shelf life" is a term used to describe a potentially broad class of products in the marketplace. These products include many types of foods, e.g., vegetables, pasta, complete meals; employ many types of preparation and packaging technologies; and are subject to varying degrees of processing. The use of the term "fresh" on extended shelf life foods is subject to new § 101.95 when such use suggests or implies that the product is unprocessed. However, because of the diversity of products in the extended shelf life category, the question of what constitutes processing for such products is not being addressed in this rule and is subject to a case-by-case review by the agency.

336. Some comments suggested that terms that refer to packaging technology (e.g., "freshness seal," "Stay Fresh seal") would be prohibited under the agency's proposed definition for "fresh." These comments suggested that FDA does not have the authority to

prohibit the use of such terminology as it relates to packaging, specifically in cases where use of these terms are properly qualified. The comments said that such a prohibition would hamper the development of improved packaging technology. Comments also stated that the agency does not have sufficient evidence to suggest that consumers are misled when code dates and freshness guarantees (e.g., guaranteed fresh until) are used on foods. Some comments argued that phrases such as "vacuum packed," "vacuum sealed to lock in freshness," and "for maximum freshness use before a specific date," serve as tools for consumers to distinguish "fresh" product from "stale" product. One comment stressed that vacuum packaging is analogous to blast freezing in that both techniques allow foods to maintain their fresh state.

A small number of comments opposed permitting this use of the term "fresh." Another comment stated that the use of "fresh" in a guarantee statement (e.g., guaranteed fresh) should be restricted and should only be allowed if a food in question meets the definition for "fresh."

The agency has reviewed these comments and has concluded that the use of terms such as "freshness seal," "guaranteed fresh until," "and vacuum packed to preserve freshness," when they relate only to the function of the package and do not imply or suggest that the food itself is unprocessed, is outside the scope of this rulemaking. FDA acknowledges that these terms are used on numerous food products in the marketplace. To the extent that these terms might be used in any manner that is misleading, the agency will review specific situations on a case-by-case basis under the general misbranding provisions of section 403(a) of the act.

B. Natural

Although the use of the term "natural" on the food label is of considerable interest to consumers and industry, FDA's intent was not to establish a definition for "natural" in this rulemaking. However, the agency did note in the general principles proposal (56 FR 60421 at 60466) that, because of the widespread use of this term, and the evidence that consumers regard many uses of this term as noninformative, the agency would consider establishing a definition. Further, the agency stated that it believed that if the term "natural" is adequately defined, the ambiguity in the use of this term, which has resulted in misleading claims, could be abated. Therefore, the agency solicited comments on several issues that the agency must consider in deciding how to address the use of this term on foods, including: (1) Should the agency establish a definition for "natural" so that the term would have a common understanding among consumers, or should "natural" claims be prohibited altogether on the basis that they are false and misleading? (2) If a definition should be established, how should the agency define "natural?" (3) How should the agency proceed in developing a definition for "natural?" (4) Should a food that is represented as "natural" be considered to be misbranded if it has undergone more than minimal processing (and what constitutes minimal processing?), or if it contains any artificial or synthetic ingredients? In addition, FDA asked that identification of "natural" foods accompany the comments. FDA also solicited comments on how the agency distinguishes between artificial and natural flavors in § 101.22, and on how the agency should provide for a clearer, more appropriate distinction between natural and artificial flavors.

337. The comments provided a wide range of ideas for the agency to consider on the issue of developing a definition for "natural." Some comments stated that the term "natural" should be prohibited entirely on the basis that it generates confusion when used on the label or in the labeling of foods, and that the term is also false and misleading. Some comments stated that the agency should eliminate statements such as: "all natural," "100 percent natural," and made from "100 percent natural ingredients." Some comments suggested that the agency should not consider defining "natural" while it is implementing the mandatory requirements of the 1990 amendments.

Other comments suggested that the agency should address the use of the term "natural" in a separate rulemaking.

Some comments suggested that if FDA does establish a definition for the term "natural," it should encompass those foods that do not contain artificial or synthetic ingredients. A few comments stated that processing should not necessarily preclude a product from being deemed "natural." Other comments stated that the term "natural" and claims for natural ingredients should be permitted, provided that the manufacturer uses the term in a truthful, nonmisleading manner. Comments recommended that the use of natural color ingredients should not be precluded in foods that are represented as "natural." One comment suggested that manufacturers should be allowed to make claims for natural ingredients, regardless of any policy established for labeling finished foods as "natural." One comment stated that foods containing refined sugars should be allowed to be represented as "natural," whereas foods containing artificial sweeteners should not be represented as "natural."

None of the comments provided FDA with a specific direction to follow for developing a definition regarding the use of the term "natural." However, it was suggested that FDA should work with USDA to harmonize its definition for "natural."

A small percentage of comments addressed "minimal processing." Some of these comments proposed somewhat similar definitions under which "minimal processing" would refer to those processes that are familiar to consumers and that can be performed in the home (e.g., milling, grinding, baking). One comment suggested that "minimal processing" should include fermentation. Another comment implied that "minimal processing" should include traditional processes such as smoking, roasting, freeze drying, fermenting, and the separation of a product into component parts. The remaining comments defined "minimal processing" as those processes that do not fundamentally alter a raw food or any material derived from the raw food. Finally, some comments stated that FDA's current regulations for labeling natural flavors should not be changed.

After reviewing and considering the comments, the agency continues to believe that if the term "natural" is adequately defined, the ambiguity surrounding use of this term that results in misleading claims could be abated. However, as the comments reflect, there are many facets of this issue that the agency will have to carefully consider if it undertakes a rulemaking to define the term "natural." Because of resource limitations and other agency priorities, FDA is not undertaking rulemaking to establish a definition for "natural" at this time. The agency will maintain its current policy (as discussed in the general principles proposal (56 FR 60421 at 60466)) not to restrict the use of the term "natural" except for added color, synthetic substances, and flavors as provided in § 101.22. Additionally, the agency will maintain its policy (Ref. 32) regarding the use of "natural," as meaning that nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in the food. Further, at this time the agency will continue to distinguish between natural and artificial flavors as outlined in § 101.22.

C. Organic

In the general principles proposal (56 FR 60421 at 60467), FDA noted that responsibility for regulating use of the term "organic" was assigned by Congress to USDA in Title XXI—Organic Certification, also known as the "Organic Foods Production Act of 1990." The agency stated that it would defer issuing regulations governing the term "organic" until USDA had adopted appropriate regulations.

338. The majority of the comments addressing the use of "organic" as a food label term agreed with the agency's proposal to defer action until USDA has adopted appropriate regulations governing the term "organic." A small number of comments argued that defining the term "organic" was outside the scope of the 1990 amendments and, therefore, should not be part of this regulation.

However, other comments suggested that FDA should initiate rulemaking on the use of the term "organic" on food labels. Some of these comments suggested that the term "organic" should be applied to foods free of any artificial or synthetic ingredients, pesticides, growth enhancers, harmful fertilizers, or fungicides, and that it should not be applied to foods exposed to ionizing radiation. One comment stated that "organic" should not be allowed as a labeling term because there is no "scientifically acceptable" meaning for this term. Many of the consumer comments proposed that FDA adopt USDA's future definition for "organic" and consider adopting criteria established by the Organic Foods Production Act of 1990.

Most of the comments generally supported the agency's position as expressed in the proposal. Comments that opposed FDA's decision to defer rulemaking did not provide the agency with any justification why it should proceed with rulemaking before USDA has established regulations. Therefore, the agency continues to believe that it is best to defer rulemaking regarding the use of the term "organic" until USDA has adopted appropriate regulations. At that time, FDA will determine whether any regulations governing the term "organic" are necessary.

IX. Conclusions

After review and consideration of the comments received in response to the general principles and fat/cholesterol proposals, FDA concludes that it should amend parts 5 and 101 as set forth in those proposals and in the specific revisions to those proposed regulations discussed in this document. For the purposes of this final rule, certain changes, in addition to those discussed in this document, were made for editorial purposes, clarity, and consistency only. These changes do not amend any matter of substance.

X. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive RIA that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

One particular comment to the RIA stated that the shelf flag highlighting a particular nutrient content of a food in the Giant Foods, Inc./FDA Special Dietary Alert study (SDA) that was used to estimate benefits of the 1990 amendments overestimated the benefits. The comment also noted that shelf flag highlighting may have been used in addition to highlighting the product characteristics on the label such that no similar results could be obtained unless other retailers also used shelf flags. In addition, the comment contended that it is unlikely that retailers will use shelf flags because their use may trigger additional labeling requirements.

The agency notes that these final rules will not prohibit shelf flags from being displayed by manufacturers exactly as they were displayed by Giant Foods, Inc., during the SDA study. The agency is announcing here that it is encouraging retailers to use such devices consistent with the definitions for nutrient content claims provided in this document and the definitions for health claims in the final rule published elsewhere in this issue of the **Federal Register**.

XI. Environmental Impact

The agency previously considered the environmental effects of the action being taken in this final rule. As announced in the general principles proposal (56 FR 60521) and the fat/cholesterol proposal (56 FR 60478), the agency determined that under 21 CFR 25.24(a)(8) and (a)(11), these actions are of a type that do not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

Several comments on the proposed rule suggested that there would be significant adverse environmental effects from the final rules unless the agency allowed more time between the publication of the final rules and their effective dates. The concern in these comments was that, if the agency did not allow firms more time between the publication of the final rules and their effective dates to use up existing label inventories, large stocks of labels and labeled packaging would have to be discarded. These comments questioned whether the agency had sufficiently examined the impact of disposing of obsolete labels and labeled packaging on this country's solid waste disposal capabilities. Two comments estimated the amounts of labeling from their respective industries, i.e., dairy and confectionery, that would need to be discarded following publication of FDA's final rules on several food labeling actions, including this action. However, these comments did not: (1) Provide details on how these estimates were derived, (2) identify what portion of the estimated amounts are attributable to these two actions, or (3) describe what impact the discarded labels and packaging would have on the disposal of solid waste. In its November 27, 1991, reproposed rule for mandatory nutrition labeling and proposed rule for

nutrient content claims, the agency proposed that the final rules for these actions would become effective 6 months following their publication in the **Federal Register**.

However, the agency has decided that this final rule will not be effective until May 8, 1994. FDA believes there will thus be ample time for food companies to use up most of the existing labeling and packaging stocks and to incorporate labeling language that complies with FDA's regulations into their food labels. Consequently, the comments on the potential for adverse environmental effects do not affect the agency's previous determination that no significant impact on the human environment is expected and that an environmental impact statement is not required.

XII. Paperwork Reduction Act

In the **Federal Register** of February 14, 1992 (57 FR 5395), FDA announced that the agency had submitted to the Office of Management and Budget (OMB) for its review the collection of information requirements contained in the proposed rule (November 27, 1991, 56 FR 60421) that provided, in part, for petitions regarding nutrient content claims, synonyms for those claims, and implied nutrient content claims in brand names. Also in the February 1992 document, FDA published its estimated annual collection of information burden.

Based on its consideration of the written comments received in response to the aforementioned **Federal Register** documents and the oral presentations made at the public hearing on food labeling, FDA modified the nutrient content claim petition requirements from those that were proposed. Those modifications were discussed in detail earlier in this final rule. Accordingly, FDA has also revised its estimated annual collection of information burden.

This final rule contains collection of information requirements that are subject to review by OMB under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507). Therefore, in accordance with 5 CFR part 1320, the title, description, and respondent descriptions of the collection of information requirements are shown below with an estimate of the annual collection of information burden. Included in the estimate is the amount of time for reviewing instructions, searching existing data sources, gathering necessary information, and completion and submission of petitions.

Title: 21 CFR 101.69—Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms.

Description: This final rule provides the procedures for the submission of petitions to the agency. The information included in these petitions will be reviewed by the agency, and a decision will be made in accordance with the criteria specified in this final rule.

The 1990 amendments added section 403(r)(4) to the act. This section provides that any person may petition the Secretary to make nutrient content claims that are not specifically provided for in FDA's regulations. It describes the procedures for petitions that seek to define additional nutrient content claims, to establish synonyms, and to use an implied nutrient content claim in a brand name.

Nutrient Content Claim petitions—Section 403(r)(4)(A)(i) of the act grants to any person the right to petition FDA to issue a regulation to define a nutrient content claim that has not been defined in the regulations under section 403(r)(2)(A)(i) of the act. The statute requires that such a petition include an explanation of the reasons why the claim that is the subject of the petition meets the requirements of section 403(r) of the act and a summary of the scientific data that support those reasons. Section 101.69(m) sets forth the data requirements specific to descriptor petitions.

Synonym petitions—Section 403(r)(4)(A)(ii) of the act grants the right to petition the FDA for permission to use terms in a nutrient content claim that are consistent (i.e., synonymous) with terms defined in regulations issued under section 403(r)(2)(A)(i) of the act. The petition requirements in § 101.69(n) are those that FDA believes are necessary to demonstrate that use of the proposed synonym is not misleading and is consistent with the purpose of the 1990 amendments.

Brand-name petitions—Section 403(r)(4)(A)(iii) of the act grants the right to petition FDA for permission to use an implied claim in a brand name that is consistent with terms defined by the Secretary under section 403(r)(2)(A)(i) of the act. Section 101.69(o) sets forth the data requirements specific to brand-name petitions. These requirements are, in FDA's opinion, those necessary for the petition to demonstrate that use of the proposed implied claim is not misleading and is consistent with the purpose of the 1990 amendments.

Description of Respondents: Persons and businesses, including small businesses.

Estimated Annual Reporting and Recordkeeping Burden;

Section	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Annual Burden Hours
101.69(m)	5	1	5	240	1,200
101.69(n)	10	1	10	80	800
101.69(o)	7	1	7	107	749
Total	22		22		2,749

FDA has submitted copies of the final rule to OMB for its review of these reporting requirements.

XII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. National Heart, Lung, and Blood Institute, NCEP, "Report of the Expert Panel on Blood Cholesterol Levels in Children and Adolescents," DHHS, Public Health Service, National Institutes of Health, April 7, 1991.

2. AOAC International, "Nutrient Labeling Task Force Report," *The Referee*, 16:7–12, July, 1992.

3. President's "Memorandum for Certain Department and Agency Heads on Regulatory Coordination," January 28, 1992.

4. "The Surgeon General's Report on Nutrition and Health," DHHS, Public Health Service Publication No. 88–50210 (Government Printing Office Stock No. 017–001–00465–1), U.S. Government Printing Office, Washington DC, 1988.

5. Crane, N. T., memorandum to file, Modification of USDA's Nutrient Data Base

for Standard Reference Release 9, October 15, 1992.

6. Crane, N. T., memorandum to file, Data Analysis CC1, Effect of a less Restrictive or No Weight-Based Criterion, October 15, 1992.

7. DHHS and USDA, "Nutrition and Your Health, Dietary Guidelines for Americans," 1990.

8. Crane, N. T., memorandum to file, Data Analysis CC2, Products with Reference Amounts under 100 Grams that met Proposed Criteria, October 15, 1992.

9. Crane, N. T., memorandum to file, Data Analysis CC3, Effect of Lowering Nutrient Levels per Serving, October 15, 1992.

10. Crane, N. T., memorandum to file, Data Analysis CC4, Effect of Weight-Based Criteria Applied Only to Small Serving Size Foods, October 15, 1992.

11. Crane, N. T., memorandum to file, Data Analysis CC5, Effect of Caloric Density Criteria, October 15, 1992.

12. Committee on Diet and Health, Food and Nutrition Board, Commission on Life Sciences, National Research Council, NAS, "Diet and Health: Implications for Reducing Chronic Disease Risk," National Academy Press, Washington DC, 1989.

13. Report of the 4th Workshop on Nutritional Quality and Labeling in Food Standards and Guidelines, Committee on the Nutritional Aspects of Foods Standards, International Union of Nutritional Sciences, 1989.

14. Committee on the Nutrition Components of Food Labeling, Food and Nutrition Board, IOM, NAS, "Nutrition Labeling, Issues and Directions for the 1990's," Washington, DC, National Academy Press, 1990.

15. Meier, C., "Calories, Fat, and Cholesterol: A Comparison of Modifier Words on Food Labels," doctoral dissertation, University of South Dakota, Vermillion, South Dakota, 1992.

16. Levy, A. S. et al., "Recent Trends in Beliefs about Diet/Disease Relationships: Results of the 1979–1988 FDA Health and Diet Surveys," presented at FDA/USDA Food Editor's Conference, December 1 to 2, 1988.

17. National Heart, Lung, and Blood Institute, "National Cholesterol Education Program Report of the Expert Panel on Population Strategies for Blood Cholesterol Reduction (Population Panel)," NIH Publication No. 90–3046, 1990.

18. Crane, N. T., memorandum to file, Data Analysis CC8, Caloric Content of Selected Foods, October 15, 1992.

19. Crane, N. T., memorandum to file: Data Analysis CC9, Fat Content of Selected Foods, October 15, 1992.

20. Crane, N. T., memorandum to file: Data Analysis CC6, Foods that Meet FDA's Definition for Low Saturated Fat, October 15, 1992.

21. Crane, N. T., memorandum to file, Data Analysis for Proposal, Distribution of Nutrients Across Food Categories, October 16, 1991.

22. USDA, FSIS, Policy Memo 070B, November 18, 1987.

23. Crane, N. T., memorandum to file: Data Analysis CC7, Fish and Shellfish that May Qualify for "Lean," October 15, 1992.

24. USDA, "Composition of Foods, Raw, Processed, Prepared," Agriculture Handbook No. 8–1 to 8–17, Human Nutrition Information Service, Washington, DC, 1976–1987.

25. Morris, W., "The American Heritage Dictionary of the English Language," Houghton Mifflin Co., Boston, 1976.

26. FDA's Health and Diet Survey, 1982.

27. Calorie Control Council News Release "Americans Finding 'Light' to their Liking," January 9, 1990.

28. Subcommittee on the 10th Edition of the Recommended Dietary Allowances, Food and Nutrition Board, Commission on Life Sciences, National Research Council, "Recommended Dietary Allowances, 10th ed.," Washington, DC, National Academy Press, 1989.

29. Standards and Labeling Policy Book, USDA, FSIS, p. 47, June 1991.

30. Potter, Norman N., "Heat Preservation and Processing," in *Food Science*, Ch. 8, pp. 149–150, AVI Publishing Co., Inc., Westport, Connecticut, 1968.

31. Luh, B. S. and J. G. Woodroof, "Canning of Vegetables," in *Commercial Vegetable Processing*, Ch. 6, pp. 198–199, AVI Publishing Co., Inc., Westport, Connecticut, 1975.

32. Raymond E. Newberry, letter to Clinton K. Davies, PhD, September 29, 1988.

33. Committee on Nutrition, American Academy of Pediatrics; Gilbert B. Forbes, ed., Calvin W. Woodruff, associate ed., 2d ed., Elk Grove Village, Ill.: The Academy, 1985.

34. Food Retailing Review—1992 Edition, The Food Institute Information and Research Center, Fair Lawn, NJ, February 1992, p. 254.

35. Crane, N. T., Memorandum of File, Data Analysis No. 4, Foods With 20 Percent or More of Reference Value Per Service, October 16, 1991.

List of Subjects

21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 5 and 101 are amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 21 U.S.C. 41–50, 61–63, 141–149, 467f, 679(b), 801–886, 1031–1309, secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 361, 362, 1701–1706, 2101 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11490, 11921, and 12591.

2. Section 5.61 is amended by revising the section heading and by adding a new paragraph (g) to read as follows:

§ 5.61 Food standards, food additives, generally recognized as safe (GRAS) substances, color additives, nutrient content claims, and health claims.

* * * * *

(g) The Director and Deputy Director, CFSAN are authorized to perform all of the functions of the Commissioner of Food and Drugs under section 403(r)(4) of the act regarding the issuing of decisions to grant or deny, letters of filing, and notices of proposed rulemaking in response to petitions for nutrient content claims and health claims that do not involve controversial issues.

PART 101—FOOD LABELING

3. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

4. Section 101.10 is revised to read as follows:

§ 101.10 Nutrition labeling of restaurant foods.

Nutrition labeling in accordance with § 101.9 shall be provided upon request for any restaurant food or meal for which a nutrient content claim (as defined in § 101.13 or in subpart D of this part) or a health claim (as defined in § 101.14 and permitted by a regulation in subpart E of this part) is made (except on menus). Except: That information on the nutrient amounts that are the basis for the claim (e.g., "low fat," this meal provides less than 10 grams of fat) may serve as the functional equivalent of complete nutrition information as described in § 101.9. Nutrient levels may be determined by nutrient data bases, cookbooks, or analyses or by other reasonable bases that provide assurance that the food or meal meets the nutrient requirements for the claim. Presentation of nutrition labeling may be in various forms, including those provided in § 101.45 and other reasonable means.

5. Section 101.13 is revised to read as follows:

§ 101.13 Nutrient content claims—general principles.

(a) This section and the regulations in subpart D of this part apply to foods that

are intended for human consumption and that are offered for sale.

(b) A claim that expressly or implicitly characterizes the level of a nutrient (nutrient content claim) of the type required in nutrition labeling under § 101.9, with the exception of such claims on restaurant menus, may not be made on the label or in labeling of foods unless the claim is made in accordance with this regulation and with the applicable regulations in subpart D of this part or in part 105 or part 107 of this chapter.

(1) An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the food, e.g., "low sodium" or "contains 100 calories."

(2) An implied nutrient content claim is any claim that:

(i) Describes the food or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., "high in oat bran"); or

(ii) Suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., "healthy, contains 3 grams (g) of fat").

(3) Except for claims regarding vitamins and minerals described in paragraph (q)(3) of this section, no nutrient content claims may be made on food intended specifically for use by infants and children less than 2 years of age unless the claim is specifically provided for in parts 101, 105, or 107 of this chapter.

(c) Information that is required or permitted by § 101.9 to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section. If such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.

(d) A "substitute" food is one that may be used interchangeably with another food that it resembles, i.e., that it is organoleptically, physically, and functionally (including shelf life) similar to, and that it is not nutritionally inferior to unless it is labeled as an "imitation."

(1) If there is a difference in performance characteristics that materially limits the use of the food, the food may still be considered a substitute if the label includes a disclaimer adjacent to the most prominent claim as defined in paragraph (j)(2)(iii) of this section, informing the consumer of such difference (e.g., "not recommended for frying").

(2) This disclaimer shall be in easily legible print or type and in a size no less than that required by § 101.105(i) for the net quantity of contents statement except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than one-sixteenth of an inch.

(e)(1) Because the use of a "free" or "low" claim before the name of a food implies that the food differs from other foods of the same type by virtue of its having a lower amount of the nutrient, only foods that have been specially processed, altered, formulated, or reformulated so as to lower the amount of the nutrient in the food, remove the nutrient from the food, or not include the nutrient in the food, may bear such a claim (e.g., "low sodium potato chips").

(2) Any claim for the absence of a nutrient in a food, or that a food is low in a nutrient when the food has not been specially processed, altered, formulated, or reformulated to qualify for that claim shall indicate that the food inherently meets the criteria and shall clearly refer to all foods of that type and not merely to the particular brand to which the labeling attaches (e.g., "corn oil, a sodium-free food").

(f) A nutrient content claim shall be in type size and style no larger than two times that of the statement of identity.

(g) The label or labeling of a food for which a nutrient content claim is made shall contain prominently and in immediate proximity to such claim the following referral statement: "See _____ for nutrition information" with the blank filled in with the identity of the panel on which nutrition labeling is located.

(1) The referral statement "See [*appropriate panel*] for nutrition information" shall be in easily legible boldface print or type, in distinct contrast to other printed or graphic matter, that is no less than that required by § 101.105(i) for net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the referral statement shall be no less than one-half the size of the claim but no smaller than one-sixteenth of an inch.

(2) The referral statement shall be immediately adjacent to the nutrient content claim and may have no intervening material other than, if applicable, other information in the statement of identity or any other information that is required to be presented with the claim under this section (e.g., see paragraph (j)(2) of this section) or under a regulation in subpart D of this part (e.g., see §§ 101.54 and 101.62). If the nutrient content claim appears on more than one panel of the label, the referral statement shall be adjacent to the claim on each panel except for the panel that bears the nutrition information where it may be omitted.

(3) If a single panel of a food label or labeling contains multiple nutrient content claims or a single claim repeated several times, a single referral statement may be made. The statement shall be adjacent to the claim that is printed in the largest type on that panel.

(h) In place of the referral statement described in paragraph (g) of this section,

(1) If a food, except a meal product as defined in § 101.13(l), a main dish product as defined in § 101.13(m), or food intended specifically for use by infants and children less than 2 years of age, contains more than 13.0 g of fat, 4.0 g of saturated fat, 60 milligrams (mg) of cholesterol, or 480 mg of sodium per reference amount customarily consumed, per labeled serving, or, for a food with a reference amount customarily consumed of 30 g or less or 2 tablespoons or less, per 50 g (for dehydrated foods that must have water added to them before typical consumption, the per 50 g criterion refers to the "as prepared" form), then that food must disclose, as part of the referral statement, that the nutrient exceeding the specified level is present in the food as follows: "See [*appropriate panel*] for information about [*nutrient requiring disclosure*] and other nutrients," e.g., "See side panel for information about total fat and other nutrients."

(2) If a food is a meal product as defined in § 101.13(l), and contains more than 26 g of fat, 8.0 g of saturated fat, 120 mg of cholesterol, or 960 mg of sodium per labeled serving, then that food must disclose, in accordance with the requirements as provided in paragraph (h)(1) of this section, that the nutrient exceeding the specified level is present in the food.

(3) If a food is a main dish product as defined in § 101.13(m), and contains more than 19.5 g of fat, 6.0 g of saturated fat, 90 mg of cholesterol, or 720 mg of sodium per labeled serving, then that food must disclose, in accordance with the requirements as provided in paragraph (h)(1) of this section, that the nutrient exceeding the specified level is present in the food.

(i) Except as provided in § 101.9 or in paragraph (q)(3) of this section, the label or labeling of a product may contain a statement about the amount or percentage of a nutrient if:

(1) The use of the statement on the food implicitly characterizes the level of the nutrient in the food and is consistent with a definition for a claim, as provided in subpart D of this part, for the nutrient that the label addresses. Such a claim might be, "less than 10 g of fat per serving;"

(2) The use of the statement on the food implicitly characterizes the level of the nutrient in the food and is not consistent with such a definition, but the label carries a disclaimer adjacent to the statement that the food is not low in or a good source of the nutrient, such as "only 200 mg sodium per serving, not a low sodium food." The disclaimer must be in easily legible print or type and in a size no less than required by § 101.105(i) for net quantity of contents except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than one-sixteenth of an inch;

(3) The statement does not in any way implicitly characterize the level of the nutrient in the food and it is not false or misleading in any respect (e.g., "100 calories" or "5 grams of fat"), in which case no disclaimer is required; or

(4) "Percent fat free" claims are not authorized by this paragraph. Such claims shall comply with § 101.62(b)(6).

(j) A food may bear a statement that compares the level of a nutrient in the food with the level of a nutrient in a reference food. These statements shall be known as "relative claims" and include "light," "reduced," "less" (or "fewer"), and "more" claims.

(1) To bear a relative claim about the level of a nutrient, the amount of that nutrient in the food must be compared to an amount of nutrient in an appropriate reference food as specified below.

(i)(A) For "less" (or "fewer") and "more" claims, the reference food may be a dissimilar food within a product category that can generally be substituted for one another in the diet (e.g., potato chips as reference for pretzels) or a similar food (e.g., potato chips as reference for potato chips).

(B) For "light," "reduced," "added," "fortified," and "enriched" claims, the reference food shall be a similar food (potato chip reference for potato chip), and

(ii)(A) For "light" claims, the reference food shall be representative of the type of food that includes the product that bears the claim. The nutrient value for the reference food shall be representative of a broad base of foods of that type; e.g., a value in a representative, valid data base; an average value determined from the top three national (or regional) brands, a market basket norm; or, where its nutrient value is representative of the food type, a market leader. Firms using such a reference nutrient value as a basis for a claim, are required to provide specific information upon which the nutrient value was derived, on request, to consumers and appropriate regulatory officials.

(B) For relative claims other than "light," including "less" and "more" claims, the reference food may be the same as that provided for "light" in paragraph (j)(1)(ii)(A) of this section or it may be the manufacturer's regular product, or that of another manufacturer, that has been offered for sale to the public on a regular basis for a substantial period of time in the same geographic area by the same business entity or by one entitled to use its trade name. The nutrient value(s) for a single manufacturer's product shall be the value declared in nutrition labeling on the product.

(2) For foods bearing relative claims:

(i) The label or labeling must state the identity of the reference food and the percentage (or fraction) of the amount of the nutrient in the reference food by which the nutrient has been modified, (e.g., "50 percent less fat than (reference food)" or "1/3 fewer calories than (reference food)"),

(ii) This information shall be immediately adjacent to the most prominent claim. The type size shall be in accordance with paragraph (g)(1) of this section.

(iii) The determination of which use of the claim is in the most prominent location on the label or labeling will be made based on the following factors, considered in order:

(A) A claim on the principal display panel adjacent to the statement of identity;

(B) A claim elsewhere on the principal display panel;

(C) A claim on the information panel; or

(D) A claim elsewhere on the label or labeling.

(iv) The label or labeling must also bear:

(A) Clear and concise quantitative information comparing the amount of the subject nutrient in the product per labeled serving with that in the reference food; and

(B) This statement shall appear adjacent to the most prominent claim or on the information panel.

(3) A relative claim for decreased levels of a nutrient may not be made on the label or in labeling of a food if the nutrient content of the reference food meets the requirement for a "low" claim for that nutrient (e.g., 3 g fat or less).

(k) The term "modified" may be used in the statement of identity of a food that bears a relative claim that complies with the requirements of this part, followed immediately by the name of the nutrient whose content has been altered (e.g., "Modified fat cheesecake"). This statement of identity must be immediately followed by the comparative statement such as "Contains 35 percent less fat than ————." The label or labeling must also bear the information required by paragraph (j)(2) of this section in the manner prescribed.

(l) For purposes of making a claim, a "meal product shall be defined as a food that:

(1) Makes a major contribution to the total diet by:

(i) Weighing at least 10 ounces (oz) per labeled serving; and

(ii) Containing not less than 40 g for each of at least 3 different foods from 2 or more of the following 4 food groups except as noted in paragraph (l)(1)(ii)(E) of this section:

(A) Bread, cereal, rice, and pasta group;

(B) Fruits and vegetables group;

(C) Milk, yogurt, and cheese group;

(D) Meat, poultry, fish, dry beans, eggs, and nuts group; except that;

(E) These foods shall not be sauces (except for foods in the above four food groups that are in the sauces), gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings or garnishes; and

(2) Is represented as, or is in a form commonly understood to be, a breakfast, lunch, dinner, or meal. Such representations may be made either by statements, photographs, or vignettes.

(m) For purposes of making a claim, a "main dish product" shall be defined as a food that:

(1) Makes a major contribution to a meal by

(i) Weighing at least 6 oz per labeled serving; and

(ii) Containing not less than 40 g for each of at least two different foods from two of the following four food groups except as noted in paragraph (l)(1)(ii)(E) of this section:

(A) Bread, cereal, rice, and pasta group;

(B) Fruits and vegetables group;

(C) Milk, yogurt, and cheese group;

(D) Meat, poultry, fish, dry beans, eggs, and nuts groups; except that:

(E) These foods shall not be sauces (except for foods in the above four food groups that are in the sauces) gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings, or garnishes; and

(2) Is represented as, or is in a form commonly understood to be, a main dish (e.g, not a beverage or a dessert). Such representations may be made either by statements, photographs, or vignettes.

(n) Nutrition labeling in accordance with § 101.9 or § 101.10, as applicable shall be provided for any food for which a nutrient content claim is made.

(o) Except as provided in § 101.10, compliance with requirements for nutrient content claims in this section and in the regulations in subpart D of this part, will be determined using the analytical methodology prescribed for determining compliance with nutrition labeling in § 101.9.

(p)(1) Unless otherwise specified the reference amount customarily consumed set forth in § 101.12(b) through (f) shall be used in determining whether a product meets the criteria for a nutrient content claim. If the serving size declared on the product label differs from the reference amount customarily consumed, and the amount of the nutrient contained in the labeled serving does not meet the maximum or minimum amount criterion in the definition for the descriptor for that nutrient, the claim shall be followed by the criteria for the claim as required by § 101.12(g) (e.g., "very low sodium, 35 mg or less per 240 milliliters (8 fl oz.)").

(2) The criteria for the claim shall be immediately adjacent to the most prominent claim in easily legible print or type and in a size in accordance with paragraph (g)(1) of this section.

(q) The following exemptions apply:

(1) Nutrient content claims that have not been defined by regulation and that are contained in the brand name of a specific food product that was the brand name in use on such food before October 25, 1989, may continue to be used as part of that brand name for such product, provided that they are not false or misleading under section 403(a) of the Federal Food, Drug, and Cosmetic Act (the act). However, foods bearing such claims must comply with section 403(f), (g), and (h) of the act;

(2) A soft drink that used the term "diet" as part of its brand name before October 25, 1989, and whose use of that term was in compliance with § 105.66 of this chapter as that regulation appeared in the Code of Federal Regulations on that date, may continue to use that term as part of its brand name, provided that its use of the term is not false or misleading under section 403(a) of the act. Soft drinks marketed after October 25, 1989, may use the term "diet" provided they are in compliance with the current § 105.66 of this chapter;

(3) A statement that describes the percentage of a vitamin or mineral in the food, including foods intended specifically for use by infants and children less than 2 years of age, in relation to a Reference Daily Intake (RDI) as defined in § 101.9 may be made on the label or in labeling of a food without a regulation authorizing such a claim for a specific vitamin or mineral unless such claim is expressly prohibited by regulation under section 403(r)(2)(A)(vi) of the act.

(4) The requirements of this section do not apply to:

(i) Infant formulas subject to section 412(h) of the act; and

(ii) Medical foods defined by section 5(b) of the Orphan Drug Act.

(5) A nutrient content claim used on food that is served in restaurants (except on menus) or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments shall comply with the requirements of this section and the appropriate definition in subpart D of this part, except that:

(i) Such claim is exempt from the requirements for disclosure statements in paragraphs (g) and (h) of this section and §§ 101.54(d), 101.62(c), (d)(1)(ii)(C), (d)(2)(ii)(C), (d)(3), (d)(4)(ii)(C), and (d)(5)(ii)(C); and

(ii) In lieu of analytical testing, compliance may be determined using a reasonable basis for concluding that the food that bears the claim meets the definition for the claim. This reasonable basis may derive from recognized data bases for raw and processed foods, recipes, and other means to compute nutrient levels in the foods or meals and may be used provided reasonable steps are taken to ensure that the method of preparation adheres to the factors on which the reasonable basis was determined (e.g., types and amounts of ingredients, cooking temperatures, etc.). Firms making claims on foods based on this reasonable basis criterion are required to provide to appropriate regulatory officials on request the specific information on which their determination is based and reasonable assurance of operational adherence to the preparation methods or other basis for the claim; and

(iii) A term or symbol that may in some contexts constitute a claim under this section may be used, provided that the use of the term or symbol does not characterize the level of a nutrient, and a statement that clearly explains the basis for the use of the term or symbol is prominently displayed and does not characterize the level of a nutrient. For example, a term such as "lite fare" followed by an asterisk referring to a note that makes clear that in this restaurant "lite fare" means smaller portion sizes than normal; or an item bearing a symbol referring to a note that makes clear that this item meets the criteria for the dietary guidance established by a recognized dietary authority would not be considered a nutrient content claim under § 101.13.

(6) Nutrient content claims that were part of the common or usual names of foods that were subject to a standard of identity on November 8, 1990, are not subject to the requirements of paragraphs (b), (g), and (h) of this section or to definitions in subpart D of this part.

(7) Implied nutrient content claims may be used as part of a brand name, provided that the use of the claim has been authorized by the Food and Drug Administration. Petitions requesting approval of such a claim may be submitted under § 101.69(o).

(8) The term "fluoridated," "fluoride added" or "with added fluoride" may be used on the label or in labeling of bottled water that contains added fluoride.

§ 101.25 [Removed]

6. Section 101.25 *Labeling of foods in relation to fat and fatty acid and cholesterol content* is removed from subpart B.

7. New subpart D, consisting of §§ 101.54 through 101.69, is added to read as follows:

Subpart D—Specific Requirements for Nutrient Content Claims

Sec.

101.54 Nutrient content claims for "good source," "high," and "more."
101.56 Nutrient content claims for "light" or "lite."
101.60 Nutrient content claims for the calorie content of foods.
101.61 Nutrient content claims for the sodium content of foods.
101.62 Nutrient content claims for fat, fatty acid, and cholesterol content of foods.
101.65 Implied nutrient content claims and related label statements.
101.69 Petitions for nutrient content claims.

Subpart D—Specific Requirements for Nutrient Content Claims

§ 101.54 Nutrient content claims for "good source," "high," and "more."

(a) *General requirements.* Except as provided in paragraph (e) of this section, a claim about the level of a nutrient in a food in relation to the Reference Daily Intake (RDI) established for that nutrient in § 101.9(c)(8)(iv) or Daily Reference Value (DRV) established for that nutrient in § 101.9(c)(9), (excluding total carbohydrates) may only be made on the label and in labeling of the food if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 101.13; and

(3) The food for which the claim is made is labeled in accordance with § 101.9 or § 101.10, where applicable.

(b) *"High" claims.* (1) The terms "high," "rich in," or "excellent source of" may be used on the label and in the labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that the food contains 20 percent or more of the RDI or the DRV per reference amount customarily consumed.

(2) The terms defined in paragraph (b)(1) of this section may be used on the label and in the labeling of meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The product contains a food that meets the definition of "high" in paragraph (b)(1) of this section; and

(ii) The label or labeling clearly identifies the food that is the subject of the claim (e.g., the serving of broccoli in this product is high in vitamin C).

(c) *"Good Source" claims.* (1) The terms "good source," "contains," or "provides" may be used on the label or in the labeling of foods, except meal products as described in § 101.13(l) and a main dish product as defined in § 101.13(m), provided that the food contains 10 to 19 percent of the RDI or the DRV per reference amount customarily consumed.

(2) The terms defined in paragraph (c)(1) of this section may be used on the label and in the labeling of meal products as defined in § 101.13(l) and main dish products as defined in 101.13(m), provided that:

(i) The product contains a food that meets the definition of "good source" in paragraph (c)(1) of this section; and

(ii) The label or labeling clearly identifies the food that is the subject of the claim (e.g., the serving of sweet potatoes in this product is a "good source" of fiber).

(d) *"Fiber" claims.* (1) If a nutrient content claim is made with respect to the level of dietary fiber, that is, that the product is high in fiber, a good source of fiber, or that the food contains "more" fiber, and the food is not "low" in total fat as defined in § 101.62(b)(2) or, in the case of a meal product, as defined in § 101.13(l), or main dish product, as defined in § 101.13(m), is not "low" in total fat as defined in § 101.62(b)(3), then the label shall disclose the level of total fat per labeled serving.

(2) The disclosure shall appear in immediate proximity to such claim, be in a type size no less than one-half the size of the claim and precede the referral statement required in § 101.13(g) (e.g., "contains [*x amount*] of total fat per serving. See [*appropriate panel*] for nutrition information").

(e) *"More claims."* (1) A relative claim using the terms "more," "fortified," "enriched," and "added" may be used on the label or in labeling to describe the level of protein, vitamins, minerals, dietary fiber, or potassium in a food, except as limited by § 101.13(j)(1)(i) and except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The food contains at least 10 percent more of the RDI for protein, vitamins, or minerals or of the DRV for dietary fiber or potassium (expressed as a percent of the Daily Value) per reference amount customarily consumed than an appropriate reference food; and

(ii) Where the claim is based on a nutrient that has been added to the food, that fortification is in accordance with the policy on fortification of foods in § 104.20 of this chapter; and

(iii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percentage (or fraction) that the nutrient was increased relative to the RDI or DRV are declared in immediate proximity to the most prominent such claim (e.g., "contains 10 percent more of the Daily Value for fiber than white bread"); and

(B) Quantitative information comparing the level of the nutrient in the product per labeled serving, with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., "Fiber content of white bread is 1 gram (g) per serving; (this product) 3.5 g per serving").

(2) A relative claim using the terms "more," "fortified," "enriched," and "added" may be used on the label or in labeling to describe the level of protein, vitamins, minerals, dietary fiber or potassium, except as limited in § 101.13(j)(1)(i), in meal products as defined in § 101.13(l) or main dish products as defined in § 101.13(m), provided that:

(i) The food contains at least 10 percent more of the RDI for protein, vitamins, or minerals or of the DRV for dietary fiber or potassium (expressed as a percent of the Daily Value) per 100 g of food than an appropriate reference food.

(ii) Where the claim is based on a nutrient that has been added to the food, that fortification is in accordance with the policy on fortification of foods in § 104.20 of this chapter; and

(iii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percentage (or fraction) that the nutrient was increased relative to the RDI or DRV are declared in immediate proximity to the most prominent such claim (e.g., "contains 10 percent more of the Daily Value for fiber per 3 oz than does 'X brand of product'"), and

(B) Quantitative information comparing the level of the nutrient in the product per specified weight, with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., "the fiber content of 'X brand of product' is 2 g per 3 oz. This product contains 4.5 g per 3 oz").

§ 101.56 Nutrient content claims for "light" or "lite."

(a) *General requirements.* A claim using the term "light" or "lite" to describe a food may only be made on the label and in labeling of the food if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 101.13; and

(3) The food is labeled in accordance with § 101.9, § 101.10, or § 101.36, where applicable.

(b) *"Light" claims.* The terms "light" or "lite" may be used on the label or in the labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), without further qualification, provided that:

(1) If the food derives 50 percent or more of its calories from fat, its fat content is reduced by 50 percent or more per reference amount customarily consumed compared to an appropriate reference food as specified in § 101.13(j)(1); or

(2) If the food derives less than 50 percent of its calories from fat:

(i) The number of calories is reduced by at least one-third (33 1/3 percent) per reference amount customarily consumed compared to an appropriate reference food; or

(ii) Its fat content is reduced by 50 percent or more per reference amount customarily consumed compared to the reference food that it resembles or for which it substitutes as specified in § 101.13(j)(1); and

(3) As required in § 101.13(j)(2) for relative claims:

(i) The identity of the reference food and the percent (or fraction) that the calories and the fat were reduced are declared in immediate proximity to the most prominent such claim, (e.g., "1/3 fewer calories and 50 percent less fat than our regular cheese cake");

(ii) Quantitative information comparing the level of calories and fat content in the product per labeled serving size, with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., lite cheese cake—200 calories, 4 grams (g) fat; regular cheese cake—300 calories, 8 g fat per serving); and

(iii) If the labeled food contains less than 40 calories or less than 3 g fat per reference amount customarily consumed, the percentage reduction for that nutrient need not be declared.

(4) A "light" claim may not be made on a food for which the reference food meets the definition of "low fat" and "low calorie."

(c)(1)(i) A product for which the reference food contains 40 calories or less and 3 g fat or less per reference amount customarily consumed may use the term "light" or "lite" without further qualification if it is reduced by 50 percent or more in sodium content compared to the reference food; and

(ii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the sodium was reduced shall be declared in immediate proximity to the most prominent such claim (e.g., 50 percent less sodium than our regular soy sauce); and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference food it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., "lite soy sauce 500 milligrams (mg) sodium per serving, regular soy sauce 1,000 mg per serving").

(2)(i) A product for which the reference food contains more than 40 calories or more than 3 g fat per reference amount customarily consumed may use the term "light in sodium" or "lite in sodium" if it is reduced by 50 percent or more in sodium content compared to the reference food, provided that "light" or "lite" is presented in immediate proximity with "in sodium" and the entire term is presented in uniform type size, style, color, and prominence; and

(ii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the sodium was reduced shall be declared in immediate proximity to the most prominent such claim (e.g., 50 percent less sodium than our regular canned peas); and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference food it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., "light canned peas, 175 milligrams (mg) sodium per serving, regular canned peas 350 mg per serving.")

(iii) Except for meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), a "light in sodium" claim may not be made on a food for which the reference food meets the definition of "low in sodium".

(d)(1) The terms "light" or "lite" may be used on the label or in the labeling of a meal product as defined in § 101.13(l) and a main dish product as defined in § 101.13(m), provided that:

(i) The food meets the definition of:

(A) "Low in calories" as defined in § 101.60(b)(3); or

(B) "Low in fat" as defined in § 101.62(b)(3); and

(ii)(A) A statement appears on the principal display panel that explains whether "light" is used to mean "low fat," "low calories," or both (e.g., "Light Delight, a low fat meal"); and

(B) The accompanying statement is no less than one-half the type size of the "light" or "lite" claim.

(d)(2)(i) The term "light in sodium" or "lite in sodium" may be used on the label or in the labeling of a meal product as defined in § 101.13(l) and a main dish product as defined in § 101.13(m), provided that the food meets the definition of "low in sodium" as defined in § 101.61(b)(5)(i); and

(ii) "Light" or "lite" and "in sodium" are presented in uniform type size, style, color, and prominence.

(e) Except as provided in paragraphs (b) through (d) of this section, the term "light" or "lite" may not be used to refer to a food that is not reduced in fat by 50 percent, or, if applicable, in calories by 1/3 or, when properly qualified, in sodium by 50 percent unless:

(1) It describes some physical or organoleptic attribute of the food such as texture or color and the information (e.g., "light in color" or "light in texture") so stated, clearly conveys the nature of the product; and

(2) The attribute (e.g., "color" or "texture") is in the same style, color, and at least one-half the type size as the word "light" and in immediate proximity thereto.

(f) If a manufacturer can demonstrate that the word "light" has been associated, through common use, with a particular food to reflect a physical or organoleptic attribute (e.g., light brown sugar, light corn syrup, or light molasses) to the point where it has become part of the statement of identity, such use of the term "light" shall not be considered a nutrient content claim subject to the requirements in this part.

(g) The term "lightly salted" may be used on a product to which has been added 50 percent less sodium than is normally added to the reference food as described in § 101.13(j)(1)(i)(B) and (j)(1)(ii)(B), provided that if the product is not "low in sodium" as defined in § 101.61(b)(4), the statement "not a low sodium food," shall appear on the information panel and the information on the label or labeling as specified in § 101.13(j)(2).

§ 101.60 Nutrient content claims for the calorie content of foods.

(a) *General requirements.* A claim about the calorie content of a food may only be made on the label or in the labeling of the food if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 101.13; and

(3) The food for which the claim is made is labeled in accordance with § 101.9 or § 101.10, where applicable.

(b) *"Calorie content claims."* (1) The terms "calorie free," "free of calories," "no calories," "zero calories," "without calories," "trivial source of calories," "negligible source of calories," or "dietarily insignificant source of calories" may be used on the label or in the labeling of foods, provided that:

(i) The food contains less than 5 calories per reference amount customarily consumed; and

(ii) As required in § 101.13(e)(2), if the food meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the caloric content, it is labeled to

disclose that calories are not usually present in the food (e.g., "cider vinegar, a calorie free food").

(2) The terms "low calorie," "few calories," "contains a small amount of calories," "low source of calories," or "low in calories" may be used on the label and in labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The food has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons and does not provide more than 40 calories per reference amount customarily consumed; or

(ii) The food has a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and does not provide more than 40 calories per reference amount customarily consumed and, except for sugar substitutes, per 50 g (for dehydrated foods that are typically consumed when rehydrated with only water, the per 50 g criterion refers to the "as prepared" form); and

(iii) If a food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to vary the caloric content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches (e.g., "celery, a low calorie food").

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of meal products as defined in § 101.13(l) or main dish products as defined in § 101.13(m), provided that:

(i) The product contains 120 calories or less per 100 g; and

(ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the calorie content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which it attaches.

(4) The terms "reduced calorie," "reduced in calories," "calorie reduced," "fewer calories," "lower calorie," or "lower in calories" may be used on the label or in the labeling of foods, except as limited by § 101.13(j)(1)(i) and except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The food contains at least 25 percent fewer calories per reference amount customarily consumed than an appropriate reference food as described in § 101.13(j)(1); and

(ii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the calories have been reduced are declared in immediate proximity to the most prominent such claim (e.g., reduced calorie cupcakes "33 1/3 percent fewer calories than regular cupcakes"); and

(B) Quantitative information comparing the level of the nutrient in the product per labeled serving with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., "calorie content has been reduced from 150 to 100 calories per serving").

(iii) Claims described in paragraph (b)(4) of this section may not be made on the label or labeling of foods if the reference food meets the definition for "low calorie."

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in the labeling of meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The food contains at least 25 percent fewer calories per 100 g of food than an appropriate reference food as described in § 101.13(j)(1); and

(ii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the calories have been reduced are declared in immediate proximity to the most prominent such claim (e.g., Larry's Reduced Calorie Lasagna, "25 percent fewer calories per oz (or 3 oz) than our regular Lasagna"); and

(B) Quantitative information comparing the level of the nutrient in the product per specified weight with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., calorie content has been reduced from 108 calories per 3 oz to 83 calories per 3 oz).

(iii) Claims described in paragraph (b)(5) of this section may not be made on the label or labeling of food if the reference food meets the definition for "low calorie."

(c) *Sugar content claims*—(1) *Use of terms such as "sugar free," "free of sugar," "no sugar," "zero sugar," "without sugar," "sugarless," "trivial source of sugar," "negligible source of sugar," or "dietarily insignificant source of sugar."* Consumers may reasonably be expected to regard terms that represent that the food contains no sugars or sweeteners e.g., "sugar free," or "no sugar," as indicating a product which is low in calories or significantly reduced in calories. Consequently, except as provided in paragraph (c)(2) of this section, a food may not be labeled with such terms unless:

(i) The food contains less than 0.5 g of sugars, as defined in § 101.9(c)(6)(ii), per reference amount customarily consumed or in the case of a meal product or main dish product less than 0.5 g of sugars per labeled serving; and

(ii) The food contains no ingredient that is a sugar or that is generally understood by consumers to contain sugars unless the listing of the ingredient in the ingredient statement is followed by an asterisk that refers to the statement below the list of ingredients, which states "adds a trivial amount of sugar," "adds a negligible amount of sugar," or "adds a dietarily insignificant amount of sugar;" and

(iii)(A) It is labeled "low calorie" or "reduced calorie" or bears a relative claim of special dietary usefulness labeled in compliance with paragraphs (b)(2), (b)(3), (b)(4), or (b)(5) of this section; or

(B) Such term is immediately accompanied, each time it is used, by either the statement "not a reduced calorie food," "not a low calorie food," or "not for weight control."

(2) The terms "no added sugar," "without added sugar," or "no sugar added" may be used only if:

(i) No amount of sugars, as defined in § 101.9(c)(6)(ii), or any other ingredient that contains sugars that functionally substitute for added sugars is added during processing or packaging; and

(ii) The product does not contain an ingredient containing added sugars such as jam, jelly, or concentrated fruit juice; and

(iii) The sugars content has not been increased above the amount present in the ingredients by some means such as the use of enzymes, except where the intended functional effect of the process is not to increase the sugars content of a food, and a functionally insignificant increase in sugars results; and

(iv) The food that it resembles and for which it substitutes normally contains added sugars; and

(v) The product bears a statement that the food is not "low calorie" or "calorie reduced" (unless the food meets the requirements for a "low" or "reduced calorie" food) and that directs consumers' attention to the nutrition panel for further information on sugar and calorie content.

(3) Paragraph (c)(1) of this section shall not apply to a factual statement that a food, including foods intended specifically for infants and children less than 2 years of age, is unsweetened or contains no added sweeteners in the

case of a food that contains apparent substantial inherent sugar content, e.g., juices.

(4) The terms "reduced sugar," "reduced in sugar," "sugar reduced," "less sugar," "lower sugar" or "lower in sugar" may be used on the label or in labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The food contains at least 25 percent less sugar per reference amount customarily consumed than an appropriate reference food as described in § 101.13(j)(1); and

(ii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the sugar has been reduced are declared in immediate proximity to the most prominent such claim (e.g., "these corn flakes contain 25 percent less sugar than our sugar coated corn flakes"); and

(B) Quantitative information comparing the level of the sugar in the product per labeled serving with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., "Sugar content has been lowered from 8 g to 6 g per serving").

(5) The terms defined in paragraph (c)(4) of this section may be used on the label or in the labeling of a meal product as defined in § 101.13(l) and a main dish product as defined in § 101.13(m), provided that:

(i) The food contains at least 25 percent less sugars per 100 g of food than an appropriate reference food as described in § 101.13(j)(1), and

(ii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the sugars have been reduced are declared in immediate proximity to the most prominent such claim (e.g., reduced sweet and sour shrimp dinner, "25 percent less sugar per 3 oz than our regular sweet and sour shrimp dinner"); and

(B) Quantitative information comparing the level of the nutrient in the product per specified weight with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., sugar content has been reduced from 17 g per 3 oz to 13 g per 3 oz).

§ 101.61 Nutrient content claims for the sodium content of foods.

(a) *General requirements.* A claim about the level of sodium in a food may only be made on the label and in the labeling of the food if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 101.13; and

(3) The food for which the claim is made is labeled in accordance with § 101.9 or § 101.10, where applicable.

(b) *"Sodium content claims."* (1) The terms "sodium free," "free of sodium," "no sodium," "zero sodium," "without sodium," "trivial source of sodium," "negligible source of sodium," or "dietary insignificant source of sodium" may be used on the label or in the labeling of foods, provided that:

(i) The food contains less than 5 milligrams (mg) of sodium per reference amount customarily consumed or in the case of a meal product or a main dish product less than 5 mg of sodium per labeled serving; and

(ii) The food contains no ingredient that is sodium chloride or is generally understood by consumers to contain sodium, unless the listing of the ingredient in the ingredient statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: "Adds a trivial amount of sodium," "adds a negligible amount of sodium" or "adds a dietarily insignificant amount of sodium;" and

(iii) As required in § 101.13(e)(2) if the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to disclose that sodium is not usually present in the food (e.g., "leaf lettuce, a sodium free food").

(2) The terms "very low sodium," or "very low in sodium," may be used on the label and in labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i)(A) The food has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons and contains 35 mg or less sodium per reference amount customarily consumed; or

(B) The food has a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and contains 35 mg or less sodium per reference amount customarily consumed and per 50 g (for dehydrated foods that are typically consumed when rehydrated with only water, the per 50 g refers to the "as prepared" form);

(ii) If the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to vary the sodium content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches (e.g., "potatoes, a very low-sodium food").

(3) The terms defined in paragraph (b)(2) of this section may be used on the label and in labeling of meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The product contains 35 mg or less of sodium per 100 g of product; and

(ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches.

(4) The terms "low sodium," or "low in sodium," "little sodium," "contains a small amount of sodium," or "low source of sodium" may be used on the label and in the labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i)(A) The food has a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons and contains 140 mg or less sodium per reference amount customarily consumed; or

(B) The food has a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and contains 140 mg or less sodium per reference amount customarily consumed and per 50 g (for dehydrated foods that are typically consumed when rehydrated with only water, the per 50 g criterion refers to the "as prepared" form); and

(ii) If the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to vary the sodium content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches (e.g., "fresh spinach, a low sodium food"); and

(5) The terms defined in paragraph (b)(4) of this section may be used on the label and in labeling of meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The product contains 140 mg or less sodium per 100 g; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches.

(6) The terms "reduced sodium," "reduced in sodium," "sodium reduced," "less sodium," "lower sodium," or "lower in sodium" may be used on the label or in labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The food contains at least 25 percent less sodium per reference amount customarily consumed than an appropriate reference food as described in § 101.13(j)(1).

(ii) As required for § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the sodium has been reduced are declared in immediate proximity to the most prominent such claim (e.g., "reduced sodium ————, 50 percent less sodium than regular ————"); and

(B) Quantitative information comparing the level of the sodium in the product per labeled serving with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., "sodium content has been lowered from 300 to 150 mg per serving").

(iii) Claims described in paragraph (b)(6) of this section may not be made on the label or in the labeling of a food if the nutrient content of the reference food meets the definition for "low sodium."

(7) The terms defined in paragraph (b)(6) of this section may be used on the label or in the labeling of meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The food contains at least 25 percent less sodium per 100 g of food than an appropriate reference food as described in § 101.13(j)(1), and

(ii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the sodium has been reduced are declared in immediate proximity to the most prominent such claim (e g., reduced sodium eggplant parmigiana dinner "30 percent less sodium per oz (or 3 oz) than our regular eggplant parmigiana dinner").

(B) Quantitative information comparing the level of sodium in the product per specified weight with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., sodium content has been reduced from 217 mg per 3 oz to 150 mg per 3 oz).

(iii) Claims described in paragraph (b)(7) of this section may not be made on the label or in the labeling of a food if the nutrient content of the reference food meets the definition for "low sodium."

(c) The term "salt" is not synonymous with "sodium." Salt refers to sodium chloride. However, references to salt content such as "unsalted," "no salt," "no salt added" are potentially misleading.

(1) The term "salt free" may be used on the label or in labeling of foods only if the food is "sodium free" as defined in paragraph (b)(1) of this section.

(2) The terms "unsalted," "without added salt," and "no salt added" may be used on the label or in labeling of foods only if:

(i) No salt is added during processing;

(ii) The food that it resembles and for which it substitutes is normally processed with salt; and

(iii) If the food is not sodium free, the statement, "not a sodium free food" or "not for control of sodium in the diet" appears on the information panel of the food bearing the claim.

(3) Paragraph (c)(2) of this section shall not apply to a factual statement that a food intended specifically for infants and children less than 2 years of age is unsalted, provided such statement refers to the taste of the food and is not otherwise false and misleading.

§ 101.62 Nutrient content claims for fat, fatty acid, and cholesterol content of foods.

(a) *General requirements.* A claim about the level of fat, fatty acid, and cholesterol in a food may only be made on the label or in the labeling of foods if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 101.13; and

(3) The food for which the claim is made is labeled in accordance with § 101.9 or § 101.10, where applicable.

(b) *"Fat content claims."* (1) The terms "fat free," "free of fat," "no fat," "zero fat," "without fat," "nonfat," "trivial source of fat," "negligible source of fat," or "dietarily insignificant source of fat" may be used on the label or in labeling of foods, provided that:

(i) The food contains less than 0.5 gram (g) of fat per reference amount customarily consumed or in the case of a meal product or main dish product less than 0.5 g of fat per labeled serving;

(ii) The food contains no added ingredient that is a fat or is generally understood by consumers to contain fat unless the listing of the ingredient in the ingredient statement is followed by an asterisk that refers to the statement below the list of ingredients, which states "adds a trivial amount of fat," "adds a negligible amount of fat," or "adds a dietarily insignificant amount of fat;" and

(iii) As required in § 101.13(e)(2), if the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower fat content, it is labeled to disclose that fat is not usually present in the food (e.g., "broccoli, a fat free food").

(2) The terms "low fat," "low in fat," "contains a small amount of fat," "low source of fat," or "little fat" may be used on the label and in labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i)(A) The food has a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons and contains 3 g or less of fat per reference amount customarily consumed; or

(B) The food has a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and contains 3 g or less of fat per reference amount customarily consumed and per 50 g of food (for dehydrated foods that are typically consumed when rehydrated with only water, the per 50 g criterion refers to the "as prepared" form); and

(ii) If the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower fat content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches (e.g., "frozen perch, a low fat food").

(3) The terms defined in paragraph (b)(2) of this section may be used on the label and in labeling of meal products as defined in § 101.13(l) or main dish products as defined in § 101.13(m), provided that:

(i) The product contains 3 g or less of total fat per 100 g and not more than 30 percent of calories from fat; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower fat content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches.

(4) The terms "reduced fat," "reduced in fat," "fat reduced," "less fat," "lower fat," or "lower in fat" may be used on the label or in the labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The food contains at least 25 percent less fat per reference amount customarily consumed than an appropriate reference food as described in § 101.13(j)(1); and

(ii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the fat has been reduced and are declared in immediate proximity to the most prominent such claim (e.g., "reduced fat—50 percent less fat than our regular brownies"); and

(B) Quantitative information comparing the level of fat in the product per labeled serving with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., "fat content has been reduced from 8 g to 4 g per serving").

(iii) Claims described in paragraph (b)(4) of this section may not be made on the label or in the labeling of a food if the nutrient content of the reference food meets the definition for "low fat."

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in the labeling of meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The food contains at least 25 percent less fat per 100 g of food than an appropriate reference food as described in § 101.13(j)(1); and

(ii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the fat has been reduced are declared in immediate proximity to the most prominent such claim (e.g., reduced fat spinach souffle, "33 percent less fat per 3 oz than our regular spinach souffle"); and

(B) Quantitative information comparing the level of fat in the product per specified weight with that of the reference food that it replaces is declared adjacent to the most prominent such claim or on the information panel (e.g., fat content has been reduced from 7.5 g per 3 oz to 5 g per 3 oz).

(iii) Claims described in paragraph (b)(5) of this section may not be made on the label or in the labeling of a food if the nutrient content of the reference food meets the definition for "low fat."

(6) The term "——— percent fat free" may be used on the label or in the labeling of foods, provided that:

(i) The food meets the criteria for "low fat" in paragraph (b)(2) or (b)(3) of this section;

(ii) The percent of reduction and the words "fat free" are in uniform type size; and

(iii) A "100 percent fat free" claim may be made only on foods that meet the criteria for "fat free" in paragraph (b)(1) of this section, that contain less than 0.5 g of fat per 100 g, and that contain no added fat.

(c) *"Fatty acid content claims."* The label or labeling of foods that bear claims with respect to the level of saturated fat shall disclose the level of total fat and cholesterol in the food in immediate proximity to such claim each time the claim is made and in type that shall be no less than one-half the size of the type used for the claim with respect to the level of saturated fat. Declaration of cholesterol content may be omitted when the food contains less than 2 milligrams (mg) of cholesterol per reference amount customarily consumed or in the case of a meal or main dish product less than 2 mg of cholesterol per labeled serving. Declaration of total fat may be omitted with the term defined in paragraph (c)(1) of this section when the food contains 0.5 g or less of total fat per reference amount customarily consumed or, in the case of a meal product or a main dish product, when the product contains less than 0.5 g of total fat per labeled serving. The declaration of total fat may be omitted with the terms defined in paragraphs (c)(2) through (c)(5) of this section when the food contains 3 g or less of total fat per reference amount customarily consumed or in the case of a meal product or a main dish product, when the product contains 3 g or less of total fat per 100 g and not more than 30 percent calories from fat.

(1) The terms "saturated fat free," "free of saturated fat," "no saturated fat," "zero saturated fat," "without saturated fat," "trivial source of saturated fat," "negligible source of saturated fat," or "dietarily insignificant source of saturated fat" may be used on the label or in the labeling of foods, provided that:

(i) The food contains less than 0.5 g of saturated fat per reference amount customarily consumed and the level of trans fatty acids does not exceed 1 percent of the total fat, or in the case of a meal product or main dish product, less than 0.5 g of saturated fat per labeled serving and the level of trans fatty acids does not exceed 1 percent of the total fat; and

(ii) The food contains no ingredient that is generally understood by consumers to contain saturated fat unless the listing of the ingredient in the ingredient statement is followed by an asterisk that refers to the statement below the list of ingredients which states, "adds a trivial amount of saturated fat," "adds a negligible amount of saturated fat," or "adds a dietarily insignificant amount of saturated fat;" and

(iii) As required in § 101.13(e)(2), if the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to disclose that saturated fat is not usually present in the food.

(2) The terms "low in saturated fat," "low saturated fat," "contains a small amount of saturated fat," "low source of saturated fat," or "a little saturated fat" may be used on the label or in the labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The food contains 1 g or less of saturated fatty acids per reference amount customarily consumed and not more than 15 percent of calories from saturated fatty acids; and

(ii) If a food meets these conditions without benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches (e.g., "raspberries, a low saturated fat food").

(3) The terms defined in paragraph (c)(2) of this section may be used on the label or in the labeling of meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The product contains 1 g or less of saturated fatty acids per 100 g and less than 10 percent calories from saturated fat; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches.

(4) The terms "reduced saturated fat," "reduced in saturated fat," "saturated fat reduced," "less saturated fat," "lower saturated fat," or "lower in saturated fat" may be used on the label or in the labeling of foods, except as limited by § 101.13(j)(1)(i)(A) and except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The food contains at least 25 percent less saturated fat per reference amount customarily consumed than an appropriate reference food as described in § 101.13(j)(1); and

(ii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the saturated fat was reduced are declared in immediate proximity to the most prominent such claim (e.g., "reduced

saturated fat. Contains 50 percent less saturated fat than the national average for nondairy creamers"); and

(B) Quantitative information comparing the level of saturated fat in the product per labeled serving with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., "saturated fat reduced from 3 g to 1.5 g per serving").

(iii) Claims described in paragraph (c)(4) of this section may not be made on the label or in the labeling of a food if the nutrient content of the reference food meets the definition for "low saturated fat."

(5) The terms defined in paragraph (c)(4) of this section may be used on the label or in the labeling of meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The food contains at least 25 percent less saturated fat per 100 g of food than an appropriate reference food as described in § 101.13(j)(1), and

(ii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food, and the percent (or fraction) that the fat has been reduced are declared in immediate proximity to the most prominent such claim (e.g., reduced saturated fat Macaroni and Cheese, "33 percent less saturated fat per 3 oz than our regular Macaroni and Cheese").

(B) Quantitative information comparing the level of saturated fat in the product per specified weight with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., saturated fat content has been reduced from 2.5 g per 3 oz to 1.7 g per 3 oz).

(iii) Claims described in paragraph (c)(5) of this section may not be made on the label or in the labeling of a food if the nutrient content of the reference food meets the definition for "low saturated fat."

(d) *"Cholesterol content claims."* (1) The terms "cholesterol free," "free of cholesterol," "zero cholesterol," "without cholesterol," "no cholesterol," "trivial source of cholesterol," "negligible source of cholesterol," or "dietarily insignificant source of cholesterol" may be used on the label or in the labeling of foods, provided that:

(i) For foods that contain 13 g or less of total fat per reference amount cutomarily consumed, per labeled serving, and per 50 g if the reference amount customarily consumed is 30 g or less or 2 tablespoons or less (for dehydrated foods that must have water added to them prior to typical consumption, the per 50-g criterion refers to the "as prepared form"), or, in the case of meal products, 26.0 g or less total fat per labeled serving, or, in the case of main dish products, 19.5 g or less total fat per labeled serving:

(A) The food contains less than 2 mg of cholesterol per reference amount customarily consumed or in the case of a meal product or main dish product less than 2 mg of cholesterol per labeled serving; and

(B) The food contains no ingredient that is generally understood by consumers to contain cholesterol, unless the listing of the ingredient in the ingredient statement is followed by an asterisk that refers to the statement below the list of ingredients, which states "adds a trivial amount of cholesterol," "adds a negligible amount of cholesterol," or "adds a dietarily insignificant amount of cholesterol;" and

(C) The food contains 2 g or less of saturated fatty acids per reference amount customarily consumed or, in the case of a meal product or main dish product, 2 g or less of saturated fatty acids per labeled serving; and

(D) As required in § 101.13(e)(2), if the food contains less than 2 mg of cholesterol per reference amount customarily consumed or in the case of a meal product or main dish product, less than 2 mg of cholesterol per labeled serving without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to disclose that cholesterol is not usually present in the food (e.g., "applesauce, a cholesterol-free food").

(ii) For food that contain more than 13 g of total fat per reference amount customarily consumed, per labeling serving, per 50 g if the reference amount customarily consumed is 30 g or less or 2 tablespoons or less (for dehydrated foods that must have water added to them prior to typical consumption, the per 50-g criterion refers to the "as prepared" form), or in the case of a meal product, more than 26 g of total fat per labeled serving, or, in the case of a main dish product more than 19.5 g of total fat per labeled serving:

(A) The food contains less than 2 mg of cholesterol per reference amount cutomarily consumed or, in the case of a meal product or main dish product, less than 2 mg of cholesterol per labeled serving; and

(B) The food contains no ingredient that is generally understood by consumers to contain cholesterol, unless the listing of the ingredient in the ingredient statement is followed by an asterisk that refers to the statement below the list of ingredients, which states "adds a trivial amount of cholesterol," "adds a negligible amount of cholesterol," or "adds a dietarily insignificant amount of cholesterol;" and

(C) The food contains 2 g or less of saturated fatty acids per reference amount cutomarily consumed or, in the case of a meal product or main dish product less than 2 g of saturated fatty acids per labeled serving; and

(D) The label or labeling discloses the level of total fat in a serving (as declared on the label) of the food. Such disclosure shall appear in immediate proximity to such claim preceding the referral statement required in § 101.13(g) in type that shall be no less than one-half the size of the type used for such claim. If the claim appears on more than one panel, the disclosure shall be made on each panel except for the panel that bears nutrition labeling. If the claim appears more than once on a panel, the disclosure shall be made in immediate proximity to the claim that is printed in the largest type; and

(E) As required in § 101.13(e)(2), if the food contains less than 2 mg of cholesterol per reference amount customarily consumed or in the case of a meal product or main dish product less than 2 mg of cholesterol per labeled serving without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to disclose that cholesterol is not usually present in the food (e.g., "canola oil, a cholesterol-free food, contains 14 g of fat per serving"); or

(F) If the food contains less than 2 mg of cholesterol per reference amount customarily consumed or in the case of a meal product or main dish product less than 2 mg of cholesterol per labeled serving only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is substantially less (i.e., meets requirements of paragraph (d)(4)(ii)(A) of this section) than the food for which it substitutes as specified in § 101.13(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share. As required in § 101.13(j)(2) for relative claims:

(*1*) The identity of the reference food and the percent (or fraction) that the cholesterol was reduced are declared in immediate proximity to the most prominent such claim (e.g., "cholesterol-free margarine, contains 100 percent less cholesterol than butter"); and

(*2*) Quantitative information comparing the level of cholesterol in the product per labeled serving with that of

the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., "contains no cholesterol compared with 30 mg in one serving of butter. Contains 11 g of fat per serving.").

(2) The terms "low in cholesterol," "low cholesterol," "contains a small amount of cholesterol," "low source of cholesterol," or "little cholesterol" may be used on the label or in the labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) For foods that have a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons and contain 13 g or less of total fat per reference amount customarily consumed and per labeled serving:

(A) The food contains 20 mg or less of cholesterol per reference amount customarily consumed;

(B) The food contains 2 g or less of saturated fatty acids per reference amount customarily consumed; and

(C) As required in § 101.13(e)(2), if the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all foods of that type and not merely to the particular brand to which the label attaches (e.g., "low fat cottage cheese, a low cholesterol food.").

(ii) For foods that have a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and contain 13 g or less of total fat per reference amount customarily consumed, per labeled serving, and per 50 g (for dehydrated foods that are typically consumed when rehydrated with only water, the per 50 g refers to the "as prepared" form);

(A) The food contains 20 mg or less of cholesterol per reference amount customarily consumed and per 50 g (for dehydrated foods that are typically consumed when rehydrated with only water, the per 50 g refers to the "as prepared" form);

(B) The food contains 2 g or less of saturated fatty acids per reference amount customarily consumed;

(C) As required in § 101.13(e)(2), if the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all foods of that type and not merely to the particular brand to which the label attaches (e.g., "low fat cottage cheese, a low cholesterol food").

(iii) For foods that have a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons and contain more than 13 g of total fat per reference amount customarily consumed or per labeled serving,

(A) The food contains 20 mg or less of cholesterol per reference amount customarily consumed;

(B) The food contains 2 g or less of saturated fatty acids per reference amount customarily consumed;

(C) The label or labeling discloses the level of total fat in a serving (as declared on the label) of the food. Such disclosure shall appear in immediate proximity to such claim preceding the referral statement required in § 101.13(g) in type that shall be no less than one-half the size of the type used for such claim. If the claim appears on more than one panel, the disclosure shall be made on each panel except for the panel that bears nutrition labeling. If the claim is made more than once on a panel, the disclosure shall be made in immediate proximity to the claim that is printed in the largest type; and

(D) As required in § 101.13(e)(2), if the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all foods of that type and not merely to the particular brand to which the label attaches; or

(E) If the food contains 20 mg or less of cholesterol only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is substantially less (i.e., meets requirements of paragraph (d)(4)(ii)(A) of this section) than the food for which it substitutes as specified in § 101.13(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share. As required in § 101.13(j)(2) for relative claims:

(*1*) The identity of the reference food and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., "low-cholesterol peanut butter sandwich crackers, contains 83 percent less cholesterol than our regular peanut butter sandwich crackers"); and

(*2*) Quantitative information comparing the level of cholesterol in the product per labeled serving with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., "cholesterol lowered from 30 mg to 5 mg per serving, contains 13 g of fat per serving").

(iv) For foods that have a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and contain more than 13 g of total fat per reference amount customarily consumed, per labeled serving, or per 50 g (for dehydrated foods that are typically consumed when rehydrated with only water, the per 50 g refers to the "as prepared" form),

(A) The food contains 20 mg or less of cholesterol per reference amount customarily consumed and per 50 g (for dehydrated foods that are typically consumed when rehydrated with only water, the per 50 g refers to the "as prepared" form),

(B) The food contains 2 g or less of saturated fatty acids per reference amount customarily consumed;

(C) The label or labeling discloses the level of total fat in a serving (as declared on the label) of the food. Such disclosure shall appear in immediate proximity to such claim preceding the referral statement required in § 101.13(g) in type that shall be no less than one-half the size of the type used for such claim. If the claim appears on more than one panel, the disclosure shall be made on each panel except for the panel that bears nutrition labeling. If the claim is made more than once on a panel, the disclosure shall be made in immediate proximity to the claim that is printed in the largest type; and

(D) As required in § 101.13(e)(2), if the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all foods of that type and not merely to the particular brand to which the label attaches; or

(E) If the food contains 20 mg or less of cholesterol only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is substantially less (i.e., meets requirements of paragraph (d)(4)(ii)(A) of this section) than the food for which it substitutes as specified in § 101.13(d) that has a significant (i.e., 5 percent or more of a national or regional market) market share. As required in § 101.13(j)(2) for relative claims:

(*1*) The identity of the reference food and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., "low-cholesterol peanut butter sandwich crackers, contains 83 percent less cholesterol than our regular peanut butter sandwich crackers"); and

(*2*) Quantitative information comparing the level of cholesterol in the product per labeled serving with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., "cholesterol lowered from 30 mg to 5 mg per serving, contains 13 g of fat per serving").

(3) The terms defined in paragraph (d)(2) of this section may be used on the label and in labeling of meal products as defined in § 101.13(l) or a main dish product as defined in § 101.13(m) provided that the product meets the requirements of paragraph (d)(2) of this section except that the determination as to whether paragraph (d)(2)(i) or (d)(2)(iii) of this section applies to the product will be made only on the basis of whether the meal product contains 26 g or less of total fat per labeled serving or the main dish product contain 19.5 g or less of total fat per labeled serving, the requirement in paragraphs (d)(2)(i)(A) and (d)(2)(iii)(A) of this section shall be limited to 20 mg of cholesterol per 100 g, and the requirement in paragraphs (d)(2)(i)(B) and (d)(2)(iii)(B) of this section shall be modified to require that the food contain 2 g or less of saturated fat per 100 g rather than per reference amount customarily consumed.

(4) The terms "reduced cholesterol," "reduced in cholesterol," "cholesterol reduced," "less cholesterol," "lower cholesterol," or "lower in cholesterol" except as limited by § 101.13(j)(1)(i)(A) may be used on the label or in labeling of foods or foods that substitute for those foods as specified in § 101.13(d), excluding meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) For foods that contain 13 g or less of total fat per reference amount customarily consumed, per labeled serving, and per 50 g if the reference amount customarily consumed is 300 g or less or 2 tablespoons or less (for dehydrated food that must have water added to them prior to typical consumption, the per 50-g criterion refers to the "as prepared" form):

(A) The food has been specifically formulated, altered, or processed to reduce its cholesterol by 25 percent or more from the reference food it resembles as defined in § 101.13(j)(1) and for which it substitutes as specified in § 101.13(d) that has a significant (i.e., 5 percent or more) market share; and

(B) The food contains 2 g or less of saturated fatty acids per reference amount customarily consumed; and

(C) As required in § 101.13(j)(2) for relative claims:

(*1*) The identity of the reference food and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim; and

(*2*) Quantitative information comparing the level of cholesterol in the product per labeled serving with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel.

(ii) For foods that contain more than 13 g of total fat per reference amount customarily consumed, per labeled serving, or per 50 g if the reference amount customarily consumed is 30 g or less or 2 tablespoons or less (for dehydrated foods that must have water added to them prior to typical consumption, the per 50-g criterion refers to the "as prepared" form):

(A) The food has been specifically formulated, altered, or processed to reduce its cholesterol by 25 percent or more from the reference food it resembles as defined in § 101.13(j)(1) and for which it substitutes as specified in § 101.13(d) that has a significant (i.e., 5 percent or more of a national or regional market) market share;

(B) The food contains 2 g or less of saturated fatty acids per reference amount customarily consumed;

(C) The label or labeling discloses the level of total fat in a serving (as declared on the label) of the food. Such disclosure shall appear in immediate proximity to such claim preceding the referral statement required in § 101.13(g) in type that shall be no less than one-half the size of the type used for such claim. If the claim appears on more than one panel, the disclosure shall be made on each panel except for the panel that bears nutrition labeling. If the claim is made more than once on a panel, the disclosure shall be made in immediate proximity to the claim that is printed in the largest type; and

(D) As required in § 101.13(j)(2) for relative claims:

(*1*) The identity of the reference food and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., 25 percent less cholesterol than ——————); and

(*2*) Quantitative information comparing the level of cholesterol in the product per labeled serving with that of the reference food that it replaces is declared adjacent to the most prominent claim on the information panel (e.g., "Cholesterol lowered from 55 mg to 30 mg per serving. Contains 13 g of fat per serving").

(iii) Claims described in paragraph (d)(4) of this section may not be made on the label or in labeling of a food if the nutrient content of the reference food meets the definition for "low cholesterol."

(5) The terms defined in paragraph (d)(4) of this section may be used on the label or in the labeling of meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) For meal products that contain 26.0 g or less of total fat per labeled serving or for main dish products that contain 19.5 g or less of total fat per labeled serving;

(A) The food has been specifically formulated, altered, or processed to reduce its cholesterol by 25 percent or more from the reference food it resembles as defined in § 101.13(j)(1) and for which it substitutes as specified in § 101.13(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share;

(B) The food contains 2 g or less of saturated fatty acids per 100 g; and

(C) As required in § 101.13(j)(2) for relative claims:

(*1*) The identity of the reference food, and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., "25% less cholesterol per 3 oz than ————."); and

(*2*) Quantitative information comparing the level of cholesterol in the product per specified weight with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., Cholesterol content has been reduced from 35 mg per 3 oz to 25 mg per 3 oz).

(ii) For meal products that contain more than 26.0 g of total fat per labeled serving or for main dish products that contain more than 19.5 g of total fat per labeled serving:

(A) The food has been specifically formulated, altered, or processed to reduce its cholesterol by 25 percent or more from the reference food it resembles as defined in § 101.13(j)(1) and for which it substitutes as specified in § 101.13(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share.

(B) The food contains 2 g or less of saturated fatty acids per 100 g;

(C) The label or labeling discloses the level of total fat in a serving (as declared on the label) of the food. Such disclosure shall appear in immediate proximity to such claim preceding the referral statement required in § 101.13(g) in type that shall be no less than one-half the size of the type used for such claim. If the claim appears on more than one panel the disclosure shall be made on each panel except for the panel that bears nutrition labeling. If the claim is made more than once on a panel, the disclosure shall be made in immediate proximity to the claim that is printed in the largest type; and

(D) As required in § 101.13(j)(2) for relative claims:

(1) The identity of the reference food and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., 25 percent less cholesterol than ——————); and

(2) Quantitative information comparing the level of cholesterol in the product per specified weight with that of the reference food that it replaces is declared adjacent to the most prominent claim on the information panel (e.g., "cholesterol lowered from 30 mg to 22 mg per 3 oz of product.")

(iii) Claims described in paragraph (d)(5) of this section may not be made on the label or in the labeling of a food if the nutrient content of the reference food meets the definition for "low cholesterol."

(e) *"Lean" and "extra lean" claims.* (1) The term "lean" may be used on the label or in labeling of foods except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m) provided that the food is a seafood or game meat product and as packaged contains less than 10 g total fat, less than 4 g saturated fat, and less than 95 mg cholesterol per reference amount customarily consumed and per 100 g;

(2) The term defined in paragraph (e)(1) of this section may be used on the label or in the labeling of meal products as defined in § 101.13(l) or main dish products as defined in § 101.13(m) provided that the food contains less than 10 g total fat, less than 4 g saturated fat, and less than 95 mg cholesterol per 100 g and per labeled serving;

(3) The term "extra lean" may be used on the label or in the labeling of foods except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m) provided that the food is a discrete seafood or game meat product and as packaged contains less than 5 g total fat, less than 2 g saturated fat, and less than 95 mg cholesterol per reference amount customarily consumed and per 100 g; and

(4) The term defined in paragraph (e)(3) of this section may be used on the label or in labeling of meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m) provided that the food contains less than 5 g of fat, less than 2 g of saturated fat, and less than 95 mg of cholesterol per 100 g and per labeled serving.

(f) *Misbranding.* Any label or labeling containing any statement concerning fat, fatty acids, or cholesterol that is not in conformity with this section shall be deemed to be misbranded under sections 201(n), 403(a), and 403(r) of the Federal Food, Drug, and Cosmetic Act.

§ 101.65 Implied nutrient content claims and related label statements.

(a) *General requirements.* An implied nutrient content claim can only be made on the label and in labeling of the food if:

(1) The claim uses one of the terms described in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 101.13; and

(3) The food is labeled in accordance with § 101.9 or 101.10, where applicable.

(b) *Label statements that are not implied claims.* Certain label statements about the nature of a product are not nutrient content claims unless such statements are made in a context that would make them an implied claim under § 101.13(b)(2). The following types of label statements are generally not implied nutrient content claims and are not subject to the requirements of § 101.13 and this section:

(1) A claim that a specific ingredient or food component is absent from a product, provided that the purpose of such claim is to facilitate avoidance of the substances because of food allergies (see § 105.62 of this chapter), food intolerance, religious beliefs, or dietary practices such as vegetarianism or other nonnutrition related reason, e.g., "100 percent milk free;"

(2) A claim about a substance that is nonnutritive or that does not have a nutritive function, e.g., "contains no preservatives," "no artificial colors;"

(3) A claim about the presence of an ingredient that is perceived to add value to the product e.g., "made with real butter," "made with whole fruit," "contains honey;"

(4) A statement of identity for a food in which an ingredient constitutes essentially 100 percent of a food, (e.g. "corn oil," "oat bran.");

(5) A statement of identity that names as a characterizing ingredient, an ingredient associated with a nutrient benefit (e.g., "corn oil margarine," "oat bran muffins," or "whole wheat bagels"), unless such claim is made in a context in which label or labeling statements, symbols, vignettes, or other forms of communication suggest that a nutrient is absent or present in a certain amount; and

(6) A label statement made in compliance with a specific provision of part 105 of this chapter, solely to note that a food has special dietary usefulness relative to a physical, physiological, pathological, or other condition, where the claim identifies the special diet of which the food is intended to be a part.

(c) *Particular implied nutrient content claims.* (1) Claims about the food or an ingredient therein that suggest that a nutrient or an ingredient is absent or present in a certain amount (e.g., "high in oat bran") are implied nutrient content claims and must comply with paragraph (a) of this section.

(2) The phrases "contains the same amount of [nutrient] as a [food]" and "as much [nutrient] as a [food]" may be used on the label or in the labeling of foods, provided that the amount of the nutrient in the reference food is enough to qualify that food as a "good source" of that nutrient, and the labeled food, on a per serving basis, is an equivalent, good source of that nutrient (e.g., "as much fiber as an apple," "Contains the same amount of Vitamin C as an 8 oz glass of orange juice.").

(3) Claims may be made that a food contains or is made with an ingredient that is known to contain a particular nutrient, or is prepared in a way that affects the content of a particular nutrient in the food, if the finished food is either "low" in or a good source of the nutrient that is associated with the ingredient or type of preparation. If a more specific level is claimed (e.g., "high in ——————"), that level of the nutrient must be present in the food. For example, a claim that a food contains oat bran is a claim that it is a good source of dietary fiber; that a food is made only with vegetable oil is a claim that it is low in saturated fat; and that a food contains no oil is a claim that it is fat free.

(d) *General nutritional claims.* (1) Claims about a food that suggest that the food because of its nutrient content may be useful in maintaining healthy dietary practices and that are made in association with an explicit claim or statement about a nutrient (e.g., "healthy, contains 3 grams of fat") are implied nutrient content claims covered by this paragraph.

(2) [Reserved]

§ 101.69 Petitions for nutrient content claims.

(a) This section pertains to petitions for claims, expressed or implied, that:

(1) Characterize the level of any nutrient which is of the type required to be in the label or labeling of food by section 403(q)(1) or (q)(2) of the Federal Food, Drug, and Cosmetic Act (the act); and

(2) That are not exempted under section 403(r)(5)(A) through (r)(5)(C) of the act from the requirements for such claims in section 403(r)(2).

(b) Petitions included in this section are:

(1) Petitions for a new (heretofore unauthorized) nutrient content claim;

(2) Petitions for a synonymous term (i.e., one that is consistent with a term defined by regulation) for characterizing the level of a nutrient; and

(3) Petitions for the use of an implied claim in a brand name.

(c) An original and one copy of the petition to be filed under the provisions of section 403(r)(4) of the act shall be submitted, or the petitioner may submit an original and a computer readable disk containing the petition. Contents of the disk should be in a standard format, such as ASCII format. Petitioners interested in submitting a disk should contact FDA's Center for Food Safety and Applied Nutrition for details. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall state the petitioner's post office address to which published notices as required by section 403 of the act may be sent.

(d) Pertinent information may be incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of the Food and Drug Administration. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(e) If nonclinical laboratory studies are included in a petition submitted under section 403(r)(4) of the act, the petition shall include, with respect to each nonclinical study contained in the petition, either a statement that the study has been, or will be, conducted in compliance with the good laboratory practice regulations as set forth in part 58 of this chapter or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(f) If clinical investigations are included in a petition submitted under section 403(r)(4) of the act, the petition shall include a statement regarding each such clinical investigation relied upon in the petition that the study either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter or was not subject to such requirements in accordance with § 56.104 or § 56.105 of this chapter, and that it was conducted in compliance with the requirements for informed consent set forth in part 50 of this chapter.

(g) The availability for public disclosure of petitions submitted to the agency under this section will be governed by the rules specified in § 10.20(j) of this chapter.

(h) All petitions submitted under this section shall include either a claim for a categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter.

(i) The data specified under the several lettered headings should be submitted on separate sheets or sets of sheets, suitably identified. If such data have already been submitted with an earlier application from the petitioner, the present petition may incorporate it by specific reference to the earlier petition.

(j) The petition must be signed by the petitioner or by his attorney or agent, or (if a corporation) by an authorized official.

(k) The petition shall include a statement signed by the person responsible for the petition, that to the best of his knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him pertinent to the evaluation of the petition.

(l) All applicable provisions of Part 10—Administrative Practices and Procedures, may be used by the Commissioner of Food and Drugs, the petitioner or any outside party with respect to any agency action on the petition.

(m)(1) Petitions for a new nutrient content claim shall include the following data and be submitted in the following form.

(Date)

Name of petitioner ————

Post office address ————

Subject of the petition ————

Regulations and Industry Activities Branch (HFF–312),

Food and Drug Administration,

Department of Health and Human Services,

Washington, DC 20204.

To Whom It May Concern:

The undersigned, — submits this petition under section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to (statement of the claim and its proposed use).

Attached hereto, in quadruplicate, and constituting a part of this petition, are the following:

A. A statement identifying the descriptive term and the nutrient that the term is intended to characterize with respect to the level of such nutrient. The statement should address why the use of the term as proposed will not be misleading. The statement should provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of foods on which the claim will be used. The statement shall specify the level at which the nutrient must be present or what other conditions concerning the food must be met for the use of the term in labels or labeling to be appropriate, as well as any factors that would make the use of the term inappropriate.

B. A detailed explanation, supported by any necessary data, of why use of the food component characterized by the claim is of importance in human nutrition by virtue of its presence or absence at the levels that such claim would describe. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed, and why such benefit is not available through the use of existing terms defined by regulation under section 403(r)(2)(A)(i) of the act. If the claim is intended for a specific group within the population, the analysis should specifically address nutritional needs of such group, and should include scientific data sufficient for such purpose.

C. Analytical data that shows the amount of the nutrient that is the subject of the claim and that is present in the types of foods for which the claim is intended. The assays should be performed on representative samples using the Association of Official Analytical Chemists International (AOAC International) methods where available. If no AOAC International method is available, the petitioner shall submit the assay method used, and data establishing the validity of the method for assaying the nutrient in the particular food. The validation data should include a statistical analysis of the analytical and product variability.

D. A detailed analysis of the potential effect of the use of the proposed claim on food consumption and of any corresponding changes in nutrient intake. The latter item shall specifically address the intake of nutrients that have beneficial and negative consequences in the total diet. If the claim is intended for a specific group within the population, the above analysis shall specifically address the dietary practices of such

group and shall include data sufficient to demonstrate that the dietary analysis is representative of such group.

Yours very truly,

Petitioner ————

By ————

(Indicate authority)

(2) Within 15 days of receipt of the petition, the petitioner will be notified by letter of the date on which the petition was received by the agency. Such notice will inform the petitioner:

(i) That the petition is undergoing agency review (in which case a docket number will be assigned to the petition), and the petitioner will subsequently be notified of the agency's decision to file or deny the petition; or

(ii) That the petition is incomplete, e.g., it lacks any of the data required by this part, it presents such data in a manner that is not readily understood, or it has not been submitted in quadruplicate, in which case the petition will be denied, and the petitioner will be notified as to what respect the petition is incomplete.

(3) Within 100 days of the date of receipt of the petition, the Commissioner of Food and Drugs will notify the petitioner by letter that the petition has either been filed or denied. If denied, the notification shall state the reasons therefor. If filed, the date of the notification letter becomes the date of filing for the purposes of section 403(r)(4)(A)(i) of the act. A petition that has been denied shall not be made available to the public. A filed petition shall be available to the public as provided under paragraph (g) of this section.

(4) Within 90 days of the date of filing the Commissioner of Food and Drugs will by letter of notification to the petitioner:

(i) Deny the petition; or

(ii) Inform the petitioner that a proposed regulation to provide for the requested use of the new term will be published in the **Federal Register**. The Commissioner of Food and Drugs will publish the proposal to amend the regulations to provide for the requested use of the nutrient content claim in the **Federal Register** within 90 days of the date of filing. The proposal will also announce the availability of the petition for public disclosure.

(n)(1) Petitions for a synonymous term shall include the following data and be submitted in the following form.

————

(Date)

Name of petitioner ————

Post office address ————

Subject of the petition ————

Regulations and Industry Activities Branch (HFF–312),

Food and Drug Administration,

Department of Health and Human Services,

Washington, DC 20204.

To Whom It May Concern:

The undersigned, ———— submits this petition under section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to (statement of the synonymous term and its proposed use in a nutrient content claim that is consistent with an existing term that has been defined under section 403(r)(2) of the act).

Attached hereto, in quadruplicate, and constituting a part of this petition, are the following:

A. A statement identifying the synonymous descriptive term, the existing term defined by a regulation under section 403(r)(2)(A)(i) of the act with which the synonymous term is claimed to be consistent. The statement should address why the proposed synonymous term is consistent with the term already defined by the agency, and why the use of the synonymous term as proposed will not be misleading. The statement should provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of foods on which the claim will be used. The statement shall specify whether any limitations not applicable to the use of the defined term are intended to apply to the use of the synonymous term.

B. A detailed explanation, supported by any necessary data, of why use of the proposed term is requested, including an explanation of whether the existing defined term is inadequate for the purpose of effectively characterizing the level of a nutrient. This item shall also state what nutritional benefit to the public will derive from use of the claim as proposed, and why such benefit is not available through the use of existing term defined by regulation. If the claim is intended for a specific group within the population, the analysis should specifically address nutritional needs of such group, and should include scientific data sufficient for such purpose.

Yours very truly,

Petitioner ————

By ————

(Indicate authority)

(2) Within 15 days of receipt of the petition the petitioner will be notified by letter of the date on which the petition was received. Such notice will inform the petitioner:

(i) That the petition is undergoing agency review (in which case a docket number will be assigned to the petition) and the petitioner will subsequently be notified of the agency's decision to grant the petitioner permission to use the proposed term or to deny the petition; or

(ii) That the petition is incomplete, e.g., it lacks any of the data required by this part, it presents such data in a manner that is not readily understood, or it has not been submitted in quadruplicate, in which case the petition will be denied, and the petitioner will be notified as to what respect the petition is incomplete.

(3) Within 90 days of the date of receipt of the petition that is accepted for review (i.e., that has not been found to be incomplete and consequently denied, the Commissioner of Food and Drugs will notify the petitioner by letter of the agency's decision to grant the petitioner permission to use the proposed term, with any conditions or limitations on such use specified, or to deny the petition, in which case the letter shall state the reasons therefor. Failure of the petition to fully address the requirements of this section shall be grounds for denial of the petition.

(4) As soon as practicable following the agency's decision to either grant or deny the petition, the Commissioner of Food and Drugs will publish a notice in the **Federal Register** informing the public of his decision. If the petition is granted the Food and Drug Administration will list, the approved synonymous term in the regulations listing terms permitted for use in nutrient content claims.

(o)(1) Petitions for the use of an implied nutrient content claim in a brand name shall include the following data and be submitted in the following form:

————

(Date)

Name of petitioner ————

Post office address ————

Subject of the petition ————

Regulations and Industry Activities Branch (HFF–312),

Food and Drug Administration,

Department of Health and Human Services,

Washington, DC 20204.

To Whom It May Concern:

The undersigned,

————

submits this petition under section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to (statement of the implied nutrient content claim and its proposed use in a brand name).

Attached hereto, in quadruplicate, and constituting a part of this petition, are the following:

A. A statement identifying the implied nutrient content claim, the nutrient the claim is intended to

characterize, the corresponding term for characterizing the level of such nutrient as defined by a regulation under section 403(r)(2)(A)(i) of the act, and the brand name of which the implied claim is intended to be a part. The statement should address why the use of the brandname as proposed will not be misleading. It should address in particular what information is required to accompany the claim or other ways in which the claim meets the requirements of sections 201(n) and 403(a) of the act. The statement should provide examples of the types of foods on which the brand name will appear. It shall also include data showing that the actual level of the nutrient in the food qualifies the food to bear the corresponding term defined by regulation. Assay methods used to determine the level of a nutrient should meet the requirements stated under petition format item C in paragraph (k)(1) of this section.

B. A detailed explanation, supported by any necessary data, of why use of the proposed brand name is requested. This item shall also state what nutritional benefit to the public will derive from use of the brand name as proposed. If the branded product is intended for a specific group within the population, the analysis should specifically address nutritional needs of such group and should include scientific data sufficient for such purpose.

Yours very truly,

Petitioner ————

By ————

(2) Within 15 days of receipt of the petition the petitioner will be notified by letter of the date on which the petition was received. Such notice will inform the petitioner:

(i) That the petition is undergoing agency review (in which case a docket number will be assigned to the petition); or

(ii) That the petition is incomplete, e.g., it lacks any of the data required by this part, it presents such data in a manner that is not readily understood, or it has not been submitted in quadruplicate, in which case the petition will be denied, and the petitioner will be notified as to what respect the petition is incomplete.

(3) The Commissioner of Food and Drugs will publish a notice of the petition in the **Federal Register** announcing its availability to the public and seeking comment on the petition. The petition shall be available to the public to the extent provided under paragraph (g) of this section. The notice shall allow 30 days for comments.

(4) Within 100 days of the date of receipt of the petition that is accepted for review (i.e., that has not been found to be incomplete and subsequently returned to the petitioner), the Commissioner of Food and Drugs will:

(i) Notify the petitioner by letter of the agency's decision to grant the petitioner permission to use the proposed brand name if such use is not misleading, with any conditions or limitations on such use specified; or

(ii) Deny the petition, in which case the letter shall state the reasons therefor. Failure of the petition to fully address the requirements of this section shall be grounds for denial of the petition. Should the Commissioner of Food and Drugs not notify the petitioner of his decision on the petition within 100 days, the petition shall be considered to be granted.

(5) As soon as practicable following the granting of a petition, the Commissioner of Food and Drugs will publish a notice in the **Federal Register** informing the public of such fact.

(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB control number ————)

8. Subpart F is redesignated as subpart G and new subpart F, consisting of § 101.95, is added to read as follows:

Subpart F—Specific Requirements for Descriptive Claims that are Neither Nutrient Content Claims nor Health Claims

§ 101.95 "Fresh," "freshly frozen," "fresh frozen," "frozen fresh."

The terms defined in this section may be used on the label or in labeling of a food in conformity with the provisions of this section. The requirements of the section pertain to any use of the subject terms as described in paragraphs (a) and (b) of this section that expressly or implicitly refers to the food on labels or labeling, including use in a brand name and use as a sensory modifier. However, the use of the term "fresh" on labels or labeling is not subject to the requirements of paragraph (a) of this section if the term does not suggest or imply that a food is unprocessed or unpreserved. For example, the term "fresh" used to describe pasteurized whole milk is not subject to paragraph (a) of this section because the term does not imply that the food is unprocessed (consumers commonly understand that milk is nearly always pasteurized). However, the term "fresh" to describe pasta sauce that has been pasteurized or that contains pasteurized ingredients would be subject to paragraph (a) of this section because the term implies that the food is not processed or preserved. Uses of fresh not subject to this regulation will be governed by the provisions of 403(a) of the Federal Food, Drug, and Cosmetic Act (the act).

(a) The term "fresh," when used on the label or in labeling of a food in a manner that suggests or implies that the food is unprocessed, means that the food is in its raw state and has not been frozen or subjected to any form of thermal processing or any other form of preservation, except as provided in paragraph (c) of this section.

(b) The terms "fresh frozen" and "frozen fresh," when used on the label or in labeling of a food, mean that the food was quickly frozen while still fresh (i.e., the food had been recently harvested when frozen). Blanching of the food before freezing will not preclude use of the term "fresh frozen" to describe the food. "Quickly frozen" means frozen by a freezing system such as blast-freezing (sub-zero Fahrenheit temperature with fast moving air directed at the food) that ensures the food is frozen, even to the center of the food, quickly and that virtually no deterioration has taken place.

(c) *Provisions and restrictions*—(1) The following do not preclude the food from use of the term "fresh:"

(i) The addition of approved waxes or coatings;

(ii) The post-harvest use of approved pesticides;

(iii) The application of a mild chlorine wash or mild acid wash on produce; or

(iv) The treatment of raw foods with ionizing radiation not to exceed the maximum dose of 1 kiloGray in accordance with § 179.26 of this chapter.

(2) A food meeting the definition in paragraph (a) of this section that is refrigerated is not precluded from use of "fresh" as provided by this section.

Dated: December 17, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 92-31504 Filed 12-28-92; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 105

[Docket No. 91N-384L]

RIN 0905-AD08

Food Labeling: Label Statements on Foods for Special Dietary Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food labeling regulations to conform them to the requirements of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). With the passage of the 1990 amendments to the Federal Food, Drug, and Cosmetic Act (the act), certain provisions concerning label statements on foods for special dietary use in reducing or maintaining caloric intake or body weight are no longer appropriately included in that regulation but are now more appropriately defined as nutrient content claims applicable to the general population and regulated under 21 CFR part 101. FDA is making changes in 21 CFR 105.66 to reflect this fact. FDA is also announcing its intention to reexamine 21 CFR part 105 and revise that part as necessary to ensure that it provides appropriate coverage for foods for special dietary use.

DATES: Effective May 8, 1994, except as to any provisions that may be stayed by the filing of proper objections; written objections and requests for a hearing by February 5, 1993.

ADDRESSES: Written objections may be sent to the Dockets Management Branch (HFS-155), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Elizabeth J. Campbell, Center for Food Safety and Applied Nutrition (HFS-155), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5229.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 27, 1991 (56 FR 60421), FDA published a proposed rule entitled "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms" (the general principles proposal) that would, among other things, establish general principles for the use of claims describing the nutrient content of a food and define certain specific nutrient content claims that can be used to describe the levels of certain nutrients in a food.

The general principles proposal was issued in response to the 1990 amendments (Pub. L. 101-535) to the act. With respect to nutrient content claims, the 1990 amendments amended the act by adding section 403(r)(1)(A) (21 U.S.C. 343(r)(1)(A)) which states that a food is misbranded if it bears a claim in its label or labeling that either expressly or implicitly characterizes the level of any nutrient of the type required to be declared as part of the nutrition labeling, unless such claim is made using terms which are defined in regulations adopted by the agency under section 403(r)(2).

The proposed regulations on nutrient content claims included provisions similar or identical to some provisions in § 105.66, which addresses foods for special dietary use in reducing or maintaining caloric intake or body weight. Therefore, the general principles proposal included several changes in § 105.66 to eliminate redundancy in the regulations and to conform § 105.66 to the 1990 amendments. Specifically, FDA proposed to redesignate requirements for terms such as "low calorie" and "reduced calorie," for other comparative calorie claims, and for sugar claims from § 105.66 to new § 101.60, which defines terms used to make nutrient content claims for the calorie content of foods. This redesignation is necessary because terms such as "low calorie" and "reduced calorie" are no longer appropriately regulated under the regulations for foods for special dietary use but are now more appropriately defined under the 1990 amendments as nutrient content claims for foods intended for use by the general population. FDA also proposed to delete from § 105.66 any inappropriate reference to specific nutrient content claims or similar terms and any statement that is inconsistent with the 1990 amendments.

FDA also proposed to delete the exemption (§ 105.66(e)(3)) for formulated meal replacements and other foods that are represented for special dietary use as a whole meal from the requirements in § 105.66(e)(1). These requirements bear on the use of label terms that suggest usefulness as low calorie or reduced calorie foods, such as "diet," "dietetic," "artificially sweetened," and "sweetened with nonnutritive sweetener." FDA proposed to remove this exemption so that such claims could be expressly permitted under § 105.66, and thus not be prohibited as implied nutrient content claims under the 1990 amendments, until more appropriate regulations can be issued. The agency stated its view that claims that are permitted under § 105.66 meet the requirements of section 403(r) of the act (56 FR 60421 at 60458).

FDA noted in the proposal that a significant portion of § 105.66 remains appropriate for regulating foods that are for special dietary use (56 FR 60421 at 60457). Such foods are those that are specifically represented as, or that purport to be, useful as part of a weight control plan, as opposed to those that are simply represented as being low or reduced in calories (although products low or reduced in calories can be useful in reducing or maintaining body weight). The agency did not propose to remove the remaining portion of § 105.66, which includes requirements for label statements about nonnutritive sweeteners and for the use of the term "diet" and related terms. FDA noted, however, that it plans to reexamine the provisions remaining in § 105.66 and initiate additional rulemaking as appropriate (56 FR 60421 at 60457).

FDA is publishing a final rule based on the general principles proposal and on a related proposal (56 FR 60421 at 60478, November 27, 1991) concerning nutrient content claims related to the fat, fatty acid, and cholesterol content of food elsewhere in this issue of the **Federal Register**. This final rule effecting revisions in § 105.66 is being published as a separate document because § 105.66 was issued under the authority of section 403(j) of the act. Thus, revisions to § 105.66 must be made in accordance with the formal rulemaking procedures in section 701(e) of the act (21 U.S.C. 371(e)). Under these procedures, there is an opportunity to object to the provisions of a final rule and to request a public hearing on that objection. Such an opportunity is not provided as part of the notice and comment procedures apply to that most of the rest of the rulemaking that FDA is doing in response to the 1990 amendments.

The agency received only a few comments in response to the proposed revisions in § 105.66. Some of the comments received by the agency addressed matters concerning other regulations in 21 CFR part 105 (i.e., §§ 105.62 and 105.67) which are outside the scope of this rulemaking and are not being addressed here. However, after review of these comments, FDA believes that other regulations in part 105 may need to be reexamined, and that additional rulemaking may need to be initiated to ensure that these regulations

fully address their subject matter. In its reexamination of § 105.66, FDA will consider among other things, whether that regulation adequately describes foods for use in reducing or maintaining body weight, such as formulated meal replacements, whether it appropriately provides for use of terms such as "diet" on such foods, and whether "artificially sweetened" or "sweetened with a nonnutritive sweetener" should be included as label terms suggesting usefulness as low calorie or reduced calorie foods. These actions will be undertaken at some time in the future and FDA will solicit comments on the relevant issues at that time.

All of the relevant comments on proposed revisions in § 105.66 supported FDA's intent to revise this regulation to conform it to the provisions of the 1990 amendments. However, some of the comments raised concerns about some of the specific actions that FDA proposed. These comments are addressed below.

II. Comments and Agency Response

1. One comment asserted that requiring formulated meal replacements that bear terms such as "diet," "dietetic," "artificially sweetened," and "sweetened with nonnutritive sweetener" to meet the requirements for low or reduced calorie foods, or to make another comparative calorie claim, would effectively ban the sale of these foods. The comment stated that formulated meal replacements do not meet the definition of "low calorie" or "reduced calorie," and that a "reference" food would have to be identified to make a "reduced calorie" or other comparative calorie claim. The comment pointed out that FDA did not address what the reference food should be for formulated meal replacements. The comment requested that FDA provide in the regulations that a formulated meal replacement or other food that is represented to be of special dietary use as a whole meal, and that bears terms such as "diet," "dietetic," "artificially sweetened," or "sweetened with nonnutritive sweetener," not be required to be a "low calorie" or "reduced calorie" food, or to bear another comparative calorie claim, if its labeling is not false or misleading, and the product is useful as part of a weight loss or weight control program.

As noted above, FDA had proposed to delete the exemption in § 105.66(e)(3) for formulated meal replacements and other foods that are represented to be of special dietary use as a whole meal, from the requirements in § 105.66(e)(1) so that such foods would be expressly authorized to make "diet," "dietetic," or "artificially sweetened" claims under § 105.66. Thus, these claims on these foods would not be prohibited as unauthorized implied nutrient content claims under the 1990 amendments. However, FDA has reconsidered the circumstances under which claims should be regarded as implied nutrient content claims and as claims for special dietary use. As stated in the final rule on nutrient content claims, published elsewhere in this issue of the **Federal Register**, the agency does not consider claims made solely to portray the usefulness of a food for supplying a particular dietary need that exists by reason of a physical, physiological, pathological, or other condition, as described in part 105, to be a nutrient content claim subject to § 101.13. On the other hand, a claim of dietary usefulness made in a context that is relevant to the general population (e.g., where the label states that the food is "low calorie") would be subject to the requirements for nutrient content claims. FDA views a claim such as "use as part of a weight reduction program," made in conjunction with terms such as "diet," "dietetic," "artificially sweetened," or "sweetened with nonnutritive sweetener," on a formulated meal replacement to be a claim that solely portrays the usefulness of the food for a special dietary need, as described in part 105. Thus, such a claim by itself, without any other reference to nutrient aspects of the food relative to the general population, is not a nutrient content claim. Therefore, FDA concludes that there is no need to subject formulated meal replacements to the requirements of § 105.66(e)(1) to preclude claims such as "diet" on such products from being prohibited as implied nutrient content claims.

FDA, thus, has decided not to delete § 105.66(e)(3) and thus will continue to permit formulated meal replacements and other foods that are represented to be of special dietary use as whole meals to use terms such as "diet," "dietetic," "artificially sweetened," and "sweetened with nonnutritive sweetener" on their labels and labeling without having to comply with the requirements of § 105.66(e)(1). Therefore, the concern raised that formulated meal replacements are unable to comply with the requirements of § 105.66(e)(1) is moot.

However, FDA advises that the use of terms such as "diet," "dietetic," "artificially sweetened," and "sweetened with nonnutritive sweetener" on the label or in the labeling of any food, including a food for special dietary use, is subject to the act's general prohibition against false or misleading labeling in section 403(a) of the act. Thus, FDA can take action against any false or misleading use of a term such as "diet." For example, if a food that is not a formulated meal replacement purported on its label to be a formulated meal replacement to avoid the requirement that foods using the label term "diet" either be low in calories, reduced in calories or bear another comparative calorie claim, FDA would consider the food to be misbranded because it is falsely represented as a formulated meal replacement. Such a food would also be in violation of § 105.66(e)(1) because it is not a formulated meal replacement. FDA is likely to take action against any food that uses terms such as "diet," "dietetic," "artificially sweetened," and "sweetened with nonnutritive sweetener" on its label or in its labeling in this manner.

2. A comment stated that FDA should amend § 105.66(e)(1) in the final rule to clarify that this regulation applies only when the specific terms "diet," "dietetic," "artificially sweetened," and "artificially sweetened with nonnutritive sweetener" appear on the label as self-contained terms, but not when a term such as "diet" is used in a statement that represents the product to be useful as part of a weight loss "diet." The comment stated that the proposal could be misunderstood to mean that FDA is prohibiting the use of all other claims suggesting that a product is useful in a weight loss "diet" if that product does not meet the definition for "low calorie" or "reduced calorie." The comment stated that such an interpretation would be inconsistent with FDA's express intention of permitting such claims as stated in the final rule establishing § 105.66 (43 FR 43248 at 43253, September 22, 1978), wherein the agency stated:

> * * * any food may make a claim of special dietary usefulness for weight control on some basis other than its being "low calorie," "reduced calorie," or comparatively useful * * *. The claim must not be misleading and the basis for the claim must be conspicuously and clearly stated in conjunction with the claim. These foods may make appropriate claims, e.g., "for calorie restricted diets" or "useful for weight control."

The agency advises that it continues to hold the position that it stated in the final order establishing § 105.66. In that rulemaking, FDA stated that a food that purports to be useful for weight control on some other basis than its being "low calorie," "reduced calorie," or comparatively useful in controlling calorie intake is subject to the provisions of § 105.66(a) and (b) but not § 105.66(e). The agency stated that to

comply with § 105.66(a) and (b), such foods must bear nutrition labeling, labeling about the presence of nonnutritive ingredients, and a conspicuous and nonmisleading statement about the basis of the claim (43 FR 43248 at 43253, September 22, 1978).

Concerning the matter raised by the comment, i.e., the use of statements incorporating the term "diet" on foods for special dietary use intended for weight reduction, the agency concludes that such statements do not invoke the requirements of § 105.66(e), except when made on meal replacements or other foods represented to be of special dietary use as a whole meal, which are subject to § 105.66(e)(3), when they are used in a manner that does not suggest that the food is a "low calorie" or "reduced calorie" food. Such foods are subject to the requirements of § 105.66(a) and (b). However, the revision of the regulation sought by this comment, i.e., a provision in the regulation clarifying the circumstances where § 105.66(e) applies, is beyond the scope of this rulemaking. FDA stated in the general principles proposal that it only intended to make changes in § 105.66 at this time that are necessary to conform this section to the 1990 amendments. FDA will fully consider any necessary clarification of § 105.66(e)(1) in this regard when it initiates additional rulemaking on this section as stated above.

3. One comment suggested that the "Weight Watchers" line of foods falls within the provisions of § 105.66 because it provides information on the product label that suggests that these products can be useful in an overall weight-control diet plan. In addition, this same comment expressed concern that use of the brand name "Weight Watchers" would be prohibited on those products introduced into the marketplace after October 25, 1989, i.e., the date after which products introduced into the marketplace that make nutrient content claims in their brand names must use terms in the claims that are defined by the agency in a regulation, or that have been approved by the agency in response to a petition (section 403(r)(2)(A)(i), (r)(2)(C), and (r)(4)(A)(iii) of the act).

FDA advises that, in general, it would regard a brand name such as "Weight Watchers," when accompanied by information on the product label that suggests that the product can be useful in an overall weight-control diet plan, without any other reference to nutrient aspects of the food relative to the general population, to be a claim that solely portrays the usefulness of the food for a special dietary need as described in part 105 (see comment 1 of this document). Under these circumstances, such a claim is subject to the provisions of § 105.66 and is not a nutrient content claim. Accordingly, such a claim in a brand name may continue to be used on such products irrespective of whether a specific product under that brand name was introduced into the marketplace before October 25, 1989.

III. Conclusions

After review and consideration of the comments received in response to the November 27, 1991, proposal, FDA concludes that no evidence or information has been presented that would alter the agency's tentative determination that it should amend § 105.66 to conform that regulation to the provisions of the 1990 amendments. Therefore, FDA is amending § 105.66 as proposed with the exception of the revision in the final rule discussed in comment 1 of this document. FDA has also corrected two inadvertent errors that appeared in the proposal in the codified text of paragraph (e)(1). First, the proposed text omitted the words "such as" that had immediately preceded "diet," "dietetic," "artificially sweetened," or "sweetened with nonnutritive sweetener" in the existing regulation. It was not the agency's intent to delete these words from the revised text, and thus, they are being restored in the final rule. Secondly, FDA has conformed paragraph (e)(1) with respect to comparative calorie claims to paragraph (d). FDA has also made other minor editorial revisions in the text of the final rule for internal consistency.

IV. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the general principles proposal (56 FR 60467). At that time, FDA determined under § 25.24(a)(11) that the actions proposed therein (which include this action) are of a type that do not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

4. Several comments on the general principles proposal suggested that there would be significant adverse environmental effects from the actions proposed therein because they would cause large stocks of labels and labeled packaging materials to be discarded and require a great number of trees to be harvested to provide new labeling material. One comment estimated the number of label units from the dairy industry that would need to be discarded following publication of FDA's final rules on several food labeling actions, including this action. However, this comment did not: (1) Show how these estimates were derived, (2) identify what portion of the estimated amounts are attributable to this action, or (3) describe what impact the discarded labeling and packaging would have on the disposal of solid waste.

Neither the 1990 amendments nor FDA's proposed regulations require a food company to make nutrient content claims on its product labels. Food companies have known since November 8, 1990, the date of enactment of the 1990 amendments, that possibly by May 8, 1993, their labels would not be able to include nutrient content claims unless the claims conformed to FDA's regulations. In the general principles proposal (56 FR 60421) the agency proposed that this final rule would become effective 6 months after its date of publication in the **Federal Register**. However, the agency has determined that this final rule will become effective May 8, 1994. FDA believes that this effective date will allow ample time for food companies to use up most of the label and packaging stocks that existed on November 8, 1990, and that contained nutrient content claims. Consequently, the comments on the potential for adverse environmental effects do not affect the agency's previous determination that no significant impact on the human environment is expected, and that an environmental impact statement is not required.

V. Economic Impact

In accordance with the Regulatory Flexibility Act (Pub. L. 96–354), FDA has reviewed the final rule to redesignate certain requirements in § 105.66 to § 101.60 to determine its impact on small entities, including small businesses. Although the food labeling reform initiative taken as a whole, would result in a major rule, FDA has determined that redesignating certain requirements in § 105.66 to § 101.60 for conformance to the 1990 amendments, will not result in a significant impact on a substantial number of small entities. FDA has not received any new information or comments that would alter this determination. Therefore, FDA certifies in accordance with the Regulatory Flexibility Act, that no significant impact on a substantial number of small entities will derive from this action.

In accordance with Executive Order 12291, FDA has carefully analyzed the economic effects of this final rule, and the agency has determined that the rule, if promulgated, will not be a major rule as defined by that order.

VI. Objections

Any person who will be adversely affected by this regulation may at any time on or before December 10, 1992, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. FDA will publish notice of the objections that the agency has received or lack thereof in the **Federal Register.**

List of Subjects in 21 CFR Part 105

Dietary foods, Food grades and standards, Food labeling, Infants and children.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 105 is amended as follows:

PART 105—FOODS FOR SPECIAL DIETARY USE

1. The authority citation for 21 CFR part 105 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 411, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 350, 371, 376).

2. Section 105.66 is revised to read as follows:

§ 105.66 Label statements relating to usefulness in reducing or maintaining body weight.

(a) *General requirements.* Any food that purports to be or is represented for special dietary use because of usefulness in reducing or maintaining body weight shall bear:

(1) Nutrition labeling in conformity with § 101.9, or, where applicable, § 101.36 of this chapter, unless exempt under that section; and

(2) A conspicuous statement of the basis upon which the food claims to be of special dietary usefulness.

(b) *Nonnutritive ingredients.* (1) Any food subject to paragraph (a) of this section that achieves its special dietary usefulness by use of a nonnutritive ingredient (i.e., one not utilized in normal metabolism) shall bear on its label a statement that it contains a nonnutritive ingredient and the percentage by weight of the nonnutritive ingredient.

(2) A special dietary food may contain a nonnutritive sweetener or other ingredient only if the ingredient is safe for use in the food under the applicable law and regulations of this chapter. Any food that achieves its special dietary usefulness in reducing or maintaining body weight through the use of a nonnutritive sweetener shall bear on its label the statement required by paragraph (b)(1) of this section, but need not state the percentage by weight of the nonnutritive sweetener. If a nutritive sweetener(s) as well as nonnutritive sweetener(s) is added, the statement shall indicate the presence of both types of sweetener, e.g., "Sweetened with nutritive sweetener(s) and nonnutritive sweetener(s)."

(c) *"Low calorie" foods.* A food purporting to be "low calorie" must comply with the criteria set forth for such foods in § 101.60(b)(2) and (b)(3) of this chapter.

(d) *"Reduced calorie" foods and other comparative calorie claims.* A food purporting to be "reduced calorie" or otherwise containing fewer calories than a reference food must comply with the criteria set forth for such food in § 101.60(b)(4) and (b)(5) of this chapter.

(e) *Label terms suggesting usefulness as low calorie or reduced calorie foods.* (1) Except as provided in paragraphs (e)(2) and (e)(3) of this section, and in § 101.13(q)(2) of this chapter for soft drinks, a food may be labeled with terms such as "diet," "dietetic," "artificially sweetened," or "sweetened with nonnutritive sweetener" only if the claim is not false and misleading, and the food is labeled "low calorie" or "reduced calorie" or bears another comparative calorie claim in compliance with part 101 of this chapter and this section.

(2) Paragraph (e)(1) of this section shall not apply to any use of such terms that is specifically authorized by regulation governing a particular food, or, unless otherwise restricted by regulation, to any use of the term "diet" that clearly shows that the food is offered solely for a dietary use other than regulating body weight, e.g., "for low-sodium diets."

(3) Paragraph (e)(1) of this section shall not apply to any use of such terms on a formulated meal replacement or other food that is represented to be of special dietary use as a whole meal, pending the issuance of a regulation governing the use of such terms on foods.

(f) *"Sugar free," and "no added sugar."* Criteria for the use of the terms "sugar free" and "no added sugar" are provided for in § 101.60(c) of this chapter.

Dated: October 22, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 130

[Docket No. 91N–0317 et al.]

RIN 0905–AD08

Food Standards: Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the General Provisions for food standards to prescribe a general definition and standard of identity for foods named by use of a nutrient content claim defined in part 101 (21 CFR part 101) (such as "fat free," "low calorie," and "light") in conjunction with a traditional standardized name (for example "reduced fat sour cream"). FDA is taking this action to assist consumers in maintaining healthy dietary practices by providing for modified versions of certain standardized foods that bear descriptive names that are meaningful to consumers. FDA believes that this action will promote honesty and fair dealing in the interest of consumers. This rule applies only to standards of identity and not to standards of quality or fill.

EFFECTIVE DATE: May 8, 1994.

FOR FURTHER INFORMATION CONTACT: Shellee A. Davis, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5112.

SUPPLEMENTARY INFORMATION:

I. Background

One of the main purposes of the Nutrition Labeling and Education Act of 1990 (Pub. L. 101–535) (the 1990 amendments) was to establish the circumstances in which claims could be made that describe the nutrient content of food. In response to the requirements of the 1990 amendments, elsewhere in this issue of the **Federal Register**, in a document entitled "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definitions of Terms" (hereinafter referred to as the nutrient content claims final rule), FDA is establishing in part 101 definitions for such nutrient content claims together with general principles and procedures governing their use.

In the **Federal Register** of November 27, 1991 (56 FR 60512), FDA published a proposal to amend the General Provisions for food standards to prescribe a general definition and standard of identity for foods named by use of a nutrient content claim defined in part 101 (e.g., "fat free," "low calorie," and "light") in conjunction with a traditional standardized name (e.g., "reduced fat sour cream"). Interested persons were given until February 25, 1992, to comment on the proposed regulation.

FDA received approximately 200 responses, each of which contained one or more comments, from trade and retail associations, government organizations, manufacturers, consumers, retailers, consumer groups, State groups, private organizations, professional societies, and universities. The comments generally supported the proposal. Several comments addressed issues outside the scope of the proposal (e.g., serving size and nutrition labeling) that will not be discussed here. A number of comments suggested modification and revision in various provisions of the proposal. A summary of the suggested changes and the agency's responses follow.

II. Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term Under the 1990 Amendments

A. General Comments

1. Appropriateness and Need for Regulation

In the proposal, FDA invited comments with respect to the appropriateness and need for a general standard in proposed § 130.10 to establish the requirements for modified foods named by use of a nutrient content claim and a standardized term (56 FR 60512 at 60517).

1. Several comments stated that it is important to keep the present standards of identity as they are. One comment stated that, while allowing for the establishment of standards of identity for products like "light sour cream" and "lowfat ice cream," FDA must ensure that the existing standards for "milk," "sour cream," "ice cream," or "butter" are not diluted or debased. These comments stated that under no circumstances should a product that has undergone any form or degree of defatting be allowed to be called simply "milk," "sour cream," or "ice cream."

The agency agrees with these comments. FDA is not amending any of the existing standards of identity with this regulation. Under section 403(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(g)), a food is misbranded if it purports to be or is represented as a food for which a definition and standard of identity has been 0prescribed by regulation, unless it conforms to such definition and standards.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule entitled "Food Labeling: Use of Nutrient Content Claims for Butter Products," which adds new § 101.67. Except as provided in new § 101.67 for "butter," any food whose name includes a standardized term must conform to the standard of identity for that food found in parts 131 through 169 (21 CFR parts 131 through 169) or in new § 130.10. For example, a food labeled as "ice cream" must conform to the standard for ice cream in § 135.110, or it is misbranded. Similarly, a food labeled as "lowfat ice cream" must comply with new § 130.10. New § 130.10(a) states that the nutrient content claim must comply with the requirements of § 101.13 and with the requirements of the regulations in part 101 that define the particular nutrient content claim that is used. Thus, use of the term "lowfat" on a label for "lowfat ice cream" must comply with § 101.13 and § 101.62(b)(2) (i.e., the food must contain 3 grams (g) or less of fat per serving and per 50 g of food). New § 130.10(a) also provides that the "lowfat ice cream" must comply with the relevant standard in all other respects (e.g., major ingredients and the freezing process) except as provided in new § 130.10(b), (c), and (d).

2. One comment expressed concern that each modified food permitted to use a standardized food name meet consumer expectations. The comment suggested that if consumers no longer want or expect standardized products to have certain characteristics, the standards should be changed.

FDA appreciates the concern expressed by the comment. Section 401 of the act (21 U.S.C. 341) gives the agency authority to establish definitions and standards of identity for foods whenever such action will promote honesty and fair dealing in the interest of consumers. FDA has traditionally established individual standards to provide consumers with foods that include a modifier, such as a nutrient content claim or some other descriptive term, and a standardized term in their name. For example, the agency has established a standard of identity for milk in § 131.110 (21 CFR 131.110), but there are 17 other standards in part 131 (21 CFR part 131) that use the term "milk" in the name of the food (e.g., "cultured milk" (§ 131.112), "evaporated milk" (§ 131.130), and "skim milk" (§ 131.143)). FDA does not believe that use of these modifiers with

the term "milk" is confusing to consumers because these terms are defined by the standards.

FDA believes that establishing a general definition and standard of identity for modified versions of standardized foods that qualify for use of a nutrient content claim is a more efficient way to provide consumers with these foods than having to issue temporary marketing permits to each manufacturer desiring to market test a new modified food and, ultimately, establishing individual new food standards for each new modified version. New § 130.10 provides that the nutrient content claims that are used with standardized terms must be defined by FDA regulation. The food must comply with the nutrient content claim definition and with the requirements in new § 130.10 concerning performance characteristics, addition of nutrients and other ingredients, and labeling. Such requirements will ensure not only that a "lowfat" version of a standardized food is low in fat, but also that the food appropriately bears the standardized name. Therefore, FDA concludes that use of nutrient content claims with a standardized name will promote honesty and fair dealing in the interest of consumers.

2. Scope of Regulation

3. One comment stated that it presumed that the agency did not intend that proposed § 130.10 be mandatory.

FDA advises that the comment's presumption is incorrect, at least to the extent that a firm wants to make a food under the provisions of new § 130.10. The agency is establishing a general definition and standard of identity for such foods. Section 403(g) of the act states that a food is misbranded if it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401 of the act, unless it conforms to such definition and standard, and its label bears the name of the food specified in the definition and standard. Therefore, modified foods that conform to the definition and standard established in new § 130.10 must be labeled with the name provided under new § 130.10 or be misbranded under section 403(g) of the act. For example, sour cream must contain not less than 18 percent milkfat (§ 131.160). A sour cream product containing 12 percent milkfat and conforming to the standard of identity for sour half-and-half (§ 131.185) must be labeled in compliance with § 131.185(d) as either "sour half-and-half" or "cultured sour half-and-half." A sour cream product containing 9 percent milkfat that conforms to new § 130.10 and to the definition of "light" in § 101.56 must be labeled as "light sour cream."

4. One comment stated that proposed § 130.10(a) should be revised to make the intended scope of the regulation explicit. It stated that, as written, proposed § 130.10(a) creates an undesirable ambiguity with respect to foods that substitute for standardized foods that are themselves substitutes for one another (e.g., butter and margarine or cream cheese and neufchatel cheese). The comment suggested that FDA revise the language of proposed § 130.10(a) to limit the scope of proposed § 130.10 to "foods that substitute for a standardized food * * * and that use the name of that standardized food in their statement of identity but that do not comply * * *." The comment noted that a statement in the preamble limited the intended scope of proposed § 130.10 to substitute foods whose statement of identity includes the name of a standardized food. The comment added that an alternative way to solve the problem would be to provide in proposed § 130.10(a) that, in the case of a food that substitutes for more than one standardized food, the modified food needs to comply with proposed § 130.10 only with respect to one standardized food.

The agency agrees with the comment. Foods that comply with any standard of identity established in parts 131 through 169, are not subject to new § 130.10, even if they would qualify for a nutrient content claim as a modified version of a standardized food (e.g., sour half-and-half (§ 131.185) cannot be labeled as reduced fat sour cream under new § 130.10). However, foods that do not comply with a standard, that are modified versions of standardized foods, that qualify for use of a nutrient content claim, and that use the traditional standardized name in their statement of identity are the standardized foods that are defined by new § 130.10. This is consistent with the approach that FDA took in the proposal (56 FR 60512).

The agency has been persuaded by the comment that new § 130.10(a) should be revised to limit the scope of the regulation. Therefore, FDA is revising new § 130.10(a), as requested by the comment, to state: "* * * foods that substitute for a standardized food * * * and that use the name of that standardized food in their statement of identity but that do not comply * * *." In addition, FDA is revising the title of the regulation to delete the term "substitute" because new § 130.10 applies only to a certain category of substitute foods and not to all types of substitute foods as defined under §§ 101.3(e)(4) and 101.13(d). FDA believes that these revisions will more clearly establish the scope of the regulation and eliminate confusion as to foods that may substitute for other foods in a more general sense. Therefore, FDA concludes that these revisions will promote honesty and fair dealing in the interest of consumers.

FDA also agrees with the comment that in the case of a food that qualifies as a modified version of more than one standardized food, the food must be named under new § 130.10 only with reference to one standardized food. The § 130.10 product is a substitute for the standardized food that is named in its statement of identity. For example, cream cheese is defined in § 133.133 (21 CFR 133.133) as a product containing at least 33 percent milkfat by weight of the cream cheese. Neufchatel cheese (§ 133.162 (21 CFR 133.162)) is a product similar to cream cheese except that the milkfat content is not less than 20 percent but less than 33 percent by weight of the finished food. A reduced fat cream cheese-type product containing 15 percent milkfat may be considered a modified version of either cream cheese or neufchatel cheese because it contains at least 25 percent less fat than either food. Under new § 130.10, if the product is called "reduced fat cream cheese," it is a modified version of "cream cheese" because "cream cheese" is the standardized term used in conjunction with the nutrient content claim. If the product is called "reduced fat neufchatel cheese," it is a modified version of "neufchatel cheese."

5. One comment asked how this regulation would affect the nonstandard substitute cheese category (e.g., cheese containing vegetable oil in place of milkfat). It also asked if the regulations regarding "imitation" and "substitute" foods cited in § 101.3(e) would remain intact, or if this regulation would trigger the development of new requirements.

This final rule only sets forth the requirements for certain modified versions of standardized foods that qualify for the use of a nutrient content claim. Foods that do not use a traditional standardized term but use a nutrient content claim must comply with the general requirements of § 101.13 and the specific requirements for the particular nutrient content claim as well as the other provisions on common or usual names (§ 102.5 (21 CFR 102.5)). A modified food that does use a traditional standardized term but that does not comply with the traditional standard of identity or with

new § 130.10 must be labeled either as an "imitation," if it is nutritionally inferior, or as a "substitute," "alternative," or other appropriate term, if it is not nutritionally inferior, as specified in § 101.3(e) which will remain in effect. For example, a mozzarella cheese product made with skim milk and vegetable oil does not comply with the standard for mozzarella cheese (§ 133.155) or with new § 130.10(d)(2) and, therefore, must be labeled as "imitation mozzarella cheese" if nutritionally inferior to mozzarella cheese or as "mozzarella cheese alternative" or "mozzarella cheese substitute" if it is not nutritionally inferior. For this reason, FDA concludes that there is no need to amend the definitions for "imitation" or "substitute" foods in § 101.3(e) at this time.

6. One comment stated that there should be some listing of the standards as to which proposed § 130.10 is intended to apply. It stated that there was uncertainty as to when a particular food is subject to the general rule or requires individual agency action. Another comment stated that there is no reason to exclude any category of standardized foods from this proposal and urged FDA to retain the general applicability of the generic standard to all standardized foods in the final rule.

The agency disagrees that it needs to establish a specific list of standards to which new § 130.10 is to apply. New § 130.10(a) states that the foods prescribed by this general definition and standard of identity are those foods that substitute for a standardized food defined in parts 131 through 169. Thus, a modified version of any food defined by a standard of identity would be subject to new § 130.10, and no more specificity in new § 130.10 is necessary. This generic standard will minimize the need to establish individual new standards or to amend existing standards. FDA will establish new standards or amend existing ones if it determines that such action is necessary to promote honesty and fair dealing in the interest of consumers.

However, FDA notes that at the present time some standardized foods that are merely processed (e.g., canned green beans and canned wax beans (§ 155.120 (21 CFR 155.120)), tomato juice (§ 156.145 (21 CFR 156.145)), canned oysters (§ 161.145 (21 CFR 161.145))) cannot be modified so that the food does not comply with the traditional standard of identity, although they may still qualify to bear a defined nutrient content claim. For example, salt is an optional ingredient in the standard of identity for canned green beans and canned wax beans (§ 155.120). Therefore, if the product contains no added salt, the product remains the standardized food under § 155.120 and outside the scope of new § 130.10, although it may still qualify to bear a "no added salt" claim.

B. Product Deviations

In the proposal, FDA requested comments concerning how far a product may deviate from a standard and still qualify for use of the standardized name (56 FR 60512 at 60518).

7. Several comments stated that it is unnecessary for FDA to try to establish specific, quantitative limits. One comment stated that the agency should apply the general criteria for determining whether a food is a "substitute" for a standardized food. It stated that those criteria, which have been developed primarily through case law over the years, are based on everyday characteristics of the food that would be significant to the consumer, such as taste, texture, and appearance. Importantly, such an approach would conform to the President's directive, which requires regulations to use performance standards, not command-and-control techniques.

Several comments urged the agency to establish guidelines as to how much a modified food can deviate from the standardized product and still comply with proposed § 130.10.

The agency agrees that general requirements as to how far a modified food may deviate from the standard of identity and still use the standardized name are necessary. FDA also acknowledges that general criteria concerning significant characteristics of foods that are important to consumers have been developed primarily through case law, and the agency will use these criteria as needed for enforcement purposes. Some general requirements were included in the proposal and are now mandated by new § 130.10. A § 130.10 food must not be nutritionally inferior to the standardized food (new § 130.10(b)) and must have similar performance characteristics as the standardized food, including physical properties, flavor characteristics, functional properties, and shelf life (new § 130.10(c)).

In addition, under new § 130.10(d)(1), ingredients mandated to be present in a food by a standard of identity must also be present in the § 130.10 food. FDA believes that consumers expect certain ingredients to be present in specific foods. For example, the agency believes that consumers expect that a product such as "light mayonnaise" contains a significant amount of vegetable oil and egg yolk because these ingredients are required to be present in regular mayonnaise (§ 169.140). Thus, FDA has added new § 130.10(d)(4) to require that mandated ingredients must be present in a significant amount if the food is to be considered a modified version of the traditional standardized food. A significant amount is defined in that paragraph as at least that amount of the ingredient that is necessary to achieve the technical effect that the ingredient provides to the traditional standardized food. FDA concludes that this requirement in new § 130.10(d)(4) will promote honesty and fair dealing in the interest of consumers because it will ensure that a § 130.10 food will bear an appropriate relationship to the traditional standardized food.

8. One comment requested that FDA recognize that the removal of sugar and calories from a juice would result in a product that is still juice (e.g., "reduced calorie orange juice" or "light orange juice"). It added that the principles for naming products that are nutritionally modified versions of standardized products should be no different for standardized juices than for other standardized products. The comment requested that FDA ensure that this regulation is consistent with the regulation on percent juice labeling.

FDA agrees that the principles for naming products that are modified versions of standardized juice products should be no different than for other modified products. The agency recognizes that the reduction of sugars from a juice, and the subsequent sweetening of the product with a safe and suitable sweetener that provides an insignificant amount of calories, results in a modified juice product. Use of a sweetener with the same caloric density as the sugar naturally present in the juice is prohibited under new § 130.10(d)(2) because it would be replacing the sugar component of the juice with a similar ingredient from another source. For example, sucrose and glucose that have been removed from orange juice (§ 146.135 (21 CFR 146.135)) could not be replaced with fructose even though fructose is sweeter than the sucrose and glucose that are naturally present in orange juice. If, on the other hand, the product has been reduced in sugars so that it qualifies for use of a nutrient content claim and complies in all other aspects to new § 130.10, then the product is a food defined by new § 130.10 and must be labeled accordingly.

FDA notes that juices are defined in part by their Brix level or soluble solids content. The soluble solids of juices consist primarily of sugars. If any of the

sugars have been removed from a juice, the resulting product is a modified juice. As discussed in the final rule on percent juice labeling published elsewhere in this issue of the **Federal Register**, modified juices cannot use the percent juice labeling values in § 101.30 because of the reduced soluble solids content. The manufacturer would have to develop an alternate means of determining the percent juice in modified juice products.

9. Several comments stated that they considered the allowance of additional moisture in a modified cheese product to be necessary. One comment added that maximum moisture content requirements are as much barriers to lower fat versions of standardized products as minimum fat requirements.

Another comment added that other deviations from the standard, such as different levels of total solids or the use of modified processing conditions, are frequently required to meet the performance characteristics of the traditional standardized food and should be explicitly permitted in this regulation. It recommended that the last sentence of proposed § 130.10(a) be changed to read, "The food shall comply with paragraphs (b), (c), and (d) of this section." It further recommended that the following sentence be added at the beginning of proposed § 130.10(c):

Deviations from noningredient provisions of the standard of identity (such as moisture content, food solids content requirements, or processing conditions) are permitted in order that the substitute food possess performance characteristics similar to those of the standardized food.

FDA agrees that there are noningredient requirements mandated by some standards in parts 131 through 169 that could restrict manufacturers' ability to produce modified foods under new § 130.10. The agency recognizes that in some standardized foods, such as cheeses, the standard mandates a maximum moisture content, and that modified foods may not conform to this requirement and still retain the necessary performance characteristics to use the standardized name.

New § 130.10(a) states that the foods prescribed by this general definition and standard of identity are those foods that substitute for a standardized food but that do not comply with the standard because of a deviation that is described by a nutrient content claim. FDA noted in the proposal that the ingredients used in the modified version of the standardized food should be those ingredients provided for by the traditional standard with only those deviations necessary to attain an acceptable finished product that meets the requirements of the nutrient content claim that is used (56 FR 60512 at 60519). Thus, under new § 130.10(d)(1) the agency is providing for the addition of safe and suitable ingredients not normally found in the standardized food so that § 130.10 foods are not inferior in performance characteristics to the traditional standardized food. In like manner, FDA believes that the modified version of the standardized food should comply with the noningredient provisions of the traditional standard with only those noningredient deviations necessary to attain an acceptable finished product that meets the requirements of the nutrient content claim that is used.

For the above reasons, FDA has been persuaded by the comments that modifications to the regulation are needed to allow for deviations from the noningredient requirements of the standards. Therefore, the agency is adding a new sentence at the beginning of new § 130.10(c) which states:

Deviations from noningredient provisions of the standard of identity (e.g., moisture content, food solids content requirements, or processing conditions) are permitted in order that the substitute food possesses performance characteristics similar to those of the standardized food.

In addition, the agency is amending the last sentence of new § 130.10(a) to read: "The food shall comply with the relevant standard in all other respects, except as provided in paragraphs (b), (c), and (d) of this section." The agency believes that this action will: (1) Increase the manufacturers' ability to produce modified foods under new § 130.10, (2) provide consumers with a greater variety of such foods, and (3) assist consumers in maintaining healthy dietary practices. The agency notes, however, that this exception does not apply to processes that are important to public safety such as pasteurization. FDA concludes that this action will promote honesty and fair dealing in the interest of consumers.

10. One comment stated that the requirement of nutritional equivalency (new § 130.10(b)) for lower fat ice creams mitigates the need for lower fat ice creams to meet the 4.5 pounds per gallon requirement in the standard of identity for ice cream in § 135.110.

FDA agrees with the comment. FDA published an advance notice of proposed rulemaking (ANPRM) (Docket No. 88P–0251) in the **Federal Register** of January 22, 1991 (56 FR 2149) concerning the filing of several petitions to amend the standards for ice cream and ice milk and to establish standards for reduced fat, lowfat, and nonfat ice creams. The petitions requested that FDA establish a minimum weight of 4.0 pounds per gallon for the lower fat products.

A comment received in response to the ANPRM that opposed the reduction in weight stated that the change could be construed as intentionally deceiving the consumer. The comment stated that while there are economic and competitive advantages, there appears to be no other serious justification for such cheapening of the product.

However, most of the comments received in response to the ANPRM that addressed the minimum weight issue supported the proposed minimum requirement of 4.0 pounds per gallon. They stated that the processing and formulation changes that accompany the removal of fat in the manufacture of fat reduced ice cream products result in a less dense product. According to these comments, creaminess and product stability, which are lessened by fat removal, can be improved by increasing the amount of air incorporated into the product or by utilizing more precise control of the freezing process.

FDA concludes that it is reasonable to exempt modified ice cream products from the minimum weight requirement of 4.5 pounds per gallon, so that these products can achieve the performance characteristics (e.g., creaminess) of ice cream, as long as the product is not nutritionally inferior to ice cream. The agency concludes that this exemption will assist consumers in maintaining healthy dietary practices by providing for modified ice cream products that have performance characteristics that are similar to ice cream. This exemption is provided by the new sentence that is being added to the beginning of new § 130.10(c). However, FDA does not believe that fat reduced ice cream products should contain less than 4.0 pounds per gallon, as recommended by the petitioners of these ice cream products, because the desired effects can be achieved within this allowance, and the modified foods should resemble the traditional standardized foods as closely as possible.

The inclusion of air in § 130.10 foods (e.g., nonfat ice cream, light margarine, and reduced fat peanut butter) in excess of that which is reasonably required to achieve the performance characteristics of the standardized food for which it substitutes constitutes deception and will be deemed to adulterate the food under section 402(b) of the act in that excess air is substituting for a valuable constituent. Therefore, FDA is including in new § 130.10(c) a requirement that deviations from provisions of the standard must be the minimum necessary to achieve this effect, or the

food will be deemed to be adulterated under section 402(b) of the act. FDA believes that this requirement will promote honesty and fair dealing in the interest of consumers.

Serving size issues relating to "aerated" products (i.e., products that include added air) that are sold by weight are addressed elsewhere in this issue of the **Federal Register** in a document entitled "Food Labeling: Serving Sizes."

C. Nutrient Content Claims

11. Several comments stated that the use of nutrient content claims such as "lowfat," "lite," and "reduced" should not be allowed on the label of standardized foods because they are confusing, even if they are defined.

Other comments expressed concerns about the required labeling, arguing that it is excessive. One comment urged FDA not to include too many restrictions on the wording or use of nutrient content claims because such restrictions would only befuddle the consumer and defeat the purpose of the claims.

FDA is establishing definitions for a number of nutrient content claims in the nutrient content claims final rule. In defining these terms, FDA has carefully considered each nutrient content claim to ensure that it will be meaningful to consumers. The definitions for the claims and § 101.13 prescribe the specific labeling that must accompany the claim. As consumers learn what a claim means, they will be able to understand that a product such as "light margarine" has been modified in a way that has reduced its fat content. Thus consumers will be able to easily identify the food and will be able to find out more about the food through information on the label. Therefore, FDA concludes that no action is necessary in response to these comments.

12. One comment stated that only expressed nutrient content claims should be used with the names of standardized foods. It stated that implied nutrient content claims such as "light" or "healthy" should not be used in this manner (e.g., "healthy ice cream").

The agency agrees with the comment. However, the term "light" is not an implied claim and is being defined as an expressed nutrient content claim as discussed in the nutrient content claims final rule. In § 101.13(b)(1), FDA defines an "expressed nutrient content claim" as any direct statement about the level (or range) of a nutrient in the food, e.g., "low sodium." An "implied nutrient content claim" is defined in § 101.13(b)(2) as any claim that describes the food or an ingredient therein in such a manner that suggests that a nutrient is absent or present in a certain amount (e.g., "high in oat bran"), or that suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., "healthy, contains 3 g of fat").

Because the name of a new modified food distinguishes it from the standardized food, the claim must be expressed for consumers to understand how the new modified food differs from the traditional food. Therefore, FDA concludes that only expressed nutrient content claims may be used in the name of the food under new § 130.10. Implied claims may be used as provided in § 101.13(b)(2) but not in conjunction with the name of the § 130.10 food. Therefore, the agency is modifying new § 130.10(a) and (e) to state that the nutrient content claim must be an expressed claim. FDA believes that this revision will promote honesty and fair dealing in the interest of consumers.

D. Nutritional Inferiority

13. One comment stated that in determining nutritional inferiority, there is no clear indication of the nutrients and levels thereof that a § 130.10 food is expected to match. It stated that some specifications should be made, or provisions should be included, for developing nutrient data bases for those standardized foods that § 130.10 foods with nutrient content claims must match to avoid "nutritional inferiority."

FDA disagrees with the comment. New § 130.10 sets forth general requirements for foods named by use of an expressed nutrient content claim and a standardized term. Under new § 130.10(b), the modified product must not be nutritionally inferior, as defined in § 101.3(e)(4), to the standardized food. FDA believes that this general requirement is adequate because § 101.3(e)(4) sets very specific requirements defining nutritional inferiority. The agency concludes that new § 130.10 should not specify required amounts of essential nutrients that must be added to a modified food, and that no change is necessary in new § 130.10.

The agency adds that nutrient values for the traditional standardized product can be found in a current valid composite data base.

14. One comment agreed that § 130.10 foods should not be nutritionally inferior to the traditional standardized food. However, it stated that inferiority in any single nutrient should be defined as a "significant" reduction, that is, a reduction of 10 percent or more of the Reference Daily Intake/Daily Reference Value (RDI/DRV) of a nutrient that is present in a "measurable amount." In addition, the comment stated that nutritional inferiority of the product itself should not be based on inferiority in a single nutrient. It stated that in such cases, the unavoidable reduction of one nutrient could be compensated by meaningful additions or improvements in one or more other nutrients. For example, the comment stated, there are some foods for which it is difficult or impossible to reduce the amount of a component such as fat without also reducing the amount of a nutrient such as protein. It stated that the reduction in protein could be balanced by additions of vitamin A and riboflavin.

FDA disagrees with this comment. According to § 101.3(e), a food that is nutritionally inferior to another food is an imitation of that food and must be labeled as such. Section 101.3(e)(4)(i) defines nutritional inferiority as any reduction in the content of an essential nutrient that is present in a measurable amount (excluding fat or calories). Section 101.3(e)(4)(ii) defines a measurable amount of an essential nutrient in a food as 2 percent or more of the DRV of protein or the RDI of any vitamin or mineral listed under § 101.9(c)(7)(iv). The agency considers a measurable amount to be a significant amount for this purpose. All nutrients that are considered in determining the status of a food under § 101.3(e)(4) are important, and the agency does not believe that the addition of one nutrient could compensate for another. Therefore, FDA concludes that foods that have significantly less protein or other essential nutrients than a standardized food are not modified versions of the standardized food, do not comply with the requirements of this regulation, and must be labeled as "imitation."

15. One comment stated that the agency should reconsider the requirement that any modified food, identified as a "light," "reduced," or "lowfat" version of a standardized food, in which there is a nutrient reduction be fortified in order not to be called "imitation." The comment stated that such nutrient addition was not necessary because the comparative nutrition label will clearly identify the nutritional differences between these two different foods.

The agency disagrees with the comment. Although FDA agrees that the nutritional differences between these products would be apparent from the nutrition information, foods that are

nutritionally inferior to the standardized food must be labeled as "imitation" under section 403(c) of the act. New § 130.10 does not include imitation foods.

16. One comment requested that the agency clarify that when the modified food substitutes for more than one standardized food, the modified food should be deemed in compliance with proposed § 130.10 if it is nutritionally equivalent to any of the several standardized foods. The comment stated that cottage cheese (21 CFR 133.128) and lowfat cottage cheese (21 CFR 133.131) may vary in vitamin A content based on their different fat levels. Thus, the comment stated, a nonfat cottage cheese should be considered nutritionally equivalent under new § 130.10 if its vitamin A content is equivalent to that required by either food standard because it clearly is a modified version of either food.

FDA disagrees with this comment. The agency recognizes that a nonfat cottage cheese product could be compared to cottage cheese (§ 133.128), dry curd cottage cheese (§ 133.129) or one of the lowfat cottage cheese products (§ 133.131). The agency acknowledges that target levels for nutrients necessary to determine nutritional equivalency of a food will depend on whether the food is compared to one food or another. However, the § 130.10 food must not be nutritionally inferior to the standardized food whose name is used in the name of the food. FDA concludes that because the reference food in the name "nonfat cottage cheese" is "cottage cheese," it would be misleading to consumers to make the comparison of nutritional equivalency to any other cottage cheese product.

E. Performance Characteristics

In the proposal for this final rule, FDA requested comments concerning: (1) The requirement that the performance characteristics of the new product be similar to those of the standardized food, (2) the performance properties that are of greatest importance to consumers, and (3) what differences in performance characteristics a modified standardized product should be able to have and still be considered to resemble the standardized food closely enough to be included in that product category (56 FR 60512 at 60519 and 60521).

17. Several comments stated that it would be acceptable to a consumer that wants lower fat foods to have products with fat replacers resemble the original products as closely as possible, especially with respect to texture, taste, and nutrition. One comment urged FDA to set high standards for performance requirements for § 130.10 foods. It stated that without appropriately high standards, consumers may be misled by the use of familiar names, and that, ultimately, the value of the standards themselves will be diluted.

Two comments suggested that, in order to use the name of the standardized product with a nutrient content claim, the product must perform at least one of the principal functions of the standardized product substantially as well as the standardized product. Consumers can then choose to purchase the modified product instead of the standardized product for use in that function. One comment added that a reduced fat cheese must at a minimum be suitable for eating directly from the package or for melting and cooking. It stated that the product need not serve both purposes, so long as the performance deficiencies are clearly and prominently labeled on the front of the package.

The agency agrees that the § 130.10 food should resemble the standardized food in as many ways as possible. FDA also agrees that at a minimum, a modified food must perform at least one of the principal functions of the standardized product as well as the standardized food. FDA believes that consumers should be able to count on using a modified food in the same manner that they use the traditional standardized food in, at the very least, one of the principal functions as the standardized food. To achieve this objective, FDA is requiring in new § 130.10(c) that modified standardized foods must resemble the standardized foods, and that differences in the performance characteristics must be clearly stated on the principal display panel of the label. In addition, the agency is adding a statement to new § 130.10(c) to require that "the modified product must perform at least one of the principal functions of the standardized product substantially as well as the standardized product." FDA believes that this action is necessary to ensure the minimum necessary similarity between the modified and traditional products and, thus, will promote honesty and fair dealing in the interest of consumers.

18. One comment questioned what methods the agency would use to measure significant differences in product quality and to monitor critical performance characteristics.

FDA expects that modified versions of standardized foods will perform in a manner that is generally acceptable to the public. New § 130.10 requires that the performance characteristics of the food be similar to those characteristics of its standardized counterpart unless the differences between the two foods are explicitly stated on the label. In addition, the § 130.10 food must perform at least one of the principal functions of the standardized food substantially as well as the standardized product. Although it was not the agency's intent to develop specific performance standards for each product, FDA plans to examine the performance characteristics and product quality of these modified versions of standardized foods, as it would for other types of food products, through scientific reviews or experimental investigations. In addition, FDA will use all avenues available to the agency (e.g., sample analysis, inspections, surveys, and followup investigations of consumer and trade complaints) to identify products that do not comply with the new regulation and will enforce this regulation as the need arises.

F. Labeling of Performance Characteristics

19. Several comments objected to the requirement in proposed § 130.10(c) that if there is a significant difference in performance characteristics between the food under proposed § 130.10 and the standardized food, the label must include a statement informing the consumer of such difference. One comment stated that some performance characteristics (e.g., flavor or texture) tend to be more subjective, and that if a flavor comparison is not favorable, manufacturers would not be inclined to call attention to such a difference. It stated that it would be a disincentive to food manufacturers to reduce the fat content in food. Another comment stated that a regulation to require a label statement pointing out differences in performance is not necessary unless health or safety is involved. One comment stated that the most specificity FDA should include in this regulation regarding performance characteristics is a reference to substantial equivalence in organoleptic and nutritional qualities.

One comment stated that manufacturers would find it advisable, for marketing reasons, to inform the consumer how a modified version of a standardized food performs differently than the standardized product. One comment supporting the label statements noted that bread spreads currently on the market are erratic about stating whether they can be used for cooking, and that consumers are confused as a result. Other comments expressed concern about diluting the value of the standards if consumers are

misled by the use of familiar names on modified products.

Under sections 201(n) (21 U.S.C. 321(n)) and 403(a) of the act, the label or labeling of the food must disclose to consumers what they are buying when they purchase these modified foods. Information disclosing differences in performance characteristics (e.g., physical properties, flavor characteristics, functional properties, and shelf life) is a material fact under section 201(n) of the act because it bears on the consequence of the use of the article. Accordingly, this information must be communicated to the consumer on the product label, or the labeling would be misleading, and the product would be misbranded under section 403(a) of the act.

Therefore, a provision in new § 130.10(c) that requires disclosure of differences in performance characteristics between the modified food and the traditional standardized food is fully consistent with the act.

FDA is providing for noningredient deviations in new § 130.10(c) (e.g., moisture content) and for the use of safe and suitable ingredients for certain specified purposes in new § 130.10(d)(1) (e.g., to add flavor) in order that the modified food may possess similar performance characteristics as the traditional standardized food. FDA believes that these provisions in new § 130.10 provide manufacturers ample latitude in producing modified products.

20. Two comments recommended that the label statement be mandatory only for differences in performance characteristics that materially limit the uses of the modified food compared to the traditional standardized food that it resembles. One comment stated that market forces will encourage manufacturers to inform consumers about positive differences, and that consumers who select a product for its reformulated nutrient content will not be misled if they are not told about a positive change that the manufacturer believes is not sufficiently important to highlight on the product label. The comment noted that FDA would not object if the label did not alert consumers to a minor improvement in a performance characteristic that consumers consider to be relatively unimportant for that food, such as the freezing point of eggnog. In addition, the comment stated, a product may have several differences in performance characteristics, and several label statements could be confusing to consumers. The comment recommended that FDA modify new § 130.10(c) by limiting the labeling requirement to adverse changes that materially affect the use of the product.

The agency has been persuaded by these comments. FDA agrees that there are differences in performance characteristics that consumers may not deem to be important, such as the freezing point of eggnog. Consumers commonly store eggnog at refrigerator temperatures, and, therefore, the freezing point of this product is not of material interest to consumers. In addition, FDA believes that unnecessary label statements may be confusing to consumers and may detract from other important information on the label.

Therefore, the agency is revising new § 130.10(c) to state that:

> * * * if there is a significant difference in performance characteristics that materially limits the uses of the food compared to the uses of the standardized food, the label shall include a statement informing the consumer of such difference (e.g., if appropriate, "not recommended for cooking").

21. Comments also suggested that FDA affirm in the final rule that statements of differences in performance characteristics can be presented as recommendations for use.

FDA agrees with the comments suggesting that differences in performance characteristics may be presented as recommendations for use. For example, a reduced fat margarine may not perform the same as margarine for use in frying. A statement such as "not recommended for frying purposes" or as "recommended for use only as a spread" would be acceptable to advise consumers of the difference in performance characteristics.

22. Comments also asked whether shelf life could be presented as a date by which the product should be used.

The agency agrees that a date by which a product should be used is an appropriate manner to express differences in shelf life.

23. Several comments objected to the requirement in proposed § 130.10(c) that label statements concerning differences in performance characteristics must appear on the principal display panel within the bottom 30 percent of the area of the label panel with appropriate prominence, in type that shall be no less than one-half the size of the type used in such claim but no smaller than one-sixteenth of an inch. One comment noted a conflict with proposed § 101.13(d)(1) with regard to location of this information on the label. Some comments addressed concerns about label clutter on the principal display panel and stated that these concerns are enhanced by the proposed requirement that the bottom 30 percent of the principal display panel contain a statement of any differences in performance characteristics between the § 130.10 food and the standardized food. Comments urged FDA to allow the statements to appear on any panel of the food product. One comment added that a simple requirement of proximity and appropriate prominence should be more than adequate to prevent consumer confusion. One comment stated that the proposed requirements are excessive and fail to meet the requirements of the President's directive that regulation should rely on market mechanisms to the maximum extent possible. It stated that consumers who buy nutritionally modified versions of familiar foods and are disappointed with their performance, because they did not know in advance what to expect, simply will not buy again, and the products will quickly fail. It added that FDA does not need to regulate this guaranteed result. Some comments stated that they did not believe it necessary to prescribe a minimum type size for this disclosure statement, but that the statement should appear on the principal display panel in a clear and conspicuous fashion.

The agency disagrees with these comments. Different brands of a particular modified food may have different performance characteristics depending on the manufacturing technology used in making the § 130.10 food. For example, reduced fat cheddar cheese made by one manufacturer may be suitable only for melting and cooking, while another brand may be suitable only for eating directly from the package as a snack. Therefore, consumers must be informed about the characteristics of a food to make judgments concerning the use of a product before purchase. The necessary information must appear on the same part of the label as the name of the § 130.10 food (i.e., the principal display panel) so that consumers can make informed choices. Moreover, this regulation is consistent with the President's directive because it is providing increased flexibility to the market in that it provides that qualifying versions of standardized foods may be sold under names that consumers recognize.

Under section 403(f) of the act, FDA believes that the statement informing consumers of differences in performance characteristics must appear on the label with such conspicuousness and in such terms as to render it likely to be read and understood by the consumer under customary conditions of purchase and use. The agency concludes that the statement must appear in the same area of the label as the statement of identity for the

modified product so that consumers will know where to find such information. Moreover, because the statement is a material fact that helps to describe the differences between the modified food and the traditional food, it must appear in close proximity to the statement of identity. See, e.g., *United States* v. *An Article of Food * * * "Manischewitz * * * Diet Thins,"* 377 F. Supp. 746, 749 (E.D. N.Y. 1974).

FDA recognizes that it inadvertently proposed in § 130.10 to require statements informing consumers of differences in performance characteristics to appear in possibly two separate locations on the label. The agency acknowledges that one statement is sufficient to inform consumers. To be consistent with the labeling of other foods, the agency concludes that the statement concerning differences in performance characteristics must appear on the label in compliance with the requirements of § 101.13(d)(1). Thus, the agency has modified new § 130.10(c) to state that the statement explaining differences in performance characteristics must appear on the label in compliance with the requirements of § 101.13(d).

G. Ingredients

1. Ingredients Provided for By the Regulation

24. Two comments objected to FDA restricting the major ingredients used in § 130.10 foods to those specified in the standard. One comment stated that this provision would not empower consumers to select a healthy diet but would restrict the number of apparent "healthy" choices available by requiring products made with alternate ingredients to bear unappealing names. It also stated that this provision would not provide an incentive to manufacturers to develop nutritionally improved foods but would restrict their ability to develop such products by unnecessarily limiting the technology available.

The agency disagrees with these comments. The agency believes that foods named by use of a nutrient content claim and a standardized term must resemble the standardized food in as many ways as possible, or the use of the standardized term would be misleading to consumers. Therefore, FDA concludes that the ingredients used in the modified version of the standardized food should be those ingredients provided for by the traditional standard, with only those deviations necessary to attain an acceptable finished product that meets the requirements of the nutrient content claim that is used and new § 130.10.

2. Safe and Suitable Ingredients

25. Several comments stated that proposed § 130.10(d) should provide for the use of safe and suitable ingredients generally in accordance with current good manufacturing practices rather than limiting them to specific functions. One comment stated that the language in proposed § 130.10(d) concerning ingredient substitutions should be broadened to encompass all of the product characteristics embraced by proposed § 130.10(c) and by the definition of "substitute" in § 101.13(d). Another comment added that safe and suitable ingredients should be allowed for purposes of improving appearance as well as the other characteristics mentioned in the proposal.

FDA disagrees that the use of safe and suitable ingredients should be extended for all purposes. The agency believes that § 130.10 foods should deviate from the standard of identity only when necessary to achieve the functions of ingredients or components of ingredients that are no longer present in the mandated quantities. As required in new § 130.10(c), the performance characteristics (e.g., physical properties, flavor characteristics, functional properties, and shelf life) of the modified food must be similar to those of the traditional standardized food. FDA believes that the use of safe and suitable ingredients added as necessary to improve texture, add flavor, prevent syneresis, and extend shelf life adequately compensates for any deficiencies in performance characteristics. As discussed previously, § 130.10 foods do not include all substitute foods. Therefore, FDA does not believe that new § 130.10(d) should be broadened to encompass all types of substitute foods.

However, FDA concedes that the use of safe and suitable ingredients to improve the appearance of a product has merit. For example, modified foods with significantly less fat may appear more translucent than the standardized food. Thus, such ingredients are necessary to ensure that the product is not inferior in performance characteristics. Therefore, FDA is amending new § 130.10(d)(1) to provide that safe and suitable ingredients may be added to improve the appearance of a modified food named by use of a nutrient content claim and a standardized term.

26. One comment stated that it believes that to "add flavor" includes sweetness and requested that FDA confirm this interpretation by including a parenthetical "(including sweetness)" following "add flavor" in proposed § 130.10(d)(1).

FDA disagrees with the premise of this comment. In § 170.3(o)(12), FDA defines "flavoring agents and adjuvants" as substances added to impart or help impart a taste or aroma in food. FDA defines nonnutritive and nutritive sweeteners separately from flavoring agents in § 170.3(o)(19) and (o)(21). In addition, labeling requirements for flavors differ significantly from those for sweeteners.

However, FDA does agree that the use of safe and suitable sweeteners to add sweetness should be provided for in new § 130.10 for modified foods. Many standards of identity provide only for the use of safe and suitable nutritive sweeteners or nutritive carbohydrate sweeteners (e.g., sour cream (§ 131.160), eggnog (§ 131.170), and margarine (§ 166.110)). Nonnutritive sweeteners could be effectively used to add the sweetness, but not the calories, that would otherwise be contributed by nutritive sweeteners in the traditional standardized food. Therefore, FDA believes that the use of safe and suitable sweeteners to add sweetness would assist consumers in maintaining healthy dietary practices. Thus, the agency is revising new § 130.10(d)(1) to provide that safe and suitable ingredients may be added to add sweetness to a modified food named by use of a nutrient content claim and a standardized term. When a sweetener that meets the "safe and suitable" definition in new § 130.3(d) is used in the formulation of a modified food for the purpose of adding sweetness to that food, the sweetener must be declared on the food label in accordance with all applicable regulations. FDA believes that this action will promote honesty and fair dealing in the interest of consumers.

27. One comment questioned whether the provision for the use of "safe and suitable" ingredients in § 130.10 foods would promote long-term product development, even though short-term product innovation may benefit from this policy. This comment further contended that allowing these foods into the marketplace would: (1) Erode the market share of traditional standardized foods, (2) harm the integrity of traditional standardized foods, and (3) lead to consumer confusion by blurring the differences between these standardized foods and their modified counterparts.

FDA disagrees with this comment. The agency believes that providing for the use of "safe and suitable" ingredients to improve texture, add flavor, prevent syneresis, extend shelf

life, improve appearance, or add sweetness in modified versions of standardized foods should not stifle long-term product development, nor should the introduction of these foods into the marketplace be damaging to the food industry on the whole.

On the contrary, standards of identity have been criticized as being too strict and confining, and because they limit food companies from achieving true product innovations. For instance, the dairy industry purportedly has been harmed because many of the products that dairy processing companies manufacture are subject to rigid standards of identity that require specific fat content. As a result, these firms have not been able to create new dairy food products that respond to consumer needs and demands for products that are reduced in fat and in calories.

FDA anticipates that there will be shifts in dietary consumption patterns from traditional foods that are higher in calories or in fat to modified forms of these foods that are reformulated to be lower in calories or in fat. However, this pattern of increased consumption of modified forms of traditional foods should help consumers to achieve recommended nutritional goals and should have a beneficial impact on the public health. In addition, FDA believes that the development, production, sale, and consumption of these reformulated foods will contribute to overall industry growth. Although the agency acknowledges that there is the potential that sales of certain standardized foods may remain stagnant or may even decline, these changing patterns in consumers' food purchasing habits in relation to recommended nutritional goals should create new opportunities for innovative food processors to develop a virtually limitless array of new products that will ultimately lead to an overall increase in sales and an expansion into new markets.

Regarding consumer confusion about the differences between a traditional standardized food and a modified form of such food bearing one or more nutrient content claims on its label, the agency believes that the use of carefully defined nutrient content claims as a part of the statement of identity on the label will enable purchasers of the modified versions of standardized foods to distinguish these foods from their standardized counterparts. New § 130.10 provides for proper labeling of these foods and the listing of all ingredients in the ingredient statement. Adequate product labeling, including defined nutrient content claims, accompanying label statements, and nutrition labeling, will enable consumers to distinguish traditional foods from modified versions of these foods, thereby contributing to improved consumer understanding of the characteristics of the products that they are purchasing.

28. One comment inquired whether specific caseinates would meet the "safe and suitable" definition and be permissible for use in § 130.10 foods.

FDA advises that the "safe and suitable" definition in new § 130.3(d) would permit the use of caseinates in foods subject to new § 130.10 provided that the standard of identity for the traditional food in question provides for such use. For example, the standard of identity for ice cream in § 135.110 permits the optional addition of one or more of the caseinates listed in § 135.110(c) in an ice cream mix containing not less than 20 percent total milk solids. Caseinates may be added to ice milk (§ 135.120) when the content of total milk solids is not less than 11 percent. FDA believes that it is reasonable to permit the use of such caseinates in modified versions of ice cream, provided that the product contains equivalent levels of nonfat milk solids to those contained in a 10 percent milkfat ice cream. That is, the modified product must contain at least 10 percent nonfat milk solids, and caseinates could be added after this minimum nonfat milk solids requirement has been met. FDA believes that modified ice cream, regardless of the milkfat content, should contain at least 10 percent of nonfat milk solids to ensure that the § 130.10 ice cream is not nutritionally inferior to ice cream with respect to calcium and protein. The addition of caseinates to replace the milk solids content constitutes deception and will be deemed to adulterate the food under section 402(b) of the act (21 U.S.C. 342(b)) in that caseinates are substituting for a valuable constituent.

On the other hand, the standards of identity for cheeses and related cheese products in part 133 (21 CFR part 133) do not provide for the use of caseinates. Therefore, under new § 130.10(d)(1) manufacturers may not use this class of ingredients in modified versions of cheese products as replacements for the optional dairy ingredients listed in the standards of identity in part 133. However, use of small amounts of safe and suitable caseinates may be used for the reasons listed in new § 130.10(d)(1) (e.g., to improve texture) in modified versions of standardized foods as appropriate.

Any caseinates used in a § 130.10 food must be declared in the ingredient statement according to new § 130.10(f), including identification with an asterisk if the use of caseinates is not provided for by the traditional standard.

3. Addition of Water and High Moisture Ingredients

In the proposal, FDA requested comment from interested persons concerning the appropriateness of the addition of high moisture ingredients and water to foods as ingredients to replace fat and calories in modified products (56 FR 60512 at 60520).

29. A number of comments requested that FDA provide for the addition of water. Two comments stated that the addition of water is critical to the manufacture of modified standardized products such as modified salad dressing and mayonnaise. One comment added that the emulsifying properties of certain gums are activated only by the addition of water. Several comments stated that it is appropriate to allow for the addition of water as long as it is appropriately labeled. Conversely, two comments requested that FDA not permit the addition of water to a food subject to proposed § 130.10.

A number of comments stated that the addition of high moisture ingredients to foods subject to proposed § 130.10 is appropriate. One comment noted that moisture content variability may occur because of water contributed by safe and suitable ingredients that are components of such foods. It added that provision should be made to require that such moisture differentials are accurately and adequately reflected on the label of foods subject to new § 130.10. Another comment stated that where, with current technology, the production of reduced fat products is not possible without the addition of high moisture ingredients, their addition should be permitted.

One comment stated that most current fat reduction technologies require the addition of high moisture ingredients and water. It recommended that FDA allow high moisture ingredients and water to replace fat in § 130.10 products, and that FDA use performance standards rather than deviations from a "recipe" to protect consumers. Another comment recommended that FDA allow the use of high moisture ingredients and water to the level necessary to replace fat and calories, as long as the modified food is not nutritionally inferior to the traditional food.

FDA agrees that the addition of water may be necessary for the hydration of some ingredients that would be permitted under the safe and suitable ingredient provision. In addition, FDA notes that there is consumer demand to

purchase products that have a significant reduction in fat and calories. Water is an ingredient that could effectively accomplish this purpose when used to replace fat and calories in modified products. Therefore, the agency is adding new § 130.10(d)(5) to provide for the addition of water as an ingredient to replace fat and calories in modified products. FDA believes that such addition of water will assist consumers in maintaining healthy dietary practices by providing for an ingredient that will allow manufacturers to produce a greater variety of modified versions of traditional standardized foods. Moreover, the consumer is protected against the possibility of excess water being added by new § 130.10(c), which states that deviations from the ingredient and noningredient provisions of the traditional standard must be the minimum necessary to qualify for the nutrient content claim while maintaining similar performance characteristics as the standardized food, or the food will be adulterated under section 402(b) of the act.

FDA also agrees that the use of high moisture ingredients is necessary to reduce calories and fat in some foods. Comments did not mention any specific high moisture ingredients that the regulation should include. Therefore, all high moisture ingredients used in a § 130.10 food must either be ingredients that are provided for by the respective standard of identity or provided for by the safe and suitable ingredient provision of new § 130.10(d)(1).

The agency notes that some foods subject to new § 130.10 may need to exceed the moisture requirements of the respective standards of identity to make a nutrient content claim. For example, the standard of identity for cheddar cheese (§ 133.113) stipulates a maximum moisture content of 39 percent by weight and a minimum milkfat content of 50 percent by weight of the solids. Under new § 130.10(c), a reduced fat cheddar cheese may exceed the maximum moisture level stipulated by § 133.113 concurrent with the 50-percent reduction in the fat content, but it still must not be nutritionally inferior. The increase in moisture content occurs because less whey is drained from the product during processing. The high moisture ingredients would, therefore, be the same dairy ingredients (i.e., milk, nonfat milk, or cream) provided for by the traditional standard.

The addition of water and high moisture ingredients must be declared in the ingredient statement as required in new § 130.10(f). Because new § 130.10(b) requires that the modified food must not be nutritionally inferior to the standardized food, a modified food that contains significantly less calcium or any other nutrient than the standardized food because of the use of water or a high moisture ingredient must be labeled as an imitation. FDA believes that moisture differentials will be adequately reflected on the label through order of predominance ingredient labeling and labeling of any differences in performance characteristics (e.g., shorter shelf life because of increased moisture content).

4. Flavors

30. Two comments urged FDA to exempt from the labeling requirement of § 101.22(i) those flavors added solely at the level necessary to replace flavors lost by reformulation of the food. The comments also said that there was no reason to exempt any flavor added in amounts greater than necessary to maintain the flavor of the traditional food.

FDA disagrees that there is a need to exempt flavors added to replace flavors lost by reformulation of the food from the requirements of § 101.22(i). Section 101.22(i) only refers to the labeling of characterizing flavors. Natural and artificial flavors that do not characterize a food need only be declared in the ingredient statement. However, FDA believes that consumers should be informed from information on the principal display panel when artificial characterizing flavors have been added to a food.

In the **Federal Register** of January 19, 1973 (38 FR 2139), FDA proposed a uniform labeling policy for flavor designation that was patterned, with appropriate modification, after the ice cream standard of identity in § 20.1 (21 CFR 20.1) (current § 135.110 (21 CFR 135.110)). According to the standard, ice cream may or may not be characterized by the addition of flavoring ingredients. The existing standard in 1973 listed the optional characterizing ingredients (§ 20.1(b)) that could be used in ice cream. These characterizing ingredients, not the individual flavors contributed by the milk, cream, and other optional ingredients, were the flavors subject to the labeling provisions.

Therefore, the flavors that are lost by reformulation are likely not to be those that characterize the food but those that are an inherent part of the basic required ingredients that are no longer present in the reformulated food. Thus, they need only be declared in the ingredient statement as natural or artificial flavors, as appropriate. For example, natural and artificial eggnog flavor components may be added to light eggnog to add flavor. These flavor components must be included in the declaration of ingredients but need not appear anywhere else on the label. However, if a natural and artificial eggnog flavor that comprises the total eggnog flavor profile is added to a light eggnog, it is a characterizing flavor and must be labeled according to § 101.22(i). If any portion of the characterizing flavor is artificial, it must be labeled as artificial flavor under § 101.22(i).

31. A comment objected to FDA's choice of "light margarine" as an example of a § 130.10 food using a standardized name. According to the comment, this example implied that the label of a food with the name "light margarine" would have to comply with the flavor labeling regulations of § 101.22 if artificial butter flavor were used in the food for flavoring purposes.

According to § 166.110(b)(7) (21 CFR 166.110(b)(7)) on flavoring substances in margarine, "if the flavoring ingredients impart to the food a flavor *other* than in semblance of butter, the characterizing flavor shall be declared as part of the name of the food in accordance with § 101.22 of this chapter" (emphasis added). Flavoring ingredients that impart the flavor of butter to margarine thus may be added to the food without declaring such flavor as part of the name of the food.

Because the intent in producing "light margarine" is to modify the fat and calorie content and not the flavor, the agency believes that it is reasonable to treat the declaration of flavoring ingredients on the label of "light margarine" in a like manner to their declaration on the label of margarine that complies with the standard of identity in § 166.110. The use of an artificial butter flavor in the formulation of a "light margarine" would not, therefore, necessitate the naming of this food as "light margarine; artificially flavored" as the preamble to the November 27, 1991, proposal (56 FR 60512 at 60519) stated. The agency reiterates, however, that natural and artificial flavors other than those in semblance of butter in "light margarine" must be declared in the ingredient statement in accordance with the applicable sections of part 101.

5. Fat Analogs

In the proposal, FDA stated that it is aware of the recent development of fat analogs and requested comments from interested persons concerning the appropriateness of the use of approved fat analogs to replace the fat in foods subject to proposed § 130.10 (56 FR 60512 at 60520).

32. A number of comments stated that it would be appropriate to allow for the

addition of fat analogs in modified versions of standardized foods that are subject to proposed § 130.10. One comment recommended that FDA not impose any unique requirements on the use of fat analogs as replacements for fat and calories. Several comments stated that the addition of fat analogs would be appropriate as long as the food is properly labeled. One comment urged the use of a prominent disclosure statement of ingredients such as fat analogs on the principal display panel.

One comment stated that the use of approved fat analogs should be permitted in proposed § 130.10 foods only: (1) Where a particular analog is appropriate for the type of food in view of the composition of the standardized food (e.g., dairy fat analogs for dairy products), and (2) use of an analog is necessary to achieve a substantial reduction in fat. The comment stated that limiting the uses of analogs to those appropriate for a particular product category would serve the consumer interest in limiting deviations from standardized products to those really necessary to achieve reductions of fat.

Another comment stated that without the ability to use fat analogs, food manufacturers may find it difficult or impossible to accomplish the desired reductions in fat while maintaining product performance. It urged FDA to provide for the use of these ingredients in proposed § 130.10, rather than requiring a much more cumbersome regulatory process in the future. It stated that a statement should be added to proposed § 130.10(d) to the effect that fat substitutes that are approved for use in the food may replace the milkfat or other fat required by the standard.

Several comments stated that no addition of fat analogs should be allowed for a food subject to proposed § 130.10. One comment was concerned that the use of fat analogs would significantly alter the identity of the food and, therefore, the food would no longer resemble the traditional food. Other comments stated that fat analogs should not replace ingredients that would provide more healthful nutrients in modified foods.

FDA believes that there may be some instances where the use of fat analogs is appropriate and may be necessary to reduce the fat and calories while maintaining the performance characteristics of a food. The use of fat analogs will allow manufacturers to produce a variety of modified foods with greater reductions in fat and with the same performance characteristics as the traditional food. Thus, consumers will benefit by having a greater variety of modified foods available.

However, under § 130.10(d)(1), the fat analog used in § 130.10 foods must be safe and suitable as defined in new § 130.3(d). Moreover, under § 130.10(c), the amount used must be the minimum necessary to achieve similar performance characteristics as with the fat they replace, and under § 130.10(c). In addition, FDA agrees with the comment that stated that the fat analog must be appropriate for use in the particular type of food. New § 130.10(d)(2) states that an ingredient or component of an ingredient that is specifically required by the standard must not be replaced or exchanged with a similar ingredient from another source unless the traditional standard provides for the addition of such ingredient. The § 130.10 food must resemble the traditional standardized food. Thus, the major ingredients of a category of products should be from that variety of food (e.g., the major ingredients in dairy products should be dairy ingredients), and some ingredients are not appropriate to add to some modified foods that use the traditional standardized name. For example, under new § 130.10(d)(2), vegetable oil is not an appropriate ingredient to replace the milkfat in dairy products, or the fat in egg products, if the food is to use the standardized name as provided for in new § 130.10. Similarly, a fat analog from a vegetable or egg source is not an appropriate ingredient to replace the milkfat in dairy products using the standardized terms unless the dairy product provides for the use of egg or vegetable ingredients.

Therefore, FDA is adding a provision to new § 130.10(d)(5) to permit the use of safe and suitable fat analogs in accordance with new § 130.10(c), (d)(1), and (d)(2) in modified versions of the standardized food. The addition of fat analogs must be declared in the ingredient statement as required in new § 130.10(f). Because new § 130.10(b) requires that the modified food must not be nutritionally inferior to the standardized food, a modified food that contains significantly less of any nutrient than the standardized food because of the use of fat analogs must be labeled as an imitation. FDA believes that any use of fat analogs would be adequately reflected on the label through order of predominance ingredient labeling.

6. Use of Similar Ingredients

33. One comment suggested that the requirement that ingredients "specifically required" in new § 130.10(d)(2) either needs to be defined or its relationship to "mandatory" and "characterizing" ingredients needs to be explained by FDA. The comment said it assumed that it was FDA's intent in the proposed rule to not allow substitution for ingredients with similar ingredients that are deemed to be mandatory by the standard. FDA agrees with this comment. Ingredients that are specifically required by the standard are mandatory ingredients in standardized foods. Characterizing ingredients may be as optional ingredients under some standards (e.g., ice cream (§ 135.110)) and in those cases are not mandatory. The provision in new § 130.10(d)(2) prohibits the replacement or exchange of ingredients specifically required or mandated by the traditional standard with functionally similar ingredients from other sources that are not provided for by the traditional standard.

34. One comment stated that only dairy products should be used to replace milkfat in dairy products.

FDA agrees that dairy ingredients should be used to replace milkfat in dairy products. However, FDA acknowledges that other ingredients may be needed in small amounts to replace all of the functions of the milkfat that has been removed. A safe and suitable ingredient may be added to improve texture, prevent syneresis, add flavor, extend shelf life, improve appearance, or add sweetness under new § 130.10(d)(1), so long as it meets the requirements of the other parts of new § 130.10(d) and the label of the food complies with new § 130.10(f)(2). FDA adds that as stated previously, any fat analog used in dairy products must be from a dairy source.

35. One comment stated that proposed § 130.10(d)(2) is unnecessary and has the potential to be misinterpreted as, for example, prohibiting the use of a synthetic fat replacer to replace milkfat.

FDA disagrees that proposed § 130.10(d)(2) is unnecessary. Some ingredients are not appropriate to add to some modified foods that use the standardized name. In new § 130.10(d)(5), FDA is specifically providing for the use of safe and suitable fat analogs in new § 130.10 foods to replace fat and calories. However, some fat analogs are not appropriate for a particular type of food and are prohibited from use in a modified food by new § 130.10(d)(2). For example, the standard for sour cream (§ 131.160) states that sour cream contains not less than 18 percent milkfat. FDA believes that replacing the milkfat in sour cream with vegetable oil would be misleading because consumers expect sour cream to be a dairy product. Similarly, consumers would be misled if a fat analog from a

vegetable source replaced the milkfat in sour cream.

7. Ingredients Prohibited By the Reference Standard

36. Several comments opposed proposed § 130.10(d)(3), which states that an ingredient or component of an ingredient that is specifically prohibited by the standard cannot be added to a substitute food under this section.

Two comments requested that proposed § 130.10(d)(3) be made more flexible. One comment stated that the use of nutritionally insignificant amounts of ingredients, such as colorings and flavorings, could be permitted in § 130.10 foods, even if they are specifically forbidden by a standard of identity, to enhance the consumer acceptance of the substitute food. Another comment requested that FDA permit the use of flavorings simulating the flavor of a cheese of any age or variety in reduced fat versions of pasteurized process cheese to achieve a similar product to the traditional full fat counterpart.

FDA disagrees that safe and suitable ingredients specifically prohibited by a standard should be provided for in a substitute food under new § 130.10. There are valid reasons why these ingredients were specifically excluded in the traditional standard (e.g., economic deception or inappropriateness for the type of food). However, in some cases there are other quality ingredients that may be added for the same purposes.

For example, the agency finds that simulated cheese flavors are unsuitable for use in cheese and related cheese products. Although new § 130.10(d)(1) would permit ingredients to add flavor in substitute foods, flavoring ingredients that are specifically prohibited by standards of identity from inclusion in such foods are specifically prohibited in the modified form of such food (new § 130.10(d)(3)). The standard of identity for pasteurized process cheese in § 133.169(d)(6) specifically excludes any flavorings that, singly or in combination with other ingredients, simulate the flavor of a cheese of any age or variety from use in such food. However, "safe and suitable enzyme modified cheese" may provide a source of flavor in pasteurized process cheese, and this source of flavor is one of the optional ingredients that the agency now permits in this food, as specified in § 133.169(d)(9).

37. One comment asked that the use of "skim milk cheese for manufacturing" in § 133.189 be permitted in the formulation of fat-modified pasteurized process cheese, even though the standard of identity in § 133.169 does not now provide for this lower fat, "traditional" dairy ingredient.

FDA disagrees with this comment. Although skim milk cheese for manufacturing is an ingredient in the same class as other cheese ingredients used in the manufacture of the pasteurized process cheese products, because the standard for pasteurized process cheese (§ 133.169) specifically prohibits the use of this ingredient, this lower fat cheese ingredient may not be used in modified versions of this food. Manufacturers wanting to utilize this ingredient in pasteurized process cheese products must label the product as a nonstandardized food or, if appropriate, as pasteurized process cheese food (§ 133.173) or a modified version of pasteurized process cheese food.

Persons interested in providing for the use of skim milk cheese for manufacturing in modified versions of pasteurized process cheese (§ 133.169) may petition the agency to amend the standard.

H. Nomenclature

38. Several comments stated that they believed that allowing the use of the name of a standardized food on foods to which additional safe and suitable ingredients are added is deceiving to consumers, in direct conflict with the standards of identity concept/procedure, and should not be permitted. Comments stated that if FDA is going to permit optional ingredients to be added to standardized foods to accomplish the performance criteria cited in proposed § 130.10(d)(1), it should require that terms such as "substitute" or "modified" be used in the name of the food.

FDA disagrees with these comments. The major ingredients in a substitute food under new § 130.10 must be ingredients mandated by the relevant standard of identity. The only deviations from the standard that are authorized are those that are necessary to make the nutrient content claim, to ensure that the food meets the performance characteristics of the traditional standardized food, and to ensure the food is not nutritionally inferior to the traditional standardized food. FDA believes that the use of the nutrient content claim in the name of the food and the use of asterisks in the ingredient statement will alert consumers to the fact that the food contains ingredients that differ from those found in the standardized food. Therefore, FDA concludes that consumers will be adequately informed of differences between the § 130.10 food and the traditional standardized food. Because the § 130.10 food is itself a standardized food, it does not need to be labeled as a substitute.

39. One comment requested that the agency clarify that use of "substitute," "alternate," and a distinctive common or usual name remain viable for naming nonstandardized foods. Another comment stated that FDA should require the use of the term "substitute" in conjunction with a standardized name of a food when one or more of the basic characterizing ingredients of a standardized dairy food has been replaced with nondairy ingredients (e.g., vegetable oil in place of milkfat).

FDA notes that § 101.3(e)(4) requires that a food that resembles a standardized food but does not comply with the standard of identity must be labeled as imitation if it is nutritionally inferior to the food, or as a substitute or alternative if it is not nutritionally inferior. As stated above, foods that comply with new § 130.10 comply with a standard of identity.

New § 130.10(d)(2) prohibits the use of functionally similar ingredients to replace an ingredient that is specifically required by the standard. Therefore, a lowfat substitute for mozzarella cheese that is made with vegetable oil would have to be labeled as "imitation mozzarella cheese" if it is nutritionally inferior to mozzarella cheese, or "mozzarella cheese substitute" or "mozzarella cheese alternative" if it is not nutritionally inferior to mozzarella cheese because it does not comply with the standard of identity for mozzarella cheese (§ 133.155) or with new § 130.10.

40. One comment stated that FDA should clearly indicate that any applicable modifier may be used if more than one is applicable.

FDA agrees that any applicable nutrient content claim, if defined by FDA, may be used if more than one is applicable.

41. Two comments stated that if the name of a standardized food, coupled with the nutrient content claim, presents a contradiction in terms (e.g., nonfat ice cream), then the use of such nutrient content claim should be restricted. One comment added that standardized dairy products (e.g., ice cream) should not be reformulated to the extent that they lose their "dairy product" identity (e.g., nonfat ice cream). They would become "nondairy" products and should be named accordingly.

FDA disagrees with these comments. In the January 22, 1991, ANPRM (56 FR 2149) concerning the filing of several petitions to amend the standards for ice cream and ice milk and to establish standards for reduced fat, low fat, and

nonfat ice creams. FDA received comments in response to the ANPRM concerning whether the use of the terms "reduced fat ice cream," "low fat ice cream," and "nonfat ice cream" is misleading to consumers.

Several comments received in response to the ANPRM maintained that consumers will recognize "reduced fat ice cream," "low fat ice cream," and "nonfat ice cream" as products that, while containing less fat than ice cream, will deliver what they have come to expect from that food, i.e., similar taste, appearance, mouthfeel, and nutrition as ice cream products. The comments also noted that the nutrition labeling on the reduced fat products will provide additional information on the fat content of the products for comparison purposes.

As noted in these comments on the ANPRM, consumers have had experience for many years with the term "nonfat" on other dairy products (e.g., nonfat milk and nonfat yogurt). In addition, FDA has issued a number of temporary marketing permits and an extension of a temporary marketing permit for "nonfat cottage cheese," a mixture of dry curd cottage cheese with a dressing that contains less than 0.5 percent of milkfat, and has granted temporary marketing permits for "no fat sour cream." FDA believes that these products are dairy products even though milkfat has been reduced or removed because the milkfat is replaced with skim milk or other dairy ingredients. Nutrition labeling will also assist consumers in making value comparisons relative to the fat reduction as well as calorie reductions in these foods. Therefore, FDA concludes that consumers will not be confused or misled by the use of the nutrient content claim "nonfat" in conjunction with a standardized term such as "ice cream."

42. One comment disagreed with the prohibition on the use of a name permitted on a food under the new generic standard of identity if that food complies with another standard. It stated that this prohibition is a barrier to directing consumers to lower fat versions of products with which they are familiar. It stated that if a modified product meets a traditional standard and the general standard, food producers should be given the option of naming the food using any of the terms allowed under those standards.

FDA disagrees that the name of a modified food that meets the requirements of another standard in parts 131 through 169 should be either name. The common or usual name of a food that has been defined by a standard of identity under section 401 of the act is the name prescribed by the standard. Foods that comply with any standard in parts 131 through 169 must use that standardized name, and this rulemaking is not intended to amend existing standards nor create duplicative standards.

As FDA stated in the proposal (56 FR 60512 at 60520), comparative labeling in accordance with regulations in part 101 may be used to provide consumers with useful information in the selection of a variety of foods.

I. Ingredient Labeling

In the proposal, FDA requested comments on the proposed approach to ingredient labeling in proposed § 130.10(f) and on other methods of identifying ingredients not provided for by the traditional standard of identity (56 FR 60512 at 60520).

43. A number of comments objected to the proposed labeling requirements that ingredients not in the standardized food be highlighted with an asterisk, with a statement following the ingredient statement. One comment urged FDA not to establish the specific words that processors must use to convey information about the amount of ingredients not in the standardized food. Several comments stated that consumers generally are not concerned about, or even interested in, how these formulations are achieved, and that the use of asterisks and label statements may be potentially confusing. Several comments stated that the proposed ingredient disclosures would be burdensome to manufacturers and would result in label clutter.

The agency also received comments strongly supporting the use of the disclosures as meaningful steps in the goal of consumer information and understanding. One comment stated that food companies need to inform the consumer as to whether adjustments have been made to their products, and that the item is no longer the same as the standardized food. It stated that the simple labeling of a product as "low fat" is not sufficient because this claim may give the consumer the impression that the product is the same as always, but contains less fat, which may or may not be true.

FDA disagrees with the comments that opposed the use of asterisks. Standards of identity regulations are established when such action will promote honesty and fair dealing in the interest of consumers. The highlighting of ingredients that are not part of the traditional standard of identity, or that are added in excess of what is permitted by that standard, is appropriate to ensure continued consumer confidence in standardized foods. FDA believes that under sections 201(n) and 403(d) of the act, consumers are entitled to know how the new standardized food differs from the traditional standardized food. In some cases, consumers may have allergies to certain ingredients that may not be normally encountered in the standardized food. Therefore, FDA finds that these ingredients must be highlighted.

44. Many comments stated that it is important for persons with hemochromatosis to know when iron is added to a food. They stated that added iron is often more biologically available than other forms of iron. Several of the comments opposed the language of proposed § 130.10(f)(2) that exempts added iron from being identified with an asterisk in the ingredient statement.

Any added iron must be listed as an ingredient in the ingredient statement. As stated in the proposal (56 FR 60512 at 60520), the consumer may be misled to believe that ingredients added to restore nutrients are present in greater amounts than needed to obtain nutritional equivalency if these nutrients are identified with an asterisk in the ingredient statement. Iron is added to a number of foods, not just standardized foods including foods under new § 130.10. Most § 130.10 foods to which iron will need to be added to ensure that the product is not nutritionally inferior are foods that must contain added iron under the traditional standard of identity (e.g., enriched bread, rolls, and buns (§ 136.115)). The agency notes that nutrition labeling will inform consumers of any iron present in significant amounts in the food. Thus, FDA concludes that persons with hemochromatosis will be adequately informed of added iron in any food, and that the use of an asterisk in the ingredient statement is not necessary for nutrients added to a § 130.10 food.

45. Two comments stated that FDA should require that the principal display panel of the label contain a referral statement directing consumers to the ingredient statement to be informed of any nonstandard ingredients. One comment recommended that this statement should be tailored to different types of foods, based on the ingredients that characterize the foods to consumers. For example, the comment noted, dairy products could be labeled with the term "made with nonstandard nondairy ingredients." In addition, the comment stated that products that meet the nutrient content claim requirements, but are made only from standard ingredients, could be permitted to use the term "pure" as part of the common

or usual name ("pure reduced fat sour cream").

The agency disagrees with these comments. FDA believes that this additional labeling is not necessary because the ingredients that are not in the traditional standardized food are already identified with an asterisk in the ingredient statement. FDA also disagrees with this use of the term "pure." The agency has not defined the term "pure" and believes that the use of the term in the requested manner could cause consumer confusion because of its ambiguity.

46. One comment stated that if these products contain saccharin, aspartame, or acesulfame potassium, they should clearly state this fact on the front label.

FDA notes that a product is misbranded under section 403(o)(1) of the act if it contains saccharin, unless, its label and labeling bear the following statement: "USE OF THIS PRODUCT MAY BE HAZARDOUS TO YOUR HEALTH. THIS PRODUCT CONTAINS SACCHARIN WHICH HAS BEEN DETERMINED TO CAUSE CANCER IN LABORATORY ANIMALS." This statement must be located in a conspicuous place on the label and labeling, as proximate as possible to the name of such food, and must appear in conspicuous and legible type in contrast by typography, layout, and color with other printed matter on such label and labeling.

FDA also notes that § 172.804 (21 CFR 172.804) requires that the label of any food containing aspartame bear, either on the principal display panel or on the information panel, the following statement: "PHENYLKETONURICS: CONTAINS PHENYLALANINE." The statement must appear in the labeling prominently and conspicuously as compared to other words, statements, designs or devices and in bold type and on clear contrasting background in order to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

The regulation in § 172.800 (21 CFR 172.800) concerning acesulfame potassium requires no special label statements. However, whenever acesulfame potassium, aspartame, or saccharin are ingredients in a food, the name of the ingredient must appear in the ingredient declaration according to part 101.

The comment did not provide any basis for requiring special label statements concerning the addition of these sweeteners for foods subject to new § 130.10. FDA believes that the above requirements provide adequate notice of the presence of these ingredients when they are used. Therefore, FDA concludes that no additional statements need be required other than those that are required by the act and current FDA regulations, including the use of asterisks and label statements required in new § 130.10(f)(2).

J. Label Format

47. Two comments suggested that FDA should develop more simplified principal display panel labeling requirements and consider a mandatory format for comparative labeling of § 130.10 foods. The comment gave the following example: Reduced Fat "Modified" Cheddar Cheese; 25 percent Less Fat than Cheddar Cheese; Side panel provides nutrition information, per serving size comparisons, and nonstandardized (*) ingredients.

FDA disagrees with this comment. The principal display panel labeling requirements for use of nutrient content claims are mandated by the 1990 amendments and regulations in part 101 concerning the claim. New § 130.10(c) requires additional labeling on the principal display panel only when there are differences in performance characteristics. FDA concludes that the requirements that it is adopting are the minimum necessary to ensure that the labeling of § 130.10 foods is informative, adequate, and not misleading. In addition, FDA believes that except as provided in new § 130.10(c), it is not necessary to mandate a particular format for the principal display panel.

K. Existing Standards Using Nutrient Content Claims

48. One comment expressed concern about FDA's tentative decision to exclude from this rule standards of identity that already incorporate nutrient content claims (e.g., lowfat milk). Another comment stated that FDA should give serious consideration to eliminating the existing standards of identity for those foods that have a nutrient content claim as part of their standardized names, in cases where the remainder of the name is also a standardized term.

The agency appreciates the concerns expressed in these comments. FDA did not include existing standards in the proposal to this final rule because Congress exempted nutrient content claims that are part of the name of a food defined by an existing standard of identity even if the use of the term in the standardized name is not consistent with the definition for the term that FDA adopts (section 403(r)(5)(C) of the act). However, the legislative history makes clear that this exemption was included in the law because of the preexisting standards of identity and the possibility that these standards would conflict with the definitions adopted under the new law. The legislative history goes on to state that to the extent that those standards do provide definitions that are different from the definitions in the regulations issued by FDA under the 1990 amendments, one basic purpose of the 1990 amendments will be partially undermined. Therefore, the legislative history points out that the Secretary (and, by delegation, FDA) has the authority to correct this problem by amending the standards of identity to conform with the regulations issued under section 403(r) of the act (H. Rept. 101–538, 101st Cong., 2d sess. 22 (June 13, 1990)).

FDA will consider amending the existing standards of identity that use nutrient content claims in a food name to make them consistent with the definitions that the agency is adopting. The agency's options include amending standards of identity to comply with the nutrient content claim or deleting some standards and allowing the use of these claims with standardized terms in accordance with new § 130.10. Thus, FDA does intend to consider taking the actions suggested by these comments, although it is unable to do so at this time.

L. Legal and Policy Analysis

49. One comment stated that the same legal and policy analysis applies to foods that substitute for foods standardized by statute as to foods that substitute for foods standardized by regulation. It suggested that the preamble to the final rule adding new § 130.10 state that the same legal and policy analysis applies to foods subject to new § 130.10 as to foods subject to § 101.67.

FDA disagrees with this comment. Butter, nonfat dry milk, milk, and oleomargarine or margarine are foods that have been defined by statute. Under section 401 of the act, FDA has modified the definitions and has established standards of identity for nonfat dry milk, milk, and oleomargarine or margarine. However, under section 401 of the act, FDA is prohibited from establishing standards for butter. Therefore, the legal and policy analysis of butter is different from foods standardized by regulation. Proposed § 101.67 deals only with the use of nutrient content claims for butter. FDA can establish standards for other foods under section 401 of the act, and terms that are standardized by regulation are those that may be used under new § 130.10.

III. Pending Petitions

As stated in the proposal (56 FR 60513 at 60516), FDA has received petitions from: (1) The Milk Industry Foundation (MIF) (Docket No. 88P-0329), H. P. Hood, Inc. (Docket No. 89P-0105), and Crowley Foods, Inc. (Docket No. 89P-0403) to establish a standard for "light sour cream;" (2) MIF (Docket No. 88P-0334) and H. P. Hood, Inc. (Docket No. 89P-0329) to establish a standard for "light eggnog;" and (3) the International Ice Cream Association (IICA), the Public Voice for Food and Health Policy, Kraft General Foods, and the Calorie Control Council to amend the standards for "ice cream" and "ice milk" and to establish standards for "reduced fat ice cream," "lowfat ice cream," and "nonfat ice cream" (Docket No. 88P-0251).

FDA has received a number of applications from companies desiring to market test "nonfat cottage cheese." The agency has issued approximately 22 temporary marketing permits for the product. MIF filed a petition, dated November 2, 1991 (Docket No. 91P-0448), to establish a standard of identity for "nonfat cottage cheese." MIF stated in its petition that establishing a standard of identity for "nonfat cottage cheese" would enhance public health, satisfy consumer demand, and promote honesty and fair dealing in the interest of consumers.

All of the petitions are requesting that the agency establish standards for modified versions of traditional standardized foods. Nutrient content claims for the fat content of foods are defined in § 101.62 and include "nonfat" (§ 101.62(b)(1)), "low fat" (§ 101.62(b)(2)), and "reduced fat" (§ 101.62(b)(4)). The term "light" or "lite" is defined in § 101.56. New § 130.10 establishes the requirements for use of these defined nutrient content claims with a standardized term. Therefore, the agency is responding to the above petitions by adopting this final rule. However, new § 130.10 does not encompass some portions of the petitions to amend the standards for ice cream and ice milk. Therefore, FDA is responding to those portions of the petitions to amend the standards for ice cream and ice milk in a separate proposal published elsewhere in this issue of the **Federal Register**.

50. One comment requested that to ensure that there is consistency in nomenclature regarding nutrient modified ice creams, FDA should take final action on the petition from the IICA to establish specific standards for modified ice creams and defer the applicability of the provisions of the 1990 amendments to the products within the scope of the IICA petition until 12 months after: (1) The effective date of regulations that FDA adopts in response to the IICA petition, or (2) FDA takes final action to reject the petition, whichever is applicable.

The agency disagrees with the comment. The standard of identity for ice milk (§ 135.120) states that its milkfat content is more than 2 percent but not more than 7 percent. The agency realizes that some reduced fat ice cream products may comply with the standard of identity for ice milk and must be labeled as "ice milk." As stated above, elsewhere in this issue of the **Federal Register**, FDA is proposing changes in the standards of identity for ice cream and ice milk. The agency is proposing to repeal the standard of identity for ice milk. If FDA repeals the standard for ice milk, manufacturers would be able to label ice cream products containing more than 2 percent but not more than 7 percent milkfat according to new § 130.10.

Because FDA is taking action on the IICA petition at this time, it does not believe that deferring the applicability of the provisions of new § 130.10 for ice cream products is necessary.

IV. Noncharacterizing Changes in Standardized Foods

51. One comment stated that because the use of nutrient content claims is voluntary, and because the standardized name alone is a proper statement of identity for a standardized food, the suggested use and placement of any nutrient content claim in conjunction with the name of a standardized food that meets the requirements of the standard of identity would, of course, be optional.

FDA agrees with this comment. The labeling for foods meeting a standard of identity and qualifying for the use of a nutrient content claim must comply with the respective standard of identity in parts 131 through 169 and the requirements of § 101.13 concerning nutrient content claims. Because these foods are not modified foods, they do not fall within the scope of new § 130.10. Therefore, FDA concludes that the use of a nutrient content claim in the name of a food complying with a standard of identity is not mandatory. For example, reduced cholesterol liquid eggs may still comply with the standard for liquid eggs (§ 160.115) although part or all of the cholesterol has been removed. The nutrient content claim "reduced cholesterol" may appear as part of the statement of identity in conjunction with the standardized name, or it may appear elsewhere on the label, according to applicable sections of part 101, with the statement of identity consisting of the standardized name.

V. Conclusion

In response to comments submitted regarding the proposal for requirements for foods named by use of a nutrient content claim and a standardized term (56 FR 60512), FDA has revised new § 130.10. The following summarizes the changes being made to new § 130.10 by this final rule:

FDA has revised the title of the regulation to delete the term "substitute" because new § 130.10 applies only to a certain category of substitute foods and not all types of substitute foods as defined under § 101.3(e)(4) and § 101.13(d).

FDA has revised new § 130.10(a) to more clearly establish the scope of the regulation by adding that § 130.10 foods use the name of the traditional standardized food in their statement of identity but do not comply with the traditional standard.

The agency has revised new § 130.10(a) to state that the deviation from the standard of identity "is described by an expressed nutrient content claim that has been defined by FDA regulation."

FDA has revised the last sentence of new § 130.10(a) to read: "The food shall comply with the relevant standard in all other respects except as provided in paragraphs (b), (c), and (d) of this section."

FDA has added a new sentence to new § 130.10(c) at the beginning of the paragraph to state: "Deviations from noningredient provisions of the standard of identity (e.g., moisture content, food solids content requirements, processing conditions) are permitted in order that the substitute food possesses performance characteristics similar to those of the standardized food." In addition, FDA has included in new § 130.10(c) a requirement that deviations from ingredient and noningredient provisions of the standard must be the minimum necessary to achieve this effect or the food will be deemed to be adulterated under section 402(b) of the act.

The agency has added a statement to new § 130.10(c) to require that the modified product must perform at least one of the principal functions of the standardized product substantially as well as the standardized product.

The agency has also revised new § 130.10(c) by limiting the labeling requirement to changes that materially affect the use of the product.

Finally, FDA has revised new § 130.10(c) to require that the mandated

label statement concerning any differences in performance characteristics be in accordance with the requirements of § 101.13(d).

The agency has revised new § 130.10(d)(1) to include the use of safe and suitable ingredients to improve appearance and to add sweetness.

FDA has added new § 130.10(d)(4) to state that an ingredient specifically required by the standard as defined in parts 131 through 169 must be present in a significant amount. A significant amount of an ingredient is at least that amount that is required to achieve the technical effect provided by that ingredient in the modified food.

The agency has added new § 130.10(d)(5) to provide for the use of water and safe and suitable fat analogs in accordance with new § 130.10(c), (d)(1), and (d)(2) in modified foods to replace fat and calories.

FDA has revised new § 130.10(e) to state that the name of the substitute food "is the appropriate expressed nutrient content claim and the applicable standardized term."

VI. Environmental Impact

The agency previously considered the environmental effects of the action being taken in this final rule. As announced in the reproposed rule for mandatory nutrition labeling (56 FR 60366, November 27, 1991) and the proposed rule for nutrient claims (56 FR 60421, November 27, 1991), the agency determined that under 21 CFR 25.24(a)(8) and (11), these actions are of a type that do not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

Several comments on the proposed rule suggested that there would be significant adverse environmental effects from the final rules unless the agency allowed more time between the publication of the final rules and their effective dates. The concern in these comments was that, if the agency did not allow firms more time between the publication of the final rules and their effective dates to use up existing label inventories, large stocks of labels and labeled packaging would have to be discarded. These comments questioned whether the agency had sufficiently examined the impact of disposing of obsolete labels and labeled packaging on this country's solid waste disposal capabilities. Two comments estimated the amounts of labeling from their respective industries, i.e., dairy and confectionery, that would need to be discarded following publication of FDA's final rules on several food labeling actions, including this action. However, these comments did not: (1) provide details on how these estimates were derived, (2) identify what portion of the estimated amounts are attributable to these two actions, or (3) describe what impact the discarded labels and packaging would have on the disposal of solid waste. In its November 27, 1991, reproposed rule for mandatory nutrition labeling and proposed rule for nutrient content claims, the agency proposed that the final rules for these actions would become effective 6 months following their publication in the **Federal Register**.

However, the agency has decided to allow additional time for companies to use up their old labels. Thus, the final rule will not be effective until May 8, 1994. FDA believes there will thus be ample time for food companies to use up most of the existing labeling and packaging stocks and to incorporate labeling language that complies with FDA's regulations into their food labels. Consequently, the comments on the potential for adverse environmental effects do not affect the agency's previous determination that no significant impact on the human environment is expected and that an environmental impact statement is not required.

VII. Economic Impact

In its November 27, 1991, food labeling proposals (56 FR 60366), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), along with the food labeling proposals, and the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

List of Subjects in 21 CFR Part 130

Food additives, Food grades and standards.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 130 is amended as follows:

PART 130—FOOD STANDARDS: GENERAL

1. The authority citation for 21 CFR part 130 continues to read as follows:

Authority: Secs. 201, 306, 401, 403, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 336, 341, 343, 371).

2. Section 130.10 is added to subpart A to read as follows:

§ 130.10 Requirements for foods named by use of a nutrient content claim and a standardized term.

(a) *Description.* The foods prescribed by this general definition and standard of identity are those foods that substitute (see § 101.13(d) of this chapter) for a standardized food defined in parts 131 through 169 of this chapter and that use the name of that standardized food in their statement of identity but that do not comply with the standard of identity because of a deviation that is described by an expressed nutrient content claim that has been defined by FDA regulation. The nutrient content claim shall comply with the requirements of § 101.13 of this chapter and with the requirements of the regulations in part 101 of this chapter that define the particular nutrient content claim that is used. The food shall comply with the relevant standard in all other respects except as provided in paragraphs (b), (c), and (d) of this section.

(b) *Nutrient addition.* Nutrients shall be added to the food to restore nutrient levels so that the product is not nutritionally inferior, as defined in

§ 101.3(e)(4) of this chapter, to the standardized food as defined in parts 131 through 169 of this chapter. The addition of nutrients shall be reflected in the ingredient statement.

(c) *Performance characteristics.* Deviations from noningredient provisions of the standard of identity (e.g., moisture content, food solids content requirements, or processing conditions) are permitted in order that the substitute food possesses performance characteristics similar to those of the standardized food. Deviations from ingredient and noningredient provisions of the standard must be the minimum necessary to qualify for the nutrient content claim while maintaining similar performance characteristics as the standardized food, or the food will be deemed to be adulterated under section 402(b) of the act. The performance characteristics (e.g., physical properties, flavor characteristics, functional properties, shelf life) of the food shall be similar to those of the standardized food as produced under parts 131 through 169 of this chapter, except that if there is a significant difference in performance characteristics that materially limits the uses of the food compared to the uses of the standardized food, the label shall include a statement informing the consumer of such difference (e.g., if appropriate, "not recommended for cooking"). Such statement shall comply with the requirements of § 101.13(d) of this chapter. The modified product shall perform at least one of the principal functions of the standardized product substantially as well as the standardized product.

(d) *Other ingredients.* (1) Ingredients used in the product shall be those ingredients provided for by the standard as defined in parts 131 through 169 of this chapter and in paragraph (b) of this section, except that safe and suitable ingredients may be used to improve texture, add flavor, prevent syneresis, extend shelf life, improve appearance, or add sweetness so that the product is not inferior in performance characteristics to the standardized food defined in parts 131 through 169 of this chapter.

(2) An ingredient or component of an ingredient that is specifically required by the standard (i.e., a mandatory ingredient) as defined in parts 131 through 169 of this chapter, shall not be replaced or exchanged with a similar ingredient from another source unless the standard, as defined in parts 131 through 169 of this chapter, provides for the addition of such ingredient (e.g., vegetable oil shall not replace milkfat in light sour cream).

(3) An ingredient or component of an ingredient that is specifically prohibited by the standard as defined in parts 131 through 169 of this chapter, shall not be added to a substitute food under this section.

(4) An ingredient that is specifically required by the standard as defined in parts 131 through 169 of this chapter, shall be present in the product in a significant amount. A significant amount of an ingredient or component of an ingredient is at least that amount that is required to achieve the technical effect of that ingredient in the food.

(5) Water and fat analogs may be added to replace fat and calories in accordance with § 130.10(c), (d)(1), and (d)(2).

(e) *Nomenclature.* The name of a substitute food that complies with all parts of this regulation is the appropriate expressed nutrient content claim and the applicable standardized term.

(f) *Label declaration.* (1) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of part 101 of this chapter and part 130.

(2) Ingredients not provided for, and ingredients used in excess of those levels provided for, by the standard as defined in parts 131 through 169 of this chapter, shall be identified as such with an asterisk in the ingredient statement, except that ingredients added to restore nutrients to the product as required in paragraph (b) of this section shall not be identified with an asterisk. The statement "*Ingredient(s) not in regular _____" (fill in name of the traditional standardized food) or "*Ingredient(s) in excess of amount permitted in regular _____" (fill in name of the traditional standardized food) or both as appropriate shall immediately follow the ingredient statement in the same type size.

Dated: October 27, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 92-31506 Filed 12-28-92; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 91N-0344]

RIN 0905-AD08

Food Labeling: Use of Nutrient Content Claims for Butter

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is adopting a regulation that will permit nutrient content claims that are defined by regulation in 21 CFR part 101 to be made for butter. This action is in response to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments).

EFFECTIVE DATE: May 8, 1994.

FOR FURTHER INFORMATION CONTACT: Shellee A. Davis, Center for Food Safety and Applied Nutrition (HFS-158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5112.

SUPPLEMENTARY INFORMATION:

I. Background

In response to the 1990 amendments (Pub. L. 101-535) and to a citizen petition submitted by Johanna Farms, Inc., Flemington, NJ 08822, (Docket No. 90P-0141), FDA published in the **Federal Register** of November 27, 1991 (56 FR 60523), a proposal to adopt § 101.67, which would permit nutrient content claims that are defined by regulation in part 101 (21 CFR part 101) to be made for butter. Interested persons were given until February 25, 1992, to comment on this proposed regulation.

FDA received approximately 70 responses on the proposal, each of which contained one or more comments, from trade and retail associations, government organizations, manufacturers, consumers, retailers, consumer groups, State groups, private organizations, professional societies, and universities. The comments generally supported the proposal. Several comments addressed issues outside the scope of the proposal (e.g., serving size and nutrient content claims definitions) and will not be discussed here. A number of comments suggested modification and revision in various provisions of the proposal. A summary of the suggested changes and the agency's responses follow.

II. Use of Nutrient Content Claims for Butter Under the 1990 Amendments

A. The Proposed Approach

FDA requested comments on its proposed approach to permit nutrient content claims to be made for butter (56 FR 60523 at 60525).

1. Two comments stated that FDA had the authority to promulgate § 101.67 independent of the 1990 amendments. One of the comments said that a better approach would have been under the general provisions of proposed § 130.10 or through a standard of identity. It stated that a food that does not meet the statutory standard for butter is not butter, and that accordingly, a product with less milkfat simulating butter would need to be labeled "imitation" in the absence of some other governing agency mechanism, such as a standard of identity for "light butter." The comment maintained that since "light" would be part of the name, the product would not be butter because the definition would be different. The product would not be nutritionally inferior, the comment continued, because it would be required to provide the same nutrients as butter (except for less fat), and it would not be deceptive because properly informative labeling would be required and monitored by the agency.

The agency disagrees with the comments. As explained in the proposal (56 FR 60523 at 60524), the agency does not have the authority to establish a definition and standard of identity for "light butter." Section 401 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 341) states that no definition and standard of identity can be established for butter. Moreover, FDA has historically taken the position that a product using the term "butter" must comply with the statutory definition of butter, or its labeling would be false, and it would be misbranded under section 403(a)(1) of the act (21 U.S.C. 343(a)(1)) (see 56 FR 60523 at 60524). In addition, a food sold under the name "butter" that does not comply with the statutory standard for butter also is in violation of section 403(b) of the act in that it is sold under the name of another food.

As discussed in the proposed rule, FDA sought an interpretation that gave effect both to section 3(b)(1)(A)(viii) of the 1990 amendments (21 U.S.C. 343 note), which stated that FDA could establish a regulation that would permit a nutrient content claim, such as "light," to be made for butter, and to section 401 of the act. FDA believes that it achieved this goal in proposed § 101.67. These comments, since they rely on section 401 of the act, have not provided any basis to conclude to the contrary.

2. A number of comments opposed providing for the use of nutrient content claims for butter. Several comments recommended that the term "butter" be used only if the product complies with the statutory standard for butter, and that other names such as "dairy spread" be used for other butter products. Some comments stated that if a product is good it will develop its own distinctive name.

The agency understands the concerns expressed by these comments. However, the 1990 amendments and their legislative history make clear that Congress fully intended that a claim described in section 403(r)(1)(A) of the act (such as "light") be permitted to be made for butter (H. Rept. 101-538, 101st Cong., 2d sess. 22-23 (June 13, 1990)). Given this fact, there is no basis to require the use of terms such as "dairy spread" in the common or usual names of these products. Accordingly, FDA is allowing, as proposed, nutrient content claims to be made for butter.

B. The Nutrient Content Claim

3. Several comments expressed concern about consumers being able to identify butter products on the store shelf. The comments were concerned that nutrient content claims could mislead and confuse consumers even if they are defined.

The agency appreciates the concerns expressed by the comments. In response to the requirements of the 1990 amendments, published elsewhere in this issue of the **Federal Register**, in a document entitled "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definitions of Terms" (hereinafter referred to as the nutrient content claims final rule), FDA is establishing in part 101 definitions for nutrient content claims together with general principles governing their use. FDA has carefully considered each nutrient content claim to ensure that these definitions will be meaningful to consumers. Each of the definitions for the nutrient content claims also prescribes specific labeling that must accompany the claim. The agency believes that as consumers learn what a claim means, they will be able to understand that a product such as "light butter" is reduced a certain amount in fat. Thus, the use of nutrient content claims for butter products in accordance with new § 101.67 will not mislead or confuse consumers but will assist them in maintaining healthy dietary practices.

New § 101.67 only provides for the use for butter of nutrient content claims

that have been defined by FDA. Any product labeled as "butter" that does not come within the provisions of new § 101.67 will need to comply with the statutory standard for butter, or its labeling will be false, and it will be misbranded under the act.

FDA notes, however, that there are two potential problems that proposed § 101.67 failed to address that could cause confusion among consumers. In the proposal, FDA did not require that the nutrient content claim be included as part of the statement of identity of the butter product. Consequently, a claim could be made for the butter product in an inconspicuous location on the label, and consumers could be misled about the identity of the product that does not comply with the statutory standard for butter (section 201a of the act (21 U.S.C. 321a)).

In addition, FDA did not distinguish between express and implied claims in the proposal. Yet section 403(r)(1)(A) of the act applies to both types of nutrient content claims.

Therefore, to rectify this potential confusion, FDA is adding § 101.67(a)(4) to make clear that while nutrient content claims may be made anywhere on the label, if the product would violate section 201a of the act but for the nutrient content claim that characterizes the level of nutrients, that claim must be included as part of the common or usual name of the product. This provision will ensure that consumers are not misled about the identity of the product.

New § 101.67(a)(4) also provides that if the name of the butter product is necessary to distinguish it from butter, the claim must be an express claim as defined in new § 101.13(b)(1). If the claim is not express, consumers will not understand how the new modified food differs from the traditional food. Thus, only expressed nutrient content claims may be used in the name of the food under new § 101.67. While implied claims may be used as provided in new § 101.13(b)(2), they may not be used in conjunction with the name of the butter product because they would not be adequately informative to consumers.

4. One comment stated that FDA should decide on a more appropriate name than "light butter," such as "light butter product."

The agency does not believe the suggested additional term (i.e., "product") is necessary. If a butter product does not comply with the statutory standard for butter or the requirements of new § 101.67 set forth below, FDA requires that it be labeled either as an imitation food if it is nutritionally inferior to butter (§ 101.3(e)(1)), or as a substitute or alternative food if it is not nutritionally inferior to the food for which it substitutes, with an appropriately descriptive common or usual name that is not false and misleading, as provided for in § 102.5 (21 CFR 102.5), or, in the absence of an existing common or usual name, an appropriately descriptive term that is not false and misleading (§ 101.3(e)(2) (21 CFR 101.3(e)(2))). As explained above in comment 2 of this document, the legislative history of the 1990 amendments makes clear that Congress fully intended that a claim described in section 403(r)(1)(A) of the act (such as "light") be permitted to be made for butter (H. Rept. 101–538, supra, 22–23). Given this fact, there is no basis to require the use of additional terms such as "product" in the common or usual names of these foods. The use of a nutrient content claim that is permitted by regulation with the term "butter" in the statement of identity will provide a clear indication to consumers that the food is different from traditional butter and will describe the nature of the modification. In addition, the label must comply with all the requirements for the use of the nutrient content claim. Accordingly, the agency is not making the suggested modification to new § 101.67.

5. A number of comments suggested that FDA should develop unique nutrient content claims for butter because the proposed nutrient content claim requirements for fat in proposed § 101.62 are not appropriate or realistic for butter products. Two comments added that the use of unique nutrient claims for butter is consistent with the directive in the President's Executive Order 12630 that regulations harness the mechanisms of the market (e.g., competition in percentage reductions) to accomplish the agency's goal. One comment stated that it had test marketed a 50-percent reduced fat butter for over a year, but that the product failed to meet consumers' expectations, principally in physical performance characteristics. Another comment suggested that a reduced fat butter containing one-third less fat than butter is a product that will significantly reduce fat consumption while having all the characteristics of full-fat butter. The comments urged FDA to adopt simple definitions for nutrient content claims that will allow the industry to make dairy products with less fat and cholesterol available to consumers. One comment noted that a number of states have established regulations for light butter that differ from FDA's proposal. The comment urged FDA to use the knowledge and information obtained by these states in their respective hearing processes to modify FDA's proposed regulations to redefine the term "light" as used with butter products.

FDA notes that because no uniform set of definitions has existed for many nutrient content claims, these claims have been used in an inconsistent manner, which has resulted in consumers being confused and misled. The legislative history of the 1990 amendments makes clear that Congress was aware that many food labels bear terms such as "light" when a product may not be as "light" as the label indicated, or the product was "light" in different ways (e.g., calories or sodium). The purpose of the 1990 amendments was to correct this deceptive and misleading state of affairs by requiring that terms such as "light" have a single meaning (136 Congressional Record H5844, July 30, 1990).

The agency recognizes that because butter is at least 80 percent milkfat, a significant reduction in milkfat produces a significant change in the product. In the nutrient content claims final rule, FDA is redefining "reduced" and "less" to be a reduction of 25 percent or more. Thus, many butter products will be able to meet these requirements and make a nutrient content claim. Also, there is evidence that some manufacturers will be able to meet the 50-percent reduction to qualify for use of the term "light." Thus, FDA sees no reason to create a special set of definitions for butter products under new § 101.67.

FDA recognizes that some states and foreign governments have developed their own definitions for nutrient content claims for butter. However, FDA concludes that use of nutrient content claims in an inconsistent manner would be confusing to consumers, and, thus, the agency is not considering the use of any unique nutrient content claims for butter.

C. Minimum Milkfat Level

In the House report on the 1990 amendments, FDA is directed to consider arguments concerning the appropriate characteristics of butter. In a footnote, the report states:

> The Committee is aware that the dairy industry takes the position that products containing less than approximately 50 percent milkfat lose some of the characteristics of butter. In connection with the promulgation of the regulations, representatives of dairy interests and health experts will have the opportunity to present their views on the issue to the Secretary. (H. Rept. 101–538, supra, 23, n.3.)

In the proposal, FDA requested comments on whether its tentative

decision not to include a minimum milkfat level in proposed § 101.67 was appropriate (56 FR 60523 at 60526).

6. A number of comments concurred with the agency's tentative decision. Comments stated that there is no need to stipulate minimum levels. The comments also stated that not requiring a minimum milkfat level for butter products would leave room for advances in food processing technology that could lead to products with lower levels of milkfat and greater health benefits while still maintaining the characteristics of standardized butter. Another comment concurred as long as the product bearing the term "butter" is describable as a form of butter, because of the fact that its similarities to butter nutritionally, organoleptically, functionally, and in other ways would clearly outweigh its dissimilarities to butter.

One comment stated that FDA should set a minimum butterfat level, below which the product is no longer a butter product. However, the comment did not recommend a minimum level.

FDA agrees with the comments suggesting that a minimum milkfat level is not necessary. A product remains a butter product as long as the major ingredients used in manufacturing it are cream, milk, or constituents of milk and cream and as long as it can be used like butter. In addition, the butter product must comply with all the requirements of new § 101.67 for the use of nutrient content claims for butter products. For example, the milkfat content of butter contributes some of the basic characteristics of the food. New § 101.67(b) provides that the performance characteristics must be similar to those of butter, or the differences must be stated on the principal display panel.

The agency notes that Canadian regulations do not stipulate a minimum milkfat level for "calorie reduced butter."

Therefore, for the above reasons, the agency concludes that there is no need to specify a minimum milkfat level for butter products. The absence of a minimum level will permit technological advances that will provide consumers with butter products that have even greater reductions in fat and calories.

D. Ingredients

FDA requested comments on the use of safe and suitable nondairy ingredients to improve texture, prevent syneresis, add flavor, or extend shelf life. FDA also requested comments concerning the addition of water as well as skim milk, whey, or milk to replace milkfat as an ingredient in substitute butter products. FDA stated in the proposal that if the comments supported the use of safe and suitable nondairy ingredients and provided a substantial basis for their use, FDA might provide for the use of these ingredients in the final rule (56 FR 60523 at 60526).

(1) Safe and Suitable Nondairy Ingredients

7. A number of comments stated that the use of nondairy ingredients should not be permitted. Several comments argued that if manufacturers are adding anything that makes the food something other than butter, it should be labeled as "margarine," "spread," or "margarine." One comment stated that use of nondairy ingredients in a butter product would mislead consumers because consumers expect "butter" to be a dairy product. It added that use of such ingredients would erode the goodwill associated with the term "butter." The comment stated that the fact that current reduced fat butter products made without nondairy ingredients are not satisfactory for some cooking applications is not a reason to permit the use of such ingredients in products whose statement of identity includes the term "butter." It stated that consumers who want reduced fat, reduced calorie products for use in cooking can turn to products properly labeled as margarines and spreads.

Another comment stated that consumers purchasing and using a butter product expect it to be a 100 percent dairy product and thus made from the ingredients and constituents of the ingredients listed in section 201a of the act for standardized butter. It added that use of additional safe and suitable ingredients is not necessary for butter products. It stated that the only exception should be the permitted addition of nutrients to prevent nutritional inferiority and the permitted use of safe and suitable bacterial cultures as proposed in the regulation.

A number of other comments urged FDA to allow the use of safe and suitable nondairy ingredients to improve texture, prevent syneresis, add flavor, or extend the shelf life of the product. One comment stated that FDA should permit the addition of safe and suitable nondairy ingredients that are not fat ingredients for such purposes. Another comment urged FDA to allow the use of safe and suitable ingredients without the restriction that they must be used to maintain the traditional food's performance characteristics as long as the use is in keeping with current good manufacturing practices. The comment stated that the potential need to use safe and suitable ingredients for processing, as well as performance, purposes is most apparent for reformulated butter products because butter is a high fat food, and fat affects processing characteristics as well as final performance characteristics. Several comments argued that providing for the use of safe and suitable ingredients would allow the development of additional products with lower saturated fat, total fat, and cholesterol.

One comment stated that using current technology, "reduced fat" butter made strictly from dairy ingredients is not suitable for frying or baking. It stated that in the event that a "reduced fat" butter made primarily from dairy ingredients cannot be developed with good baking characteristics, then the field needs to remain open to "reduced fat" butter that is made with some nondairy ingredients and that has good baking properties. It added that without these additional ingredients, consumers will have trouble finding "reduced fat" butter that meets their needs and will be discouraged from shifting from full fat to reduced fat butter.

One comment argued that FDA's authority to allow the use of nutrient content claims for butter also gives the agency the authority to allow safe and suitable ingredients, including nondairy ingredients, in a product that is named by using a nutrient content claim with the term "butter." The comment added that FDA has already recognized this authority by providing for two types of ingredients (nutrients and bacterial cultures) in the proposed rule that are not permitted in standardized butter. It urged FDA to modify the regulation consistent with the regulation for substitute foods.

One comment stated that a reduction in milkfat of 50 percent in a butter product made without the use of safe and suitable nondairy ingredients results in a product that fails to meet consumers' expectations for many of the principal uses of a butter product (e.g., baking, frying, melting, sauteing). The comment stated that a light butter product that meets the proposed requirements in proposed § 101.67 (i.e., 50 percent less milkfat than butter and no ingredients other than those allowed in proposed § 101.67) is currently being marketed in Canada. The comment stated that Professor David Bandler of Cornell University testified before the New York Department of Agriculture and Markets regarding a hearing to establish a standard of identity in New York for light butter. The comment stated that Professor Bandler testified that the Canadian light butter product that he evaluated was really a

combination of butter and cream mixed together, and one could easily determine that the product may not be butter for many of the principal uses a consumer would have for butter. (Hearing Transcript, December 4, 1990. State of New York Department of Agriculture and Markets, p. 66.) The comment stated that New York and five other states have established standards for light butter and have provided for the use of safe and suitable nondairy ingredients. The comment urged FDA to allow safe and suitable nondairy ingredients in butter products for which nutrient content claims are made.

Other comments added that use of other safe and suitable ingredients was acceptable as long as the addition of these ingredients is clearly stated on the label and explained in the labeling.

The legislative history of the 1990 amendments makes clear that Congress intended that consumers should be able to use nutrient content claims made for butter to assist them in following dietary guidelines (see H. Rept. 101–538, 101st Cong., 2d sess. 10, 23 (1990)). This intent has two necessary implications. First, Congress obviously intended that FDA adopt provisions that authorize that butter products that bear nutrient content claims be marketed. This intent is reflected in section 3(b)(1)(A)(viii) of the 1990 amendments.

Secondly, it is not enough to merely allow such products on the market. If these products are to be used to accomplish the purpose envisioned by Congress, they must have consumer acceptance, and they must be available for the full range of uses for which people use butter. If not, the products will quickly disappear from the market, or the uses of these products will be so limited as to have little dietary significance.

In light of these factors and of the comments that the agency received, FDA has reconsidered the proposal and concludes that it took too narrow an approach to defining the products that can appropriately include the term "butter" in their names. The comments have demonstrated that there are instances in which the minor addition of safe and suitable nondairy ingredients is necessary to reduce the fat and calories in butter products while maintaining the characteristics of butter, thereby increasing the products' consumer acceptability.

The agency notes that the use of nondairy ingredients in a dairy product like butter is not unprecedented, does not change its character, and, thus, would not mislead consumers. FDA has reviewed the dairy standards of identity in parts 131, 133, and 135 (21 CFR parts 131, 133, and 135) to determine what nondairy ingredients may be optionally added to dairy products. A number of the dairy standards provide for the use of ingredients such as flavors, emulsifiers, and stabilizers (e.g., lowfat dry milk (§ 131.123), evaporated milk (§ 131.130), skim milk (§ 131.143), and heavy cream (§ 131.150)). The standard of identity for sour cream (§ 131.160) provides for the optional use of safe and suitable ingredients that improve texture, prevent syneresis, or extend the shelf life of the product. The standard for sour cream also provides for the optional use of fruit and fruit juice and safe and suitable natural and artificial food flavoring as flavoring ingredients. Therefore, safe and suitable nondairy ingredients are already added to many types of dairy products to improve texture, add flavor, prevent syneresis, and extend shelf life, and these products remain dairy products. If these nondairy ingredients are useful in dairy products standardized in parts 131, 133, and 135, FDA believes that they may be useful in butter products.

FDA disagrees with the comment that urged FDA to allow the use of safe and suitable ingredients without restriction. The agency concludes that butter products should contain minor amounts of safe and suitable nondairy ingredients only when necessary to achieve the functions of ingredients or components of ingredients that are no longer present in the mandated quantities. As required in new § 101.67(b), the performance characteristics (e.g., physical properties, organoleptic characteristics, functional properties, and shelf life) of the butter product must be similar to those of butter. Safe and suitable ingredients added only as necessary to butter products to improve texture, add flavor, prevent syneresis, and extend shelf life will compensate for many deficiencies in performance characteristics.

The agency disagrees that it should permit safe and suitable ingredients in butter products to be consistent with the general standard in all cases. As explained in the proposal (56 FR 60523 at 60524 and 60525) and in a document entitled "Foods Standards: Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term" (hereinafter referred to as the general standard final rule) published elsewhere in this issue of the **Federal Register**, the legal and policy analysis of butter is different from foods standardized by regulation. Therefore, butter products are not included in § 130.10 foods but are regulated separately.

However, in § 130.10(d)(1), FDA provides for the use of safe and suitable ingredients in modified standardized foods to improve texture, add flavor, prevent syneresis, extend shelf life, improve appearance, or add sweetness so that the product is not inferior in performance characteristics to the traditional standardized food. FDA believes that the additional purposes (i.e., to improve appearance and add sweetness) for adding safe and suitable ingredients to modified foods also has application to butter products. Butter products with significantly less fat may appear more translucent than butter. Thus, ingredients to improve appearance are necessary to ensure that the product is not inferior in performance characteristics. Additionally, butter products may lack the sweetness of unsalted, sweet cream butter. Thus, ingredients to add sweetness may also be necessary to ensure that the product is not inferior in organoleptic characteristics.

Thus, FDA concludes that it is reasonable to provide for the use of safe and suitable ingredients because such use would enhance manufacturers' ability to produce butter products that perform as consumers expect. However, butter products must be made from cream or milk, or their constituents, with only those safe and suitable ingredients added as necessary to improve texture, add flavor, prevent syneresis, improve shelf life, improve appearance, and add sweetness. FDA emphasizes that butter products in compliance with new § 101.67 are dairy products, and that any addition of safe and suitable nondairy ingredients must be only in minor amounts. The addition of safe and suitable nondairy ingredients to butter products labeled under § 101.67 in excess of that which is reasonably required to achieve the performance characteristics of butter produced under 21 U.S.C. 321a constitutes deception and will be deemed to adulterate the food under section 402(b) of the act in that these ingredients are substituting for a valuable constituent. Therefore, FDA is including in new § 101.67(b) a requirement that deviations from ingredient provisions of 21 U.S.C. 321a must be the minimum necessary to achieve this effect, or the food will be deemed to be adulterated under section 402(b) of the act. The agency advises that products with nondairy ingredients in excess of these amounts fall outside of new § 101.67 and must be labeled as imitation butter if nutritionally inferior to regular butter, as butter alternatives or substitutes if not nutritionally

inferior to butter, or, if appropriate, as margarine, a margarine product, or a spread.

The agency also concludes that butter products labeled according to applicable regulations will not decrease the significance associated with the term "butter." The addition of safe and suitable ingredients must be declared in the ingredient statement as required in § 101.67(c).

FDA advises that if flavors are added to a butter product, the label must comply with § 101.22. According to § 101.22(i), if the label, labeling, or advertising of a food makes any direct or indirect representations with respect to the primary recognizable flavor, by word, vignette, or other means, or if for any other reason the manufacturer or distributor of a food wishes to designate the type of flavor in the food other than through the statement of ingredients, such flavor is considered to be the characterizing flavor. If the food contains any artificial flavor that simulates, resembles, or reinforces the characterizing flavor, under § 101.22(i), the name of the food on the principal display panel or panels of the label must be accompanied by the common or usual name of the characterizing flavor, in letters not less than one-half the height of the letters used in the name of the food. In addition, the name of the characterizing flavor must be accompanied by the word or words "artificial" or "artificially flavored," in letters not less than one-half the height of the letters in the name of the characterizing flavor.

(2) Water

8. A few comments opposed the addition of water to butter products. One comment maintained that water is not an ingredient traditionally added to butter. It stated that with current technology, the addition of water is not needed to produce a reduced fat butter, and, therefore, the addition of water to butter products should not be permitted. Another comment stated that added water would constitute a deviation from the butter standard and is not required to make an acceptable reduced fat butter product.

A number of comments stated that FDA should allow food manufacturers to add water to replace milkfat and reduce the caloric content of the product. Comments stated that water should be allowed if needed to yield an acceptable "butter" product. They stated that this might allow the development of additional products with lower saturated fat, total fat, and cholesterol. Two comments stated that the addition of water would be appropriate as long as it is clearly stated on the food label.

FDA acknowledges that the addition of water is not provided for in the statutory standard for butter, but the agency has decided to permit butter products to include ingredients that are not included in the statutory standard so that consumers may purchase such products with the characteristics of butter. There is consumer demand for products that have a significant reduction in fat and calories. Water is an ingredient that can be used to produce such a reduction as a replacement for milkfat in butter products. Although FDA agrees that with current technology, the addition of water may not always be needed to produce a reduced fat butter, the consumer may benefit from the increased reduction in saturated fat, total fat, cholesterol, and calories that can be accomplished through the addition of water. Thus, the addition of water will provide more flexibility in the formulation of butter products that may have an improved nutrition profile and may perform better than butter products formulated without any water. Therefore, FDA concludes that water may be added to butter products to replace milkfat.

Water can be added to replace milkfat in butter products in potentially very large amounts. In fact, none of the comments supporting the use of water to replace milkfat suggested any maximum level. However, to preserve the food's identity as a dairy product, the amount of water added may not exceed the amount of milk or cream ingredients. Therefore, FDA is providing in new § 101.67(a)(2) that the product may contain water to replace milkfat, although the amount of water added must be less than the amount of cream, milk, or milk constituents in the product.

The addition of water must be declared in the ingredient statement as required in § 101.67(c).

E. Minimum Dairy Ingredient Requirement

9. One comment recommended that a minimum percentage by weight of dairy ingredients (milk and its natural constituent components) be required in order to use the name "butter." The comment stated that without a minimum dairy ingredient requirement, the distinction between butter and margarine essentially vanishes. However, the comment did not recommend a specific level.

The agency disagrees with the comment. As discussed above, new § 101.67(a)(2) requires that the major ingredients in butter products be milk, cream, and derivatives of milk and cream. Because these ingredients are not generally used, or are used only in small amounts, in margarine, the distinction between the two products will be maintained. Therefore, FDA concludes that the requirement in new § 101.67(a)(2) is adequate, and that there is no need to specifically establish a minimum dairy ingredient level for butter products.

F. Nutritional Inferiority

10. One comment stated that the proposed regulation lacked specificity as to what is necessary to satisfy the requirement that the product not be nutritionally inferior. It stated that the standard for margarine (§ 166.110 (21 CFR 166.110)) specifies the required amount of vitamin A (15,000 International Units (IU) per pound) and an optional level of vitamin D (1,500 IU per pound).

The agency acknowledges that the standard for margarine designates the amount of vitamin A that must be added to margarine (§ 166.110(a)(3)) and the amount of vitamin D that may optionally be added to margarine (§ 166.100(b)). However, FDA disagrees that proposed § 101.67 lacks specificity concerning nutritional inferiority. Under proposed § 101.67(a)(3), the butter product must not be nutritionally inferior, as defined in § 101.3(e)(4), to standardized butter. This general requirement is adequate because § 101.3(e)(4) sets very specific requirements defining nutritional inferiority. The agency concludes that new § 101.67 need not specify required amounts of essential nutrients that must be added to butter products, and that no change is necessary in new § 101.67. The agency notes that general points for comparison of the nutrient values of the traditional standardized product can be found in a current valid composite data base.

G. Labeling Concerning Performance Characteristics

11. One comment recommended that the label statement be mandatory only for differences in performance characteristics that materially limit the uses of the butter product compared to the traditional standardized food that it resembles. It stated that market forces will encourage manufacturers to inform consumers about positive differences, and that consumers who select a product for its reformulated nutrient content will not be misled if they are not told about a positive change that the manufacturer believes is not sufficiently important to highlight on the product label. The comment noted that FDA

would not object if the label did not alert consumers to a minor improvement in a performance characteristic that consumers consider to be relatively unimportant for that food. In addition, the comment stated, a product may have several differences in performance characteristics, and several label statements could be confusing to consumers. The comment recommended that FDA modify proposed § 101.67(b) by limiting the labeling requirement to adverse changes that materially affect the use of the product.

The agency has been persuaded by these comments. FDA agrees that there are differences in performance characteristics that consumers may not consider important. In addition, unnecessary label statements may be confusing to consumers and may detract from other important information on the label.

Therefore, the agency is modifying new § 101.67(b) to state that:

> * * * If there is a significant difference in performance characteristics that materially limits the uses of the product compared to butter, the label shall include a statement informing the consumer of such difference (e.g., if appropriate, "not recommended for baking purposes").

12. One comment noted that there is an apparent conflict in the agency's proposed requirements for the location of the disclosure of differences in performance characteristics. It stated that proposed § 101.67(b) provides that such statement must appear on the principal display panel within the bottom 30 percent of the area of the label panel; proposed § 101.67(a)(1) requires that a nutrient content claim for a butter product comply with proposed § 101.13; and proposed § 101.13(d)(1) states that if there is a difference in performance characteristics, the food may still be considered a substitute if the label includes a disclaimer adjacent to the most prominent claim. The comment requested that the final versions of proposed §§ 101.67(b) and 101.13(d)(1) be consistent. It stated that a disclosure in the bottom 30 percent of the principal display panel could easily be as prominent as, or more prominent than, a disclosure that immediately follows disclosures about the nature of the product and the reference statement. The comment stated that it is in the interest of consumers that the required disclosure of differences in performance characteristics be located in the bottom 30 percent of the principal display panel, as provided in proposed § 101.67(b). Another comment requested that FDA allow any statements concerning differences in performance characteristics to appear on any panel of the label of the product.

Under section 403(f) of the act, FDA believes that the statement informing consumers of differences in performance characteristics must appear on the label with such conspicuousness and in such terms as to render it likely to be read and understood by the consumer under customary conditions of purchase and use. The agency concludes that the statement must appear in the same area of the label as the statement of identity for the butter product so that consumers will know where to find such information. Moreover, because the statement is a material fact that helps to describe the differences between the modified food and the traditional food, it must appear in close proximity to the statement of identity. See, e.g., *United States* v. *An Article of Food * * * "Manischewitz * * * Diet Thins,"* 377 F. supp. 746, 749 (E.D. N.Y. 1974).

FDA recognizes that it inadvertently proposed in § 101.67 to require statements informing consumers of differences in performance characteristics to appear in possibly two separate locations on the label. The agency acknowledges that one statement is sufficient to inform consumers. To be consistent with the labeling of other foods, the agency concludes that the statement concerning differences in performance characteristics must appear on the label in compliance with the requirements of § 101.13(d)(1). Thus, the agency has modified new § 101.67(b) to state that the statement explaining differences in performance characteristics must appear on the label in compliance with the requirements of § 101.13(d).

13. Some comments suggested that, in order to use nutrient content claims for butter, the product must perform at least one of the principal functions of regular butter substantially as well as butter produced under section 201a of the act. Consumers can then choose to purchase the product instead of regular butter for use in that function.

FDA agrees that at a minimum, a butter product must perform at least one of the principal functions of butter substantially as well as butter as produced under 21 U.S.C. 321a. Consumers should be able to count on using a butter product in the same manner in which they use regular butter for, at the very least, one of its principal functions. To achieve this objective, FDA is requiring in § 101.67(b) that butter products must resemble butter as produced under section 201a of the act, and that differences in the performance characteristics must be clearly stated on the principal display panel of the label. In addition, the agency is adding a statement to new § 101.67(b) to require that "the modified product must perform as least one of the principal functions of butter substantially as well as butter as produced under 21 U.S.C. 321a." FDA believes that this action is necessary to ensure the minimum necessary similarity between the modified and traditional products.

H. Other Labeling

14. One comment stated that products made with nondairy ingredients should be labeled, with appropriate prominence on the principal display panel of the label, "contains nondairy ingredients."

FDA does not agree that it should require this statement on the principal display panel of the label. The agency is requiring that the major ingredients in butter products be cream, milk, or derivatives of cream or milk and is only providing for minor additions of safe and suitable ingredients (e.g., nondairy ingredients) as necessary, so that the butter product has the same characteristics as butter. Although the agency is providing for the addition of water to replace milkfat, it must not be the predominant ingredient in the product. In addition, FDA points out that new § 101.67(c)(1) requires that each of the ingredients added to the product be listed in the ingredient statement, as required by the applicable sections of part 101.

However, to further assist the consumer in differentiating between regular butter and butter products with nontraditional ingredients added, FDA is establishing a requirement in new § 101.67(c)(2) that all safe and suitable ingredients added to improve texture, prevent syneresis, add flavor, extend shelf life, improve appearance, and add sweetness and water added to replace milkfat must be appropriately identified with an asterisk in the ingredient statement. The statement "*Ingredients not in regular butter" must immediately follow the ingredient statement in the same type size. FDA is requiring similar labeling for modified standardized foods in new § 130.10, as explained in the general standard final rule.

FDA believes, however, that consumers may be misled to believe that ingredients added to restore nutrients are present in greater amounts than needed to obtain nutritional equivalency if these nutrients are identified with an asterisk in the ingredient statement. In addition, because butter has historically been a cultured product, the addition of safe and suitable bacterial cultures does not

require identification with an asterisk. Therefore, the agency is not requiring that nutrients added to restore nutrients or added safe and suitable bacterial cultures be identified by an asterisk in the ingredient statement.

15. One comment stated that the percentage of water in light butter products should be declared on the label.

FDA disagrees with the comment. As discussed above in comment 8, cream, milk, and milk constituents will be the predominant ingredients in butter products. Any water added to butter products may not be present in an amount greater than the amount of the dairy ingredients. According to § 101.4(a), all ingredients, including water, must be listed by common or usual name in descending order of predominance by weight on the label. In addition, new § 101.67(c)(2) requires that water that is added to replace milkfat must be identified with an asterisk in the ingredient statement, followed by a statement explaining that the ingredient is not in regular butter. Therefore, FDA concludes that listing water as an ingredient in this manner is adequate, and percentage labeling is not necessary.

16. One comment stated that in addition to the comparative statements allowed to appear on the label of a butter product, the label for such a product should also include a clear statement of the identity and percentage of characterizing fat or oil, for example: "Reduced Fat Butter—40% Milkfat." It stated that such a prominent statement will allow consumers to easily and readily discern the nature of the food and, thus, facilitate comparisons with other table spreads, both dairy based and vegetable based.

The agency disagrees that the additional labeling is necessary. The provisions in § 101.56(b)(3) and § 101.62(b)(4)(ii) for use of the terms "light" and "reduced fat" require that the percent reduction in fat and the identity of the reference food be declared in immediate proximity to the most prominent claim and that quantitative information comparing the fat content in the product per serving size with that of the reference food be declared adjacent to the most prominent claim or on the information panel. Under § 101.9(a), nutrition information must be provided for all butter, margarine, and substitute products. The serving size for butter, margarine, and their substitutes is one tablespoon (§ 101.12(b)). The nutrition labeling must provide information on a food product's nutrition profile, including total fat, saturated fat, and cholesterol (§ 101.9(c)(12)). In addition, information on unsaturated fat may be included in the nutrition information. The only fat ingredient permitted in butter products is milkfat, and the ingredient statement will reflect this requirement. Consumers may use this information to compare the amount of fat in butter products and margarine products. Therefore, FDA concludes that there is adequate information to inform consumers concerning the fat content of a product already required to be present on the label without requiring the additional labeling requested by the comment. However, the agency will not object if manufacturers include additional labeling to state the percentage and type of fat in the product, provided that the information is not false or misleading.

17. One comment opposed the proposed rule on the grounds that people with food sensitivities will be placed at greater risk because of difficulties of knowing what is in a product.

Section 403(i) of the act requires that all ingredients used in a food be included in the ingredient statement. Consistent with the provisions of section 403(i) of the act, FDA is including a provision in § 101.67(c)(1) that each of the ingredients used in the food must be declared on the label, as required by part 101. This requirement will ensure that consumers that have food sensitivities are informed of the presence of ingredients to which they may have allergies.

III. Conclusion

In response to comments submitted regarding the proposal for use of nutrient content claims for butter (56 FR 60523), FDA has modified proposed § 101.67. The following summarizes the changes being made to proposed § 101.67 by this final rule:

FDA has modified § 101.67(a)(2) to provide for the use of safe and suitable ingredients to improve texture, prevent syneresis, add flavor, extend shelf life, improve appearance, and add sweetness. FDA also has modified this paragraph to provide for the addition of water to replace milkfat, although the amount of water in the product must be less than the amount of cream, milk, or milk constituents.

FDA has added new § 101.67(a)(4) to require that if the product would violate section 201a of the act but for the nutrient content claim that characterizes the level of nutrients, that claim must be included as part of the common or usual name of the product.

FDA has added a statement to new § 101.67(b) to require that deviations from ingredient provisions of 21 U.S.C. 321a must be the minimum necessary to achieve similar performance characteristics as butter as produced under 21 U.S.C. 321a, or the food will be deemed to be adulterated under section 402(b) of the act.

The agency has modified § 101.67(b) by limiting the labeling requirement to changes that materially affect the use of the product.

FDA has revised § 101.67(b) to require that the mandated label statement concerning any differences in performance characteristics be in accordance with the requirements of § 101.13(d).

The agency has added a statement to new § 101.67(b) to require that the product must perform at least one of the principal functions of butter substantially as well as butter as produced under 21 U.S.C. 321a.

In new § 101.67, paragraph (c) has been redesignated as paragraph (c)(1) and new paragraph (c)(2) has been added to require that water and safe and suitable ingredients added to improve texture, prevent syneresis, add flavor, extend shelf life, improve appearance, or add sweetness shall be identified with an asterisk in the ingredient statement. The statement "*Ingredients not in regular butter" shall immediately follow the ingredient statement in the same type size.

IV. Environmental Impact

The agency previously considered the environmental effects of the action being taken in this final rule. As announced in the reproposed rule for mandatory nutrition labeling (56 FR 60366, November 27, 1991) and the proposed rule for nutrient claims (56 FR 60421, November 27, 1991), the agency determined that under 21 CFR 25.24(a)(8) and (a)(11), these actions are of a type that do not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

Several comments on the proposed rule suggested that there would be significant adverse environmental effects from the final rules unless the agency allowed more time between the publication of the final rules and their effective dates. The concern in these comments was that, if the agency did not allow firms more time between the publication of the final rules and their effective dates to use up existing label inventories, large stocks of labels and labeled packaging would have to be discarded. These comments questioned whether the agency had sufficiently examined the impact of disposing of

obsolete labels and labeled packaging on this country's solid waste disposal capabilities. Two comments estimated the amounts of labeling from their respective industries, i.e., dairy and confectionery, that would need to be discarded following publication of FDA's final rules on several food labeling actions, including this action. However, these comments did not: (1) Provide details on how these estimates were derived, (2) identify what portion of the estimated amounts are attributable to these two actions, or (3) describe what impact the discarded labels and packaging would have on the disposal of solid waste. In its November 27, 1991, reproposed rule for mandatory nutrition labeling and proposed rule for nutrient content claims, the agency proposed that the final rules for these actions would become effective 6 months following their publication in the **Federal Register**.

However, the agency has decided to not make this rule effective until May 8, 1994. FDA believes there will thus be ample time for food companies to use up most of the existing labeling and packaging stocks and to incorporate labeling language that complies with FDA's regulations into their food labels. Consequently, the comments on the potential for adverse environmental effects do not affect the agency's previous determination that no significant impact on the human environment is expected and that an environmental impact statement is not required.

V. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), along with the food labeling proposals, and the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.67 is added to subpart D to read as follows:

§ 101.67 Use of nutrient content claims for butter.

(a) Claims may be made to characterize the level of nutrients, including fat, in butter if:

(1) The claim complies with the requirements of § 101.13 and with the requirements of the regulations in this subpart that define the particular nutrient content claim that is used and how it is to be presented. In determining whether a claim is appropriate, the calculation of the percent fat reduction in milkfat shall be based on the 80 percent milkfat requirement provided by the statutory standard for butter (21 U.S.C. 321a);

(2) The product contains cream or milk, including milk constituents (including, but not limited to, whey, casein, modified whey, and salts of casein), or both, with or without added salt, with or without safe and suitable colorings, with or without nutrients added to comply with paragraph (a)(3) of this section, and with or without safe and suitable bacterial cultures. The product may contain safe and suitable ingredients to improve texture, prevent syneresis, add flavor, extend shelf life, improve appearance, and add sweetness. The product may contain water to replace milkfat although the amount of water in the product shall be less than the amount of cream, milk, or milk constituents;

(3) The product is not nutritionally inferior, as defined in § 101.3(e)(4), to butter as produced under 21 U.S.C. 321a; and

(4) If the product would violate 21 U.S.C. 321a but for the nutrient content claim that characterizes the level of nutrients, that claim shall be an explicit claim that is included as part of the common or usual name of the product.

(b) Deviations from the ingredient provisions of 21 U.S.C. 321a must be the minimum necessary to achieve similar performance characteristics as butter as produced under 21 U.S.C. 321a, or the food will be deemed to be adulterated under section 402(b) of the act. The performance characteristics (e.g., physical properties, organoleptic characteristics, functional properties, shelf life) of the product shall be similar to butter as produced under 21 U.S.C. 321a. If there is a significant difference in performance characteristics (that materially limits the uses of the product compared to butter,) the label shall include a statement informing the consumer of such difference (e.g., if appropriate, "not recommended for baking purposes"). Such statement shall comply with the requirements of § 101.13(d). The modified product shall perform at least one of the principal functions of butter substantially as well as butter as produced under 21 U.S.C. 321a.

(c)(1) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of this part.

(2) Safe and suitable ingredients added to improve texture, prevent syneresis, add flavor, extend shelf life, improve appearance, or add sweetness and water added to replace milkfat shall be identified with an asterisk in the ingredient statement. The statement "*Ingredients not in regular butter" shall immediately follow the ingredient statement in the same type size.

Dated: October 20, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 100

[Docket No. 91N-0343]

RIN 0905-AD08

State Enforcement Provisions of The Nutrition Labeling and Education Act of 1990

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to implement section 4 of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). This section provides for State enforcement of certain requirements of the Federal Food, Drug, and Cosmetic Act (the act), so long as the State gives FDA 30 days notice of its intent to act, and certain other conditions apply. The agency is adopting regulations that will provide the States with instructions on how to give the requisite 30-day notice. FDA has framed these instructions to ensure that this notification system functions efficiently. The final rule also describes relevant State and Federal obligations.

EFFECTIVE DATE: February 5, 1993.

FOR FURTHER INFORMATION CONTACT: Janice F. Oliver, Center for Food Safety and Applied Nutrition (HFS-600), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4187.

SUPPLEMENTARY INFORMATION:

I. Background

In response to the requirements of the 1990 amendments (Pub. L. 101-535), FDA published in the **Federal Register** of November 27, 1991 (56 FR 60534), a proposal to implement section 4 of those amendments. Section 4 amended section 307 of the act (21 U.S.C. 337) to provide for State enforcement of certain requirements of the act, so long as the State provides 30 days notice of its intent to act, and certain other conditions apply. The agency proposed to adopt regulations that would provide the States with instructions on how to give the requisite 30-day notice and to describe relevant State and Federal obligations. Interested persons were given until February 25, 1992, to comment.

FDA received approximately 24 responses to this proposal, each containing one or more comments, from trade associations, government organizations, individual States, food manufacturers, consumers, and consumer groups. The comments generally supported the proposal. Several comments addressed issues outside the scope of the proposal (e.g., delaying implementation of the regulations and delaying enforcement of the regulations) that will not be discussed here. A number of comments disagreed with various aspects of the proposal. These comments suggested modification and revision of various provisions of the proposal. A summary of these comments and the comments' suggested changes, along with the agency's responses, follows.

II. State Enforcement Provisions of the 1990 Amendments

A. Informal Enforcement Actions

In proposed § 100.2(j), FDA defined "informal enforcement actions," a term that is used in section 307(b)(2)(B) and (C) of the act, and defined in the agency's proposed implementing regulations, to include warning letters, recalls, and detentions as well as other administrative actions.

1. One comment suggested that FDA remove detentions as a type of informal enforcement action because FDA has no detention authority for foods.

The use of the word "detentions" in the proposal refers to detentions of imports under the provisions of section 801 of the act (21 U.S.C. 381) and detentions authorized under the provisions of the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA). The agency is authorized to detain imported food products if it appears that the products have been manufactured, processed, or packaged under insanitary conditions, or that the products are adulterated or misbranded, under the act. The agency also is authorized to detain meat, poultry, and egg products if they are found outside a plant inspected by the U.S. Department of Agriculture, and the agency has reason to believe that the products are adulterated or misbranded, under 21 U.S.C. 467f(b), 679(b), and 1052(d). Import detentions and detentions under the FMIA, PPIA, and EPIA are all administrative enforcement actions, and, therefore, informal actions under proposed § 100.2(i)(1). Consequently, the agency concludes that no change in the regulation in response to this comment is necessary.

2. Another comment suggested that FDA remove warning letters as a type of informal enforcement action. This comment stated that the agency often issues warning letters when no further action is planned by FDA, and that no response stating that corrections have been made is required from the recipient.

FDA disagrees with this comment. Warning letters are used by the agency to notify a firm that it is not in compliance with the act or with agency regulations, that failure to correct these violations may result in formal enforcement actions by FDA, and that a reply with a full statement of all corrections that have been or will be made is required within 10 days. A study of warning letters by FDA revealed that approximately 93 percent of the warning letters issued by FDA elicit a response from the recipient. Because of these facts, FDA continues to believe that it is appropriate to include warning letters as a type of informal enforcement action in the final rule. If the firm does not respond to the warning letter within the time provided in the warning letter, and the agency does not take any further action, the State will be free to act after 90 days under section 307(b)(2)(B) of the act.

3. Two comments suggested that adverse publicity be included as a type of informal enforcement action because FDA has the authority to issue publicity under section 705 of the act (21 U.S.C. 375). The agency acknowledges that it has the authority to issue publicity under section 705 of the act. The authority is conferred to the agency in situations involving imminent danger to health or gross deception of the consumer. However, the agency does not believe that it is necessary to specifically list publicity as a type of informal enforcement action in the final rule below. This type of action is included among the "other administrative enforcement actions" that are listed in proposed § 100.2(j)(1).

4. Several comments expressed concern that informal enforcement actions taken by FDA will preclude formal enforcement actions that could be taken by the State. One of these comments said there was no indication in the 1990 amendments that Congress intended the States to be preempted by anything other than formal action by FDA. Several comments wanted FDA to clarify that State and local enforcement mechanisms remain unaffected by the 1990 amendments.

Section 307(b)(2)(C) of the act states that no proceedings for the civil enforcement, or to restrain violations, of certain enumerated sections of the act may be commenced by a State if FDA has settled an informal or formal enforcement action against that food. Thus, contrary to what at least one

comment asserted, State action can be precluded by informal FDA action. Section 307 of the act, however, only applies to actions by a State to enforce certain sections of the act. Nothing in this section would preclude a State from taking action against a particular food under its own State law, even if FDA has commenced or settled an enforcement action against that food.

B. State Intervention in Criminal Proceedings

5. Several comments expressed concern that proposed § 100.2 would permit States to intervene as a matter of right in Federal criminal proceedings. The comments stated that no criminal authority was conferred upon the States by section 307(b)(1) of the act.

In response to these comments, FDA reconsidered whether to include criminal proceedings among the formal enforcement actions listed in proposed § 100.2(j)(2). While section 307(b) of the act is not clear on its face as to whether a pending criminal proceeding would, under section 307(b)(2)(B) or (C) of the act, preclude State action, there is nothing in the act to require the agency to hold that it would.

Therefore, FDA has decided to reverse the position that it tentatively took in the proposal. FDA is striking criminal actions from the list of formal enforcement actions in proposed § 100.2(j). FDA is revising this section to include only civil judicial enforcement action. As a result, § 100.2(j)(2) is coextensive with section 307(b)(1) of the act. A second result of this change will be that a pending Federal criminal action that arises out of a misbranding under the sections listed in section 307(b)(1) of the act will not serve to preclude a State from bringing a civil action under the act in Federal court against the underlying misbranding.

C. Agency Action Barring State Action Against Food in Federal Court

6. Several comments discussed the agency's statement that an agency action anywhere in the United States against the food in question would, under section 307(b)(2) of the act, bar a State action against the same food in Federal court. The majority of the comments agreed with this statement. One of the comments said that this preclusive effect should not be limited to FDA actions. This comment said that an action by a State to enforce the Federal law against a food within its jurisdiction precludes a second enforcement proceeding by another State or by FDA against the same food. The comment also said that if the States can enforce identical State regulations in the State courts, such actions should preclude an FDA action in the same State. Another comment, objecting to the agency's interpretation of the preemptive provisions of the 1990 amendments, argued that a State's action should be preempted only in cases where the FDA action will result in the discontinuation of the illegal practice in that State and in the nation. Finally, one comment requested that FDA revise proposed § 100.2 to provide that if the agency, upon notification by the State under section 307(b)(2) of the act, advises a State not to proceed, that State may not thereafter independently initiate enforcement proceedings based upon the same violations in State court under an identical State law.

The agency agrees in part with these comments. The enforcement actions available to the States under the provisions of section 307 of the act are seizure and injunction. The agency agrees that if FDA or a State brought a seizure action against a particular misbranding violation, the action would have a preclusive effect on another State or FDA. Section 304 of the act prohibits multiple seizures based on the same alleged misbranding of food. In light of the changes in section 307 of the act, who brings the first action, whether it is FDA or a State, would not be significant for the purposes of section 304 of the act. The first action filed would preclude any others.

In the case of an injunction, however, there is nothing in the act that limits the number of such actions that can be brought. Therefore, while an FDA injunction action would preclude State enforcement actions under the act for at least 90 days under section 307(b)(2), such action by a State would have no effect on FDA's or another State's ability to bring an action. However, the agency also notes that particularly in this time of limited government resources, it is highly unlikely that any jurisdiction would bring a duplicative injunction action.

The agency does not agree that a State action to enforce a State law that is identical to the act against food in its own jurisdiction precludes an FDA action based on the same violation. Section 307 of the act applies only to proceedings to enforce the act. State law cannot act to preempt Federal law or to preclude Federal action. Conversely, the act does not give FDA the authority to preclude a State from enforcing an identical State law. If FDA advises a State that the agency is commencing or has settled an enforcement action or proceeding, then the State is precluded from bringing an action under the act in Federal court. The act does not prohibit a State from enforcing an identical State law. Nonetheless, FDA intends to work with the States to attempt to ensure that State provisions that are identical to provisions in the act are interpreted by the States in a way that is as consistent as possible with FDA's interpretation of the Federal provisions.

D. State Notification Letter

7. Several comments wanted States to provide FDA with evidence supporting the proposed action. The comments said that FDA should require the same evidence from a State that it requires from one of its district offices when reviewing proposed enforcement actions. These comments also wanted a State to inform FDA of the type of enforcement action that it expects to bring. On the other hand, one comment said that FDA was requiring too much information from States, and that the information that FDA is seeking may not be available at the beginning of an investigation. The comment stated that the 1990 amendments only require that a State give notice to FDA that it intends to bring an action, and that the detailed information being asked for by FDA would needlessly delay State enforcement action where an FDA action may not even be contemplated.

FDA stated in the preamble to the proposed regulation that it wanted the States to inform it of the type of action that they planned to take (56 FR 60534 at 60535). FDA included this provision as part of a parenthetical statement in the proposed format in § 100.2(d) (i.e., "name of products covered by the notification and the enforcement action that is to be initiated"). In view of the comments, and to eliminate any possible confusion, the agency is revising proposed § 100.2(d) to include in the format for the State's notification specific provision under item I., "Type of Enforcement Action," for the State to inform FDA of the type of action it is planning to take.

The agency disagrees with the suggestion that it require more specific information as part of the State notification, including a description of the evidence that the State is relying on to support its action. The agency considered the need for States to submit evidence to support the proposed action. However, the factors that FDA will consider in reviewing State notices of their intent to enforce certain sections of the act bear on different concerns than those that the agency considers in reviewing a recommendation from a district office.

When a district recommendation for an enforcement action is reviewed within the agency, there is a great deal

of concern about the merits of the case. A decision must be made as to whether to commit the agency's resources to prosecuting it. In reviewing a State notice of intent, FDA is not responding to the merits or strengths of the State's proposed action. The agency is only trying to determine whether FDA has taken, is taking, or, in the near future, is likely to take action. The States may proceed if FDA has not commenced or settled an action. It is up to the courts to decide the merits of the State's case. The information that the agency is asking a State to submit as part of its notification is the information that is necessary to ensure that the State and FDA are not duplicating efforts. Thus, FDA rejects the suggestion that it require the same information from a State as from its district offices.

The agency also disagrees with the request that the agency limit the information necessary in a notice. The comment suggested that the notice should be limited to only the names of the State and of the official giving notice, the name of the product involved, a copy of the label involved, when appropriate, and the alleged violation of the act. Although the 1990 amendments only require that the State give notice to the agency that it intends to bring an action, the information that the agency is asking the State to include in the notification letter is the information that is necessary if the agency is to provide a timely response to the State's notice.

The purpose of section 4 of the 1990 amendments is to provide a role for State enforcement of Federal statutory provisions that have preemptive effect. (See 136 Congressional Record H5840 (July 30, 1990)). However, such a role requires close coordination between State and Federal officials. The agency believes that it is requesting the minimum amount of information that is necessary to ensure that such close coordination exists. As mentioned above, the types of action that are available to the States for the enforcement of the act under the provisions of section 307 of the act are seizure and injunction. The agency would expect that a State would normally have the information requested in proposed § 100.2(d) before it could initiate these types of actions. Thus, the agency does not believe that compiling the information that it is requesting in proposed § 100.2 will delay State action.

However, the agency has reconsidered the provisions for the State notice in light of this comment and has determined that format items E and F are redundant. Moreover, the agency recognizes that there may be situations, such as in the case of a seizure of misbranded food, where the identity of the responsible firm cannot be readily determined. Thus, the agency is modifying the format for the notice by deleting item F and revising item E to read "Name and Address of firm believed to be responsible for violations."

E. Response to State Notification Letter

8. Several comments disagreed with proposed § 100.2(h) that provided that the Director of the Division of Regulatory Guidance in the Office of Compliance at the Center for Food Safety and Applied Nutrition, FDA, will respond to the State notification letter. The comments suggested that the agency follow its existing procedures for formal enforcement actions under which such actions are taken with the concurrence of the Director of the Office of Compliance and the Chief Counsel along with review by the Office of Enforcement.

The agency disagrees with these comments. These comments do not correctly characterize the action that occurs as a result of the submission of a State notification. FDA's response to such a letter simply informs the State of action that FDA has taken or is taking, and it is not an evaluation of the merits of the State's case. The Division of Regulatory Guidance is the central focus within FDA for all enforcement actions regarding food. Thus, the agency concludes that it is appropriate that this division be given authority to inform a State whether Federal action is being taken concerning a particular product or firm.

9. Several comments stated that the relationship between the State and FDA once the State notification letter is submitted is not well understood.

Once a State has notified the agency of its intent to bring an action, FDA believes that it is incumbent on the agency to inform the State whether it (FDA) has commenced an informal or formal action pertaining to the food in question within 30 days of the State notification. FDA has reflected this obligation in proposed § 100.2(h). If FDA advises a State that the agency has commenced an informal or formal action, under section 307(b)(2)(B) of the act, the State must wait a total of 90 days before it can commence an action. FDA will also advise the State if the agency has not commenced an informal or formal action, in which case the State may proceed with its proposed action. FDA must either have an informal or formal action pending or begin such an action within 30 days of the State's initial notice, for the State to be precluded from taking the enforcement action. FDA will maintain communication with the State regarding the resolution of enforcement actions.

10. One comment requested that FDA clarify that once a State has begun an enforcement action against a particular product, "no new notice is required to add defendants to the State action where these defendants are involved in the same scheme or where these defendants are acting or participating with other defendants to sell the same product."

The question raised by the comment is too general for the agency to provide specific clarification. The agency notes that it would generally agree that the simple addition of a corporate officer as a defendant or of an additional lot of a product in an action addressing a specific violation of the act would not require a new notice. However, the extension of an action to include new corporate entities or differing products would likely require a new notice. The agency believes that proposed § 100.2(a) is sufficiently clear on this point that there is no need to revise the regulations.

F. Public Disclosure

11. One comment requested that FDA publicly disclose information contained in State notification letters, excluding trade secrets and confidential information. Several comments wanted public disclosure of information contained in FDA's response to State notification letters.

The agency believes that proposed § 100.2(i), regarding exemption from public disclosure of information in State notification letters, is appropriate. Section 20.61 of FDA's regulations (21 CFR 20.61) provides that trade secret and confidential commercial information is not available for public disclosure. Section 20.64 of FDA's regulations (21 CFR 20.64) provides that an investigatory record for law enforcement purposes may be withheld by the agency from public disclosure if disclosure of the record would interfere with enforcement proceedings and disclose investigative techniques and procedures. The State notification letter is an investigatory record in that it relates to a potential regulatory enforcement action. Such an investigatory record is available for public disclosure as provided in § 20.64(c) and (d).

Section 20.88 (21 CFR 20.88) provides that investigatory records compiled for law enforcement officials who perform counterpart functions to FDA at the State and local level are exempt from

public disclosure pursuant to § 20.64. The agency's response to a State notification letter is not available for public disclosure as provided by § § 20.64 and 20.88.

G. Preemption and Enforcement

12. Several comments expressed concern that a State could enforce a State law that is identical to a section of the act but have an interpretation of the law that is different from FDA's interpretation of the act.

FDA realizes that it is possible for State laws that are identical to Federal laws to be interpreted differently by the different States. As discussed above, the agency believes that close cooperation between FDA and the States will ensure that goals of uniformity are met while still addressing the concerns of the citizens of a State.

H. FDA's Authority to Interpret the Act

In the preamble to the proposed regulations the agency stated that to avoid any suggestion of an unconstitutional delegation to States to enforce the act, FDA retains full authority to advise States of what FDA believes is the proper interpretation of any of the sections of the act that they may seek to enforce. The agency stated that if FDA advises a State that its proposed action is inconsistent with FDA's interpretation, section 307 of the act requires that the State conform its interpretation to FDA's (56 FR 60534 at 60535 to 60536).

13. Several comments agreed, and one comment disagreed, with this agency statement. One comment wanted the final rule to add a new § 100.2(h)(3) that would require the agency to advise the States that the interpretation of the act that they seek to enforce is inconsistent with FDA's interpretation, that the labeling in question does not violate the act, and that they may not bring an enforcement proceeding. The comment that disagreed said that it is up to the courts to decide the ultimate meaning of the provisions of the act in disagreements between the States and FDA.

As stated above, FDA generally will not be issuing an interpretation to the State of the Federal requirements when it responds to a State notification letter. It will merely inform the State that the agency has commenced or settled an informal or formal enforcement action or is prosecuting or has settled a court proceeding, or has done none of these things. Therefore, the final rule does not need to include a section to require the agency to advise a State that its interpretation is inconsistent with FDA's. However, after consideration of the comments, the agency continues to believe that the position that it enunciated in the proposal is correct for the reasons that it presented (see 56 FR 60534 at 60535 to 60536). Therefore, FDA reserves the right to advise a State that its proposed action is inconsistent with FDA's interpretation of the act and will do so as circumstances warrant.

14. Several comments wanted the agency to ensure that a mechanism was available to provide the States with agency interpretations. These comments wanted FDA to impose time limits upon itself to issue interpretations.

Whenever a State would like an interpretation of the act, it may seek an advisory opinion under § 10.85 (21 CFR 10.85). FDA will respond to the request in a timely manner. The agency's Division of Federal-State Relations also will work closely with the States to ensure that FDA's interpretations of the act and the agency's regulations on food labeling are made available to the States. The State Training Branch of FDA's Office of Regulatory Affairs will conduct training classes for the States after implementation of the final regulations.

15. One comment recommended that the agency consider establishing an advisory panel of State and local officials to assist FDA in the development of interpretations.

FDA is charged by Congress to enforce requirements of the act. Therefore, FDA believes that as a general matter, it is its responsibility to interpret the act. However, the agency also recognizes the value of receiving input from State and local officials as well as others in the development of its interpretations. To this end the agency is establishing a Food Advisory Committee that will consider a broad range of questions concerning food (57 FR 8128, March 6, 1992). FDA will be including representatives from State and local governments on this committee. The agency notes that it utilizes a number of other approaches to ensure that it is aware of State and local government concerns, including participation in activities of the Association of Food and Drug Officials and regular contacts with the State through FDA's Division of Federal-State Relations. Thus, FDA does not believe that it is necessary to establish a separate standing advisory panel of State and local officials as a regular part of FDA's process of interpreting the act.

III. Conclusion

FDA is revising proposed § 100.2(d) in response to comments submitted regarding the proposal on the State enforcement provisions of the 1990 amendments (56 FR 60534). FDA has revised proposed § 100.2(d), regarding the State notification letter format, by modifying the format item E to read "E. Name and address of firm believed to be responsible for violations," deleting item F, renumbering items G, H, and I as F, G, and H, and including a new format item I to read "I. Type of enforcement action." FDA has also modified proposed § 100.2(j)(2) to read: "formal enforcement actions" include seizures, injunctions, or other civil judicial enforcement actions that pertain to the food in question." The agency has adopted the remainder of the provisions of § 100.2 as proposed with only minor editorial revisions because the agency did not receive any comments concerning them, or because, as discussed above, the comments that it did receive did not justify a change.

IV. Economic Impact

In its November 1991 proposal, FDA concluded that the proposed requirements did not constitute a major rule and that no significant impact on a substantial number of small entities, including small business, would derive from this action. FDA has not received any new information or comments on the proposal that would alter its previous determination.

V. Paperwork Reduction

Section 100.2 of this final rule contains notification requirements that were submitted for review and approval to the Director of the Office of Management and Budget (OMB), as required by section 3504(h) of the Paperwork Reduction Act of 1980. The requirements were approved and assigned OMB control number 0910–0275.

List of Subjects in 21 CFR Part 100

Administrative practice and procedure, Food labeling, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 100 is amended as follows:

PART 100—GENERAL

1. The authority citation for 21 CFR part 100 continues to read as follows:

Authority: Secs. 201, 301, 307, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 337, 342, 343, 348, 371).

2. Section 100.2 is added to subpart A to read as follows:

§ 100.2 State enforcement of Federal regulations.

(a) Under section 307 of the Federal Food, Drug, and Cosmetic Act (the act),

a State may bring, in its own name and within its own jurisdiction, proceedings for the civil enforcement, or to restrain violations, of sections 401, 403(b), 403(c), 403(d), 403(e), 403(f), 403(g), 403(h), 403(i), 403(k), 403(q), or 403(r) of the act if the food that is the subject of the proceedings is located in the State.

(b) No proceeding may be commenced by a State under paragraph (a) of this section:

(1) Before 30 days after the State has given notice to the Food and Drug Administration (FDA) that the State intends to bring such proceeding.

(2) Before 90 days after the State has given notice to FDA of such intent if FDA has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding.

(3) If FDA is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled the informal or formal enforcement action pertaining to such food.

(c) A State may intervene as a matter of right, in any court proceeding described in paragraph (b)(3) of this section.

(d) The notification that a State submits in accordance with paragraph (b) of this section should include the following information and be submitted in the following recommended format:

———————

(Date)
Name of State agency ————
Post office address ————
Street address ————
City, State, and ZIP code ————
Name of product(s) covered by the notification ————
Reporting official, title, and telephone no. ————
FAX No. ————
Agency contact (if different from reporting official), title, and telephone no. ————

Director,
Division of Regulatory Guidance (HFF-310),
Center for Food Safety and Applied Nutrition,
Food and Drug Administration,
200 C St. SW.,
Washington, DC 20204.
To Whom It May Concern:

The undersigned, ———, submits this letter of notification pursuant to section 307(b)(1) of the Federal Food, Drug, and Cosmetic Act
(21 U.S.C. 337(b)(1)) with respect to ————. (name of products covered by the notification and the enforcement action that is to be initiated)
Attached hereto, and constituting a part of this letter of notification are the following:

A. The name of the product.

B. The type and size of each product container.

C. Copy of the label and labeling of the product.

D. Manufacturing code (if applicable).

E. Name and address of firm believed to be responsible for violations.

F. Name and address of parent firm (if known).

G. Reason for the anticipated State enforcement action (list specific violations, including sections of the law violated).

H. Name of firm against which action is anticipated (if applicable).

I. Type of enforcement action.

Yours very truly,
Reporting Agency
By ————
(Indicate authority)

(e) The letter of notification should be signed by a State official authorized by the State to institute the contemplated enforcement actions.

(f) The letter of notification should be sent to the Division of Regulatory Guidance (HFF-310), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, FAX number 202-205-4642.

(g) FDA will notify the State of the date in which its letter of notification was received by FDA, Center for Food Safety and Applied Nutrition, Division of Regulatory Guidance (HFF-310) (within 2 working days after date of receipt). This date will be the date of notification for the purposes of paragraph (b) of this section.

(h) The Director, Division of Regulatory Guidance, Office of Compliance, Center for Food Safety and Applied Nutrition, FDA, will respond to the State's notification within 30 days of the date of notification by advising:

(1) Whether FDA has commenced an informal or formal enforcement action pertaining to the food that is the subject of the notification; or

(2) Whether FDA is prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled informal or formal enforcement action pertaining to such food.

(i) Information contained in State notification letters shall be exempt from public disclosure to the same extent to which such information would be so exempt pursuant to §§ 20.61, 20.64, and 20.88 of this chapter.

(j) *Definitions.* (1) "Informal enforcement actions" include warning letters, recalls, detentions, or other administrative enforcement actions that pertain to the food in question.

(2) "Formal enforcement actions" include seizures, injunctions, or other civil judicial enforcement actions that pertain to the food in question.

(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910-0275.)

Dated: October 20, 1992.

David A. Kessler,
Commissioner of Food and Drugs.
Louis W. Sullivan,
Secretary of Health and Human Services.

[FR Doc. 92-31508 Filed 12-28-92; 8:45 am]
BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 100

[Docket No. 91N-0038]

RIN 0905-AD08

State Petitions Requesting Exemption from Federal Preemption

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to provide for petitions requesting exemption from preemption for State or local food standards and for certain other State or local labeling requirements that are preempted under the provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). The regulations set out the procedures for the submission, and for agency review, of these petitions and the information that the petitioner should supply. Petitions by State and local governments seeking exemption from specified preemptive Federal requirements are specifically authorized by the 1990 amendments.

EFFECTIVE DATE: February 5, 1993.

FOR FURTHER INFORMATION CONTACT: Elizabeth J. Campbell, Center for Food Safety and Applied Nutrition (HFS-155), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5229.

SUPPLEMENTARY INFORMATION:

I. Background

In response to requirements of the 1990 amendments (Pub. L. 101-535), FDA published in the **Federal Register** of November 27, 1991 (56 FR 60528), a proposal to provide for petitions requesting exemption from preemption for State or local food standards and for certain other State or local labeling requirements that are preempted under the provisions of the 1990 amendments. The proposed regulations set out the procedures for the submission, and for agency review, of these petitions and the information that the petitioner should supply. Interested persons were given until February 25, 1992, to comment.

FDA received over 50 letters, each containing one or more comments, from industry, trade associations, States, government organizations, consumer organizations, a Congressman, and a consumer. The comments generally supported the proposal. Several letters submitted in response to the proposal addressed issues outside the scope of the proposal and will not be discussed here. A number of comments disagreed with, and requested clarification of, various aspects of the 1990 amendments or the proposal. Some of these comments suggested modification and revision in various provisions of the proposal. A summary of the comments and the agency's responses follow.

II. General Comments

1. One comment asserted that individuals should have the right to petition for exemption. The comment stated that this would allow for a more universally equitable resolution of preemption issues.

Only States and political subdivisions of States have legal standing to petition for exemption. Section 403A(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343-1(b)) provides only that upon the petition of a State or a political subdivision of a State, the Secretary may exempt a State or local requirement from the effect of section 403A(a) of the act. Thus, Congress did not provide for petitions from other parties, and the agency has no authority to grant the comment's request.

2. Some comments wanted to know if State requirements were preempted when the products in question were strictly intrastate products.

The agency advises that under section 403A(a) of the act, State requirements are not subject to preemption to the extent that they apply to intrastate products.

III. What State Laws Are Covered

A. "Not Identical To"

3. One comment suggested that whether a State or political subdivision of a State needs to seek exemption from preemption for a law or regulation should be based on whether there are substantive differences between the State and the Federal requirements.

The agency does not accept the comment. While the results under the comment's suggested test might be the same as under the agency's proposal, FDA believes its proposal is more consistent with the statutory test. Under § 100.1(c)(4), if the State requirement is identical to the Federal law, it is not subject to preemption under section 403A(a) of the act. In addition, if the State requirement does the same thing that the Federal law does, even if the words are not the same, then it is effectively the same requirement as the Federal requirement. FDA's view, as embodied in § 100.1(c)(4), is that such a State or local requirement need not be preempted, and that there is consequently no need to exempt it from preemption. Therefore, the only State requirements that are subject to preemption are those that are affirmatively different on matters that are covered by section 403A(a) of the act.

A State will only petition for exemption of a requirement from preemption if the requirement is, or the State has a good reason to believe that it is, subject to preemption. The agency believes that the petition process that it is establishing provides States with an appropriate mechanism for requesting such an exemption from preemption. If a State can adequately demonstrate the need for the labeling requirement, that such requirement will not cause a food to be in violation of Federal law, and that it will not unduly burden interstate commerce, then FDA will propose to grant the exemption.

B. More Stringent State Requirements

4. Several comments expressed concern that stringent State laws may be preempted by less restrictive Federal regulations. These comments said that States should retain the authority to enforce strict State laws that serve the needs of its citizens. One of the comments was concerned that its regulation pertaining to open dating for perishable and semiperishable food products would be preempted, and it would be precluded from enforcing these open-dating provisions. Another comment said that producers who are able to successfully differentiate their products based on superior quality should not be prevented by Federal law from marketing that product under a State standard that rewards that quality.

FDA acknowledges that some stringent State laws will be preempted by less restrictive Federal regulations. However, one of the goals of the 1990 amendments is national uniformity in certain aspects of food labeling, so that the food industry can market its products efficiently in all 50 States in a cost-effective manner (Statement of Rep. Madigan, 136 Congressional Record H12954, October 26, 1990). Thus, in enacting the 1990 amendments, Congress decided that even though Federal requirements may preempt more restrictive State requirements in certain instances, the net benefits from national uniformity in these aspects of the food label outweigh the loss in consumer protection that may occur as a result. In regard to open dating, the agency notes that State laws and regulations will not be preempted because FDA does not have authority to establish such requirements under the

sections of the act that have been given preemptive effect. Therefore, a State will not be precluded from enforcing its open-dating provisions. With respect to the latter comment, the agency advises that producers who choose to market a superior quality product are not precluded by Federal preemption from doing so.

In response to inquiries from State officials and food producers concerned about the consequences of the preemption provisions, FDA has informed them that while the agency may act in the future to remove from its regulations any provisions that permit more stringent State requirements, those provisions remain in place for the moment and presumably have the force and effect of law. FDA does not intend to interfere with actions by States to enforce their standards based on existing regulations.

C. State Common or Usual Name Regulations

5. Several comments questioned whether a State common or usual name regulation was preempted if the regulation was promulgated in conformance with § 102.5 *General principles* (21 CFR 102.5), and it is a food for which FDA has not adopted a common or usual name as a standard.

Section 403(i)(1) of the act, which requires that the label of a food bear its common or usual name, if any, is one of six misbranding sections of the act identified in section 403A(a)(3) of the act that were the subject of a study mandated by section 6(b) of the 1990 amendments. The purpose of the study was to determine which of the six sections are adequately being implemented by FDA regulations and which are not. The agency contracted with the National Academy of Sciences, Institute of Medicine (IOM) to conduct the study.

On July 28, 1992 (57 FR 33283), as required by the 1990 amendments, the agency published its proposed lists of those sections that are adequately being implemented and those sections that are not. Based on the IOM's recommendations, the agency tentatively concluded that FDA regulations in part 102 (21 CFR part 102) adequately establish procedures for the development and application of common or usual names under section 403(i)(1) of the act.

The agency is publishing elsewhere in this issue of the **Federal Register** a final rule entitled, "Certain Misbranding Sections of the Federal Food, Drug, and Cosmetic Act That Are, and That Are Not, Adequately Being Implemented by Regulation Notice of Final Lists." Based upon FDA's evaluation of the recommendations of the IOM, its consideration of the comments on the proposed lists, and other available information, the agency provides in that final rule its finding that section 403(i)(1) of the act is being adequately implemented.

Section 6(b)(3)(B) of the 1990 amendments provides that "With respect to a section which is found by the Secretary to be adequately implemented, no State or political subdivision of a State may establish or continue in effect as to any food in interstate commerce any requirement which is not identical to such section." Thus, a State common or usual name regulation promulgated in conformance with § 102.5 for a food for which there is no specific Federal common or usual name regulation is preempted. However, the agency would consider an exemption for preemption based on the conditions that led the State to believe that there was a need for the State common or usual name regulation.

D. State Standards of Identity, Quality, or Fill Regulations

6. Several comments asked whether a State standard of identity, quality, or fill is preempted if it is for a food for which there are no Federal standards.

Under section 403A(a)(1) of the act, a State may not establish or continue in effect a standard of identity, quality, or fill for a food that is the subject of a standard of identity under section 401 of the act (21 U.S.C. 341) that is not identical to the Federal standard. If there is no Federal standard of identity, quality, or fill for a particular food, then there is no basis, under the terms of section 403A(a)(1) of the act, for finding that there is Federal preemption. By contrast, under section 403A(a)(2) through (a)(5) a State may not establish or continue in effect any requirement "of the type" set forth in the sections of the act specified in section 403A(a)(2) through (a)(5). Thus, State or local requirements can be preempted under section 403A(a)(2) through (a)(5) even if no analogous Federal regulation had been promulgated.

7. A comment noted that there was a typographical error in proposed § 100.1(c)(4) in that the word "quantity" should be "quality" instead.

The agency acknowledges the typographical error, and it has replaced the word "quantity" with the word "quality" in § 100.1(c)(4) set forth below.

E. State Laws Adopted from the U.S. Department of Commerce Handbook

8. Two comments asked if the weights and measures standards for food products adopted by States from U.S. Department of Commerce publications, contained in the National Institute of Standards and Technology (NIST) Handbook 130 1992 (Uniform Packaging and Labeling Regulation and the Uniform Regulation for the Method of Sale of Commodities) and the NIST Handbook 133 (Checking the Net Contents of Packaged Goods), would be preempted under the 1990 amendments. The comments said that the requirements of these publications do not appear to be different than those in § 101.105 *Declaration of net quantity of contents when exempt* (21 CFR 101.105) but do go into more detail. The comments asked if FDA would adopt these U.S. Department of Commerce publications as part of its regulations.

The agency advises that State requirements adopting U.S. Department of Commerce publications would not be subject to preemption if the State requirements can be considered to be identical to § 101.105. FDA's view, as reflected in § 100.1(c)(4), is that the fact that the State requirements contain more detail than found in the Federal regulation does not necessarily mean that the State requirements would be subject to preemption. Preemption would occur only if the detailed information included in the State requirements imposes different or stricter requirements than provided for in § 101.105.

To resolve any concerns that a State may have about a potential conflict between its requirement and a Federal requirement, a State may petition the agency for exemption from preemption for its requirement. If FDA concludes that the State requirement is identical to the Federal requirement, the agency will advise the State of that fact and deny the State's petition without prejudice. While the agency's opinion is not binding, it will, if a question of preemption with regard to that State requirement is raised in court, provide evidence that the State requirement, in FDA's view, is not preempted. If the court later decides otherwise, the State still has the option of petitioning FDA for an exemption from preemption.

FDA is not adopting the U.S. Department of Commerce publications as part of its regulations at this time. However, because the issues surrounding the harmonization of FDA's regulations and the U.S. Department of Commerce publications that have been adopted and enforced by States are both

important and complex, the agency would welcome a meeting with the National Conference on Weights and Measures, State officials, and other interested Federal agencies to decide what steps are necessary and appropriate to ensure that FDA's regulations and the relevant Department of Commerce publications are harmonized.

9. A comment asked whether all the States that had adopted regulations identical to those the Department of Commerce publications had to petition for exemption, or whether FDA could issue a blanket exemption for all of those States.

The agency advises that it will accept blanket exemption petitions that cover circumstances such as those represented by the example of the State regulations adopted in response to the U.S. Department of Commerce's publications. If, because of the detailed information from such publications that is included in the States' requirements, the States consider their regulations to be subject to preemption, one or more States should submit an exemption petition that meets the requirements set forth below in § 100.1. Among other things, the exemption petition would need to show the authority for the petitioner to act on behalf of the other States or political subdivisions of the States, identify the State requirements and the dates that they were enacted, and include a statement of the grounds upon which the petition is based. Depending upon the circumstances, the agency will consider granting an exemption from preemption for the requirements of each of the States or political subdivisions covered by the petition.

IV. State Petitions

A. General

10. Several comments objected to the statutory provision that allows a State to petition for an exemption from preemption by Federal food labeling regulations. These comments were of the view that all State laws regarding food labeling should be preempted by Federal food labeling regulations, and that States should not be allowed to petition for an exemption. On the other hand, another comment said that State laws regarding food labeling should not be preempted by Federal regulation, and thus there is no need for a process to petition for an exemption.

Section 403A(b) of the act specifically allows a State, or a political subdivision of a State, to petition the Secretary for an exemption from preemption. It states that the Secretary may, upon being petitioned by a State, or political subdivision of a State, exempt any State or local requirement that: (1) Would not cause any food to be in violation of any applicable requirement under Federal law, (2) would not unduly burden interstate commerce, and (3) is designed to address a need for information that is not met by the misbranding sections of the act referred to in section 403A(a) of the act. Given this provision, the agency has concluded that the procedures that it is establishing for the submission and consideration of petitions for exemption from preemption are necessary to effectuate the law. Therefore, the agency rejects the comments on this point.

B. Use of Medical Device Amendments as a Model

11. One comment suggested that FDA model its regulations on State petitions for exemption from preemption under the 1990 amendments after FDA's medical device regulations for such exemptions (21 CFR 808.20, 808.25, and 808.35) rather than after the Consumer Product Safety Commission (CPSC) regulations. The comment asserted that the medical device regulations are better suited as a model because they are more comprehensive than the CPSC regulations. The comment noted that the medical device regulations require States to provide more information in the petition than they would be required to provide under proposed § 100.1 and provide interested persons with an opportunity to have an oral hearing on whether a petition should be granted.

The agency does not believe that the medical device regulations on exemption petitions are an appropriate model for implementing the 1990 amendments. The statutory provisions under which the medical device regulations were promulgated are different from the 1990 amendments in a fundamental respect. The medical device statutory provisions require a hearing. The 1990 amendments do not. Consequently, the agency chose to model its regulations after the CPSC regulations rather than the medical device regulations because the CPSC regulations provided a mechanism in which no hearing is required.

Moreover, the agency believes that the information proposed by FDA for submission by a State in its exemption petition is appropriate because it responds directly to the criteria established by section 403A(b) of the act. Accordingly, FDA is not making the suggested changes.

12. Several comments requested that FDA provide for the periodic review of granted exemptions and for the revocation of an exemption if the conditions that were present when the exemption was granted no longer exist. One comment noted that the medical device procedures provide for such revocation of previously granted exemption petitions.

The agency understands the concerns expressed by these comments and is open to citizen petitions to revoke an exemption if such revocation is warranted. However, the agency does not have the resources to commit itself to periodic reviews of exemptions granted to States. If an interested person becomes aware of a change in the conditions that led FDA to grant an exemption, that person can submit a citizen petition under § 10.30 *Citizen petition* (21 CFR 10.30) requesting revocation of that exemption. The agency will review any such petition that is submitted. If the petition shows that the conditions that justified an exemption no longer exist, the agency will consider revoking that exemption.

C What the Petition Must Show About Effect on Interstate Commerce

13. Several comments suggested that FDA should balance a State or locality's particular need against the burden on interstate commerce in determining whether an exemption petition should be granted.

The agency does not believe that the test for whether a State requirement does, in fact, "unduly burden" interstate commerce is one of balancing burden versus need. The statute anticipates that a State or locality's need for a particular labeling requirement will be assessed separately under section 403A(b)(3). In case law interpreting "undue burden," the court equated the term with unfairness. (See *Mid-South Bottling Co.* v. *NLRB*, 876 F.2d 458, 461 (5th Cir. 1989)). Applying this unfairness standard, one could argue, for example, that if a State requirement can be readily accommodated (e.g., a stick-on label) or is not applied to out-of-state firms, it does not unduly burden interstate commerce. On the other hand, if the State requirement required a completely different label than would be appropriate everywhere else in the country, a strong argument could be made that it does unduly burden interstate commerce. Accordingly, the agency is not including the suggested balancing test as a criterion for determining whether a State's petition for exemption from preemption should be granted.

14. Several comments objected to the amount of information required in a State petition on the effect that granting it will have on interstate commerce. These comments were particularly

opposed to the agency's position that States should obtain information in the form of statements from producers of food products indicating that it is practical and feasible for them to comply with the State requirement.

The congressional intent in enacting the 1990 amendments was to provide national uniformity and to allow industry to conduct business in an efficient and cost-effective manner (136 Congressional Record H12954, October 26, 1990). Accordingly, the State has the burden to show why an exemption is appropriate, and why such an exemption, if granted, would not unduly burden interstate commerce.

To meet this burden, a State will need to contact industry to determine the effect of its regulations upon interstate commerce. Although a company may say that the burden is significant, the State would have the opportunity to show as part of its petition that the company's view is overstated and, therefore, does not provide a basis for denying the petition. Accordingly, the agency is retaining this requirement in the final rule.

15. Some comments requested that FDA require States to include more information in their petitions to show not only the costs of distributing products labeled differently for different States but also the cost of changing labels if an exemption petition is granted.

The agency proposed in § 100.1(d)(2) (Part C, Statement of Grounds) to only provide States with guidance as to what a petition for exemption from preemption should contain. The agency continues to believe, and it was not persuaded by the comments to conclude otherwise, that it is not appropriate to establish requirements on the contents of a State petition for an exemption from preemption. Therefore, FDA rejects the comments on this point. However, the agency does agree that the costs of changing labels and of using different labels in different localities bear on the issue of burden on interstate commerce and, therefore, should be included in the State's petition as part of the cost of compliance.

16. Some comments suggested that, with respect to possible burdens on interstate commerce, FDA should give more specific guidance about what it intends to consider in deciding whether to grant an exemption from preemption for a State or local requirement. One comment stated that the factors depicted in proposed § 100.1(d)(2) (i.e., economic feasibility, comparison of costs of compliance, effects on the availability of a food to consumers, and the practicality of industry compliance) do not accurately or fully summarize the constitutional considerations employed by Federal courts. The latter comment suggested that a State must be able to show: (1) The important public interests its regulation supposedly furthers, (2) that the regulation treats in-state and out-of-state manufacturers or advertisers evenhandedly, (3) the degree of burden imposed by the regulation, (4) that the burden is not clearly excessive in relation to any putative local benefits, (5) that the regulation does not project the State's standards into other States, and (6) that the regulation does not unduly impede the free flow of interstate commerce.

The agency believes that the guidance that it has provided in § 100.1(d)(2) (Part C, Statement of Grounds) as to the information necessary to support an exemption petition fully reflects the considerations that the Federal courts have applied in determining whether there is an undue burden on interstate commerce. The agency, however, with the exception of item (2) above, does not object to a State addressing the listed items in an exemption petition. With respect to item (2), the agency notes that it does not have jurisdiction over products manufactured and distributed in intrastate commerce, nor does it have jurisdiction over advertising, which is regulated by the Federal Trade Commission. Therefore, FDA considers this item to be of marginal relevance to the determination that the agency must make.

D. Particular Need for Information

17. Several comments argued that FDA has misinterpreted the portion of the 1990 amendments requiring a State to show a "particular need for information" to mean that a State or locality must show that a labeling requirement fulfills a unique local need in order to exempt a requirement from preemption. The comments stated that a petition for exemption from preemption should not be denied simply because the need for information is also national in scope.

While the agency agrees with the comments' interpretation of the statute, an agency decision to grant an exemption from preemption is likely to be based largely on the agency's evaluation of the situation within the requesting State. If the need for an exemption is not only local, the agency is likely to consider whether it would not in fact be more appropriate to amend the relevant Federal regulation rather than grant an exemption. Therefore, while the agency is open and willing to consider any need for exemption asserted in a State petition, it seems prudent for such a petition to address the question of why the agency should limit its consideration to the exemption and not address the broader concern.

18. One comment suggested that FDA include a provision in the final rule that requires that petitions for exemption that are based on a claim that a particular Federal requirement fails to meet the petitioning State's particular local need be accompanied by a citizen's petition under § 10.30 to amend the Federal requirement. The comment said that the agency should defer consideration of the exemption petition until it has ruled on the citizen's petition.

The agency does not believe that such a requirement is appropriate or necessary. It would be an unnecessary burden on States to require that they submit all the information necessary for a citizen petition to amend FDA's regulations. The agency, however, has no objection to other interested persons submitting a citizen petition under § 10.30 for an amendment to a Federal regulation. Although the agency cannot commit itself to acting on such citizen petition first, it will review it as appropriate and in an expeditious manner.

19. Several comments suggested that States should be required to identify alternatives that might be used to meet the need for information without negating Federal preemption and to explain why those alternatives could not be reasonably implemented within the State. These comments argued that this requirement would satisfy the State's burden to prove that uniformity should be compromised. Not every perceived shortcoming in Federal requirements, the comment stated, must be remedied by different labeling requirements.

The 1990 amendments provide only that a State show that its requirement would not cause any food to be in violation of Federal law, would not unduly burden interstate commerce, and is designed to meet a particular need for information that is not met by the Federal requirements. There is no provision in the 1990 amendments that requires that the States identify and consider a number of alternatives beyond that for which it is seeking exemption from preemption. Accordingly, FDA is not including the suggested provision in the final rule.

V. Procedural Provisions

A. When to File—Submission of Petition Before a State Rule is Finalized

20. Several comments disagreed with the proposed requirement in § 100.1(c)(1) that States submit an exemption petition only after the State requirement has been enacted or issued as a final rule by an authorized State official and is in effect or would be in effect but for the provisions of section 403A of the act. The comments suggested that States be allowed to petition for exemption at any time once a State rulemaking proceeding starts, or when the State believes that the rule will become final. The comments said that it would be too burdensome to promulgate a State regulation only to have it preempted by the Federal regulation. The comments also requested guidance from FDA about preemption and its effects on current and possible future State laws.

Acceptance of a State petition for exemption from preemption for a State law or regulation that has not been enacted or promulgated could result in a waste of FDA resources if the State subsequently decides not to enact the law or not to adopt the regulation. FDA is willing to communicate and work with States when questions about preemption arise. However, the agency does not believe that it is prudent to accept exemption petitions for laws or regulations that are not yet enacted. Because preemption can only occur if there is a State law or regulation in effect, the agency will not grant an exemption to a proposed State law or regulation.

The agency, however, advises that a State should be aware of the possible preemption problems at the time it considers whether to adopt the law or regulation. Realizing that the primary purpose of preemption is uniformity of State laws, the State will need to find that there are particular needs that compel it to adopt the law or regulation if it is to do so in the face of the likelihood of preemption. Those are exactly the needs that ought to be brought to the agency's attention as part of the exemption from preemption process.

B. Filing State Exemption Petitions

21. Several comments recommended that proposed § 100.1(c) be revised in the final rule to set "threshold requirements for the acceptance of petitions for suitability for filing of State petitions." The comments noted that the proposed prerequisites would establish only that there is a State requirement, that the State and Federal requirements are not identical, and that the petitioner is an appropriate State official. These comments suggested that FDA not accept for filing in the first instance any exemption petition unless it contains a prima facie showing that the statutory prerequisites are met; i.e., that the proposed exemption will not result in a violation of any Federal law, will not unduly burden interstate commerce, and is designed to address a particular need for information that is not met by the preemptive Federal requirement (section 403A(b) of the act). One comment viewed a demonstration of threshold compliance with the statutory prerequisites as critical in light of the fact that under section 10(b)(2) of the 1990 amendments, a petition submitted by May 8, 1992, has the effect of staying Federal preemption until FDA takes action on the petition. The comment was concerned that because the State petitioning regulation itself is not proposed to become effective until November 8, 1992, FDA action on State petitions submitted before May 8, 1992, will be deferred for a very long time. Consequently, the comment argued that without a meaningful petition threshold regulation, even a State petition unapprovable on its face would stay Federal preemption for that time.

The agency believes that the threshold requirements it proposed in § 100.1(c) are more than adequate for determining whether a petition for exemption from preemption should be accepted for filing. The requested prima facie showing that the exemption petition has met the statutory prerequisites goes to the merits of the petition, and whether it should be granted or denied, not to whether it is suitable for filing. Given this fact, along with the complexities of the factors to be considered in determining whether the statutory prerequisites have been met by the petitioner, and the amount of time (90 days) in which the agency is expected to make a final decision on the merits of each exemption petition, FDA is not amending § 100.1(c) to grant the comments' request.

The agency notes that the suggested inclusion of additional threshold requirements for the acceptance of exemption petitions will not address the concerns expressed by the comments. The comments address the provision of section 10(b)(2) of the 1990 amendments that exempts a State requirement described in section 403A(a)(3) through (a)(5) of the act from preemption for a limited period of time if the State submits a petition under section 403A(b) of the act by May 8, 1992. Because the time limit of May 8, 1992, for submitting exemption petitions that would temporarily except State requirements from preemption has passed, any value in establishing threshold requirements for petitions submitted by that date is moot. Moreover, the agency does not believe that it can retroactively establish threshold requirements that would exclude certain or all State petitions from the exemption provisions of section 10(b)(2) of the 1990 amendments.

22. Several comments recommended that § 100.1(f)(4) and (f)(5) be revised to provide for public notification in the **Federal Register** of the filing of State exemption petitions. One comment suggested that a notice of filing of an exemption petition be sent to the petitioner. Some comments also recommended that FDA provide for a comment period between the filing of an exemption petition and the agency's response. Other comments wanted the submission of an exemption petition and the agency's responses to be made public. These comments expressed concern that without public notification, an interested person may not know that his or her interests require the filing of comments. Some comments suggested that FDA also should establish a specific time between the receipt and the filing of an exemption petition so that interested persons may provide meaningful comment.

The agency does not believe public notification in the **Federal Register** of the submission or filing of exemption petitions is necessary. Nor does the agency find it necessary to establish a comment period for either submitted or filed petitions. The procedures for the handling of petitions for exemption from preemption are generally consistent with those in § 10.30 for citizen petitions. Section 100.1(e) provides that once an exemption petition is accepted for filing, it will be made available for public examination and copying at the Dockets Management Branch under the rules provided for in § 10.20(j) (21 CFR 10.20(j)). In addition, § 100.1(f)(3) provides that the petitioner will be notified in writing of the filing and docket number of the petition. Section 100.1(f)(4) allows any interested person to submit written comments to the Dockets Management Branch on a filed petition, as provided in § 10.30(d). If the agency tentatively decides that an exemption petition has merit, it will publish in the **Federal Register** a proposal to grant the exemption, and interested persons will have an opportunity to comment on the proposal at that time.

The agency recognizes that not providing for a public notice of the filing or submission of an exemption petition in the procedures that it is establishing may limit the ability of a person who might consider the petition significant to comment on the petition before the agency makes a decision to propose to grant the exemption or to deny the petition. The agency has concluded, however, that there is no prejudice from this fact because the petition will be available at the Dockets Management Branch, comments can be submitted on the petition, and the agency will not grant the petition until after there has been rulemaking on whether such action is appropriate. Interested persons will thus have ample opportunity to comment on the petition.

23. One comment requested that FDA establish a comment period for accepting comments to a proposal to grant an exemption.

The agency points out that all FDA published proposals are subject to the requirements of § 10.40 *Promulgation of regulations for efficient enforcement of the law* (21 CFR 10.40). Section 10.40(b)(2) provides that the proposal will provide 60 days for comment, although the Commissioner of Food and Drugs may shorten the comment period (to not less than 10 days) or lengthen this time period for good cause.

24. One comment said that FDA should make a decision on the exemption petition in 90 days and not just issue a response that it has not made a decision.

The agency advises that it intends to make every effort to make its decisions on exemption petitions within the 90-day period. However, there are circumstances that arise, such as other agency priorities and a need for additional information, that may not permit the agency to respond within 90 days. Accordingly, the agency has concluded that a provision for a tentative response, similar to that which is permitted in § 10.30(e)(2)(iii), is both appropriate and warranted.

25. Some comments wanted FDA to publish a list of all petitions filed before May 8, 1992, and to act promptly on these petitions.

Five petitions from States requesting exemption from preemption were submitted to the agency by May 8, 1992. As announced in the **Federal Register** of March 14, 1991 (56 FR 10906), the agency has deferred action on these petitions and has not reviewed them to any extent at this time. These petitions are: State of California petitions on milk, dated January 7, 1991 (Docket No. 91P–0009); slack fill, dated May 6, 1992 (Docket No. 92P–0361); bottled water, dated May 8, 1992 (Docket No. 92P–0216); State of Michigan petition on nonalcoholic beverages, dated March 15, 1991 (Docket No. 92P–0360); State of Vermont petition on maple syrup, dated July 30, 1991 (Docket No. 92P–0359); and a joint petition by 44 states, territories or jurisdictions on net content, dated November 9, 1992 (Docket No. 92P–0441). The agency fully intends to respond to these petitions in the very near future.

26. One comment from a foreign country requested that FDA notify it of any State exemption petitions that could affect trade. The comment expressed concern that any exemptions not violate the General Agreement on Tariffs and Trade or the Free Trade Agreement with Canada.

The agency advises that if it should tentatively decide that an exemption petition has merit, it will publish a proposal in the **Federal Register** to grant the exemption through rulemaking. Any foreign government concerned about trade implications would have an opportunity to comment on such a proposal at that time. The agency believes that publication of proposals to grant an exemption in the **Federal Register** will provide adequate notice to foreign governments of State petitions for exemption from preemption.

C. Exemption Granted through Notice and Comment Rulemaking

27. Several comments were opposed to granting exemptions through rulemaking. The comments said there is nothing in the language of the 1990 amendments indicating the necessity for issuing exemptions in the form of regulations.

The agency considered these comments but finds no basis to change its tentative conclusion that granting of exemptions through notice and comment rulemaking is the best procedure to follow. The agency believes that rulemaking is appropriate because section 403A(b) provides that FDA is to grant the exemption by regulation, and because the granting of an exemption from preemption will have the force and effect of law. In addition, rulemaking will ensure that all interested persons have an opportunity to comment, and that all opinions are expressed. Accordingly, FDA is retaining § 100.1(f)(5)(i), as proposed, but is adding the phrase "under such conditions as it [FDA] may prescribe by regulation" to the last sentence of § 100.1(a)(2) to reflect the language of section 403A(b).

After considering the comments that FDA received on the proposal, FDA is adding a new subpart A, consisting of § 100.1.

VI. Paperwork Reduction Act

Section 100.1(d) of this final rule contains information collection requirements that were submitted for review and approval to the Director of the Office of Management and Budget (OMB), as required by section 3504(h) of the Paperwork Reduction Act of 1980. The requirements were approved and assigned OMB control number 0910–0277.

VII. Economic Impact

In its November 1991 proposal, FDA concluded that the proposed requirements did not constitute a major rule and that no significant impact on a substantial number of small entities, including small businesses, would derive from this action. FDA has not received any new information or comments on the proposal that would alter its previous determination.

VIII. Environmental Impact

The agency previously determined under 21 CFR 25.24(a)(8), as announced in the proposed rule and published in the **Federal Register** of November 27, 1991 (56 FR 60528), that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental assessment or an environmental impact statement is not required.

List of Subjects in 21 CFR Part 100

Administrative practice and procedure, Food labeling, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 100 is amended as follows:

PART 100—GENERAL

1. The authority citation for 21 CFR part 100 is revised to read as follows:

Authority: Secs. 201, 301, 307, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 337, 342, 343, 348, 371).

2. A new subpart A consisting of § 100.1 is added to read as follows:

Subpart A—State and Local Requirements

§ 100.1 Petitions requesting exemption from preemption for State or local requirements.

(a) *Scope and purpose.* (1) This subpart applies to the submission and consideration of petitions under section 403A(b) of the Federal Food, Drug, and Cosmetic Act (the act), by a State or a political subdivision of a State, requesting exemption of a State requirement from preemption under section 403A(a) of the act.

(2) Section 403A(b) of the act provides that where a State requirement has been preempted under section 403A(a) of the act, the State may petition the agency for an exemption. The agency may grant the exemption, under such conditions as it may prescribe by regulation, if the agency finds that the State requirement will not cause any food to be in violation of any applicable requirement under Federal law, will not unduly burden interstate commerce, and is designed to address a particular need for information that is not met by the preemptive Federal requirement.

(b) *Definitions.* (1) *Act* means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*).

(2) *Agency* means the Food and Drug Administration.

(3) *Commissioner* means the Commissioner of Food and Drugs.

(4) *State* means a State as defined in section 201(a)(1) of the act (which includes a territory of the United States, the District of Columbia, and Puerto Rico) or any political subdivision of a State having authority to issue food standards and food labeling regulations having force of law.

(5) *State requirement* means any statute, standard, regulation, or other requirement that is issued by a State.

(c) *Prerequisites for petitions for exemption from preemption.* The Food and Drug Administration will consider a petition for exemption from preemption on its merits only if the petition demonstrates that:

(1) The State requirement was enacted or was issued as a final rule by an authorized official of the State and is in effect or would be in effect but for the provisions of section 403A of the act.

(2) The State requirement is subject to preemption under section 403A(a) of the act because of a statutory provision listed in that section or because of a Federal standard or other Federal regulation that is in effect, or that has been published as a final rule with a designated effective date, and that was issued under the authority of a statutory provision listed in that section. For the purposes of this subpart, all petitions seeking exemption from preemption under section 403A(a)(3) through (a)(5) of the act submitted before May 8, 1992, will be considered timely even though the applicable statutory provisions or regulations are not yet in effect.

(3) The petitioner is an official of a State having authority to act for, or on behalf of, the Government in applying for an exemption of State requirements from preemption.

(4) The State requirement is subject to preemption under section 403A(a) of the act because it is not identical to the requirement of the preemptive Federal statutory provision or regulation including a standard of identity, quality, and fill. "Not identical to" does not refer to the specific words in the requirement but instead means that the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food, or concerning a food container, that:

(i) Are not imposed by or contained in the applicable provision (including any implementing regulation) of section 401 or 403 of the act; or

(ii) Differ from those specifically imposed by or contained in the applicable provision (including any implementing regulation) of section 401 or 403 of the act.

(d) *Form of petition.* (1) All information included in the petition should meet the general requirements of § 10.20(c) of this chapter.

(2) An original and one copy of the petition shall be submitted, or the petitioner may submit an original and a computer readable disk containing the petition. Contents of the disk should be in a standard format, such as ASCII format. (Petitioners interested in submitting a disk should contact the Center for Food Safety and Applied Nutrition for details.)

(3) Petitions for exemption from preemption for a State requirement shall be submitted to the Dockets Management Branch in the following form:

(Date) _____

Dockets Management Branch,
Food and Drug Administration,
Department of Health and Human Services,
rm. 1–23, 12420 Parklawn Dr.,
Rockville, MD 20857.

Petition Requesting Exemption from Preemption for State Requirement

The undersigned submits this petition under section 403A(b)of the Federal Food, Drug, and Cosmetic Act to request that the Food and Drug Administration exempt a State requirement from preemption.

The undersigned has authority to act for, or on behalf of, the (*identify State or political subdivision of the State*) because (*document petitioner's authority to submit petition on behalf of the State*).

A. Action Requested

1. Identify and give the exact wording of the State requirement and give date it was enacted or issued in final form.

2. Identify the specific standard or regulation that is believed to preempt the State requirement and the section and paragraph of the act that the standard or regulation implements.

B. Documentation of State Requirement

Provide a copy of the State requirement that is the subject of the application. Where available, the application should also include copies of any legislative history or background materials used in issuing the requirement, including hearing reports or studies concerning the development or consideration of the requirement.

C. Statement of Grounds

A petition for an exemption from preemption should contain the following:

1. An explanation of the State requirement and its rationale, and a comparison of State and Federal requirements to show differences.

2. An explanation of why compliance with the State requirement would not cause a food to be in violation of any applicable requirement under Federal law.

3. Information on the effect that granting the State petition will have on interstate commerce. The petition should contain information on economic feasibility, i.e., whether the State and Federal requirements have significantly different effects on the production and distribution of the food product; comparison of the costs of compliance as shown by data or information on the actual or anticipated effect of the State and Federal requirements on the sale and price of the food product in interstate commerce; and the effect of the State requirement on the availability of the food product to consumers. To the extent possible, the petition should include information showing that it is practical and feasible for producers of food products to comply with the State requirement. Such information may be submitted in the form of statements from affected persons indicating their ability to comply.

4. Identification of a particular need for information that the State requirement is designed to meet, which need is not met by Federal law. The petition should describe the conditions that require the State to petition for an exemption, the information need that the State requirement fulfills, the inadequacy of the Federal requirement in addressing this need, and the geographical area or political subdivision in which such need exists.

D. Environmental Impact

The petition shall contain a claim for categorical exclusion under 21 CFR 25.24 or an environmental assessment under 21 CFR 25.31.

E. Notification

Provide name and address of person, branch, department, or other instrumentality of the State government that should be notified of the Commissioner's action concerning the petition.

F. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies.

(Signature) _____

(Name of petitioner) _____

(Mailing address) _____

(Telephone number) _____

(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB number 0910–0277)

(e) *Submission of petition for exemption; public disclosure.* The availability for public disclosure of a petition for exemption will be governed by the rules specified in § 10.20(j) of this chapter.

(f) *Agency consideration of petitions.* (1) Unless otherwise specified in this section, all relevant provisions and requirements of subpart B of part 10 of this chapter, are applicable to State petitions requesting exemption from Federal preemption under section 403A(b) of the act.

(2) If a petition does not meet the prerequisite requirements of paragraph (c) of this section, the agency will issue a letter to the petitioner denying the petition and stating in what respect the petition does not meet these requirements.

(3) If a petition appears to meet the prerequisite requirements in paragraph (c) of this section, it will be filed by the Dockets Management Branch, stamped with the date of filing, and assigned a docket number. The docket number identifies the file established by the Dockets Management Branch for all submissions relating to the petition, as provided in this part. Subsequent submissions relating to the matter must refer to the docket number and will be filed in the docket file. The Dockets Management Branch will promptly notify the petitioner in writing of the filing and docket number of a petition.

(4) Any interested person may submit written comments to the Dockets Management Branch on a filed petition as provided in § 10.30(d) of this chapter.

(5) Within 90 days of the date of filing the agency will furnish a response to the petitioner. The response will either:

(i) State that the agency has tentatively determined that the petition merits the granting of an exemption, and that it intends to publish in the **Federal Register** a proposal to grant the exemption through rulemaking;

(ii) Deny the petition and state the reasons for such denial; or

(iii) Provide a tentative response indicating why the agency has been unable to reach a decision on the petition, e.g., because of other agency priorities or a need for additional information.

(g) If a State submitted a petition for exemption of a State requirement from preemption under section 403A(a)(3) through (a)(5) of the act before May 8, 1992, that State requirement will not be subject to preemption until:

(1) November 8, 1992; or

(2) Action on the petition, whichever occurs later.

Dated: October 26, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 92–31509 Filed 12–28–92; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Ch. I

[Docket No. 91N-0134]

Certain Misbranding Sections of the Federal Food, Drug, and Cosmetic Act That Are, and That Are Not, Adequately Being Implemented by Regulation; Notice of Final Lists

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing, in accordance with the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), final lists delineating which of six sections of the Federal Food, Drug, and Cosmetic Act (the act) that define circumstances in which a food is misbranded are adequately being implemented by FDA regulations and which are not. These six sections are: Sections 403(b) (offered for sale under the name of another food), 403(d) (misleading container), 403(f) (information of appropriate prominence), 403(h) (compliance with standard of quality and fill), 403(i)(1) (common or usual name), and 403(k) of the act (declaration that the product contains artificial flavoring, coloring, or preservatives) (21 U.S.C. 343(b), 343(d), 343(f), 343(h), 343(i)(1), and 343(k)).

Based upon its evaluation of the recommendations of the National Academy of Sciences, Institute of Medicine, Food and Nutrition Board (hereinafter referred to as IOM), its consideration of the comments on the proposed lists, and other available information, the agency finds that all but section 403(d) of the act are adequately being implemented.

EFFECTIVE DATE: The final lists of sections of the act that are, and that are not, being adequately implemented become effective on February 5, 1993.

FOR FURTHER INFORMATION CONTACT: Gerad L. McCowin, Center for Food Safety and Applied Nutrition (HFS-151), Food and Drug Administration, 200 C. St. SW., Washington, DC 20204, 202-205-5162.

SUPPLEMENTARY INFORMATION:

I. Background

In response to section 6(b) of the 1990 amendments (Pub. L. 101-535), FDA published in the **Federal Register** of July 28, 1992 (57 FR 33283), proposed lists that identified which of six sections of the act (sections 403(b), 403(d), 403(f), 403(h), 403(i)(1), and 403(k)) that define circumstances in which a food is misbranded are adequately being implemented by FDA regulations and which are not adequately being implemented. The agency tentatively concluded that sections 403(b), 403(f), 403(h), 403(i)(1), and 403(k) of the act are adequately being implemented, and that section 403(d) is not adequately being implemented. FDA's tentative conclusions were based on the recommendations of IOM, with whom FDA had contracted, in accordance with section 6(b) of the 1990 amendments, to study:

(A) State and local laws that require the labeling of food that is of the type required by sections 403(b), 403(d), 403(f), 403(h), 403(i)(1), and 403(k) of the Federal Food, Drug, and Cosmetic Act, and

(B) the sections of the Federal Food, Drug, and Cosmetic Act referred to in subparagraph (A) and the regulations issued by the Secretary to enforce such sections to determine whether such sections and regulations adequately implement the purposes of such sections.

Interested persons were given until September 28, 1992, to comment. FDA received six letters, each containing one or more comments, from two trade organizations, a food manufacturer, a professional organization, and a consumer organization. A summary of the issues raised by the comments and the agency's responses follow.

II. Response to Comments

A. Adequate Implementation

1. One comment objected to the criteria used by IOM to determine whether a particular section is adequately being implemented. Specifically, the comment interpreted the legislative history to provide that "adequate implementation" means full implementation of the six misbranding sections and thus requires Federal adoption of the strongest legal standards that effectively accomplish the goals of the provisions under study. The comment stated that:

> IOM's conclusions are contrary to the NLEA because the legislative history indicates that Congress intended to avoid preempting state and local governments unless the FDCA has been fully implemented, and no additional federal regulation is necessary.

The agency disagrees with this comment. The agency can find no support in the legislative history or in the 1990 amendments for a conclusion that the intent of the procedures established by section 6(b) was to identify the strongest regulations relevant to each of the six sections listed in section 403A(a)(3) of the act and to have FDA adopt those regulations.

In discussing the preemption provisions of the 1990 amendments, Congressman Waxman identified two principles that should be considered in preempting State laws. First, State laws should not be preempted unless the nature of the laws at issue makes it difficult and even impossible for companies to operate in interstate commerce. Secondly, the States should never be preempted unless a strong Federal regulatory system is in place (136 Congressional Record H5840 (July 30, 1990)). Mr. Waxman noted that the requirements for nutrition labeling and for health claims that were in the bill that had been reported out of the House Committee on Energy and Commerce (and that became the 1990 amendments) created such a strong regulatory system (id.). Implicitly, Congress also recognized the strength and adequacy of FDA's implementation of sections 401 of the act (standards of identity) and 403(g) of the act (standards of identity labeling) to which it gave preemptive effect on the date of enactment and of sections 403(c) (imitation foods), 403(e) (name and address of responsible firm and net contents declaration), and 403(i)(2) of the act (ingredient labeling) which Congress made preemptive 1 year after enactment.

However, Mr. Waxman stated that Congress was unable to determine whether the Federal standard is strong in the areas covered by sections 403(b), 403(d), 403(f), 403(h), 403(i)(1), and 403(k) of the act (136 Congressional Record H5840). Thus, he said, the bill provides for a study of Federal and State standards to determine whether additional Federal regulations on each of the sections is needed.

Further information on the nature of the study is provided by the House Manager's report:

> The purpose of this study is to provide the Secretary information upon which to determine whether federal laws are adequate once the state laws are preempted. It is anticipated that the study will identify all federal regulations that are applicable as well as State laws that will be preempted. The study should also survey local laws, but it is not anticipated that every local law will need to be identified.

(136 Congressional Record H5842 (July 30, 1990)).

It is clear from this legislative history that what Congress intended was for FDA, through a contractor, to compare its regulations implementing the sections of the act in question with those of the States. To the extent that

that study identified major matters covered by those sections that the States were addressing but FDA was not, FDA would have to address those matters before the sections in question would be preemptive.

However, there is nothing in the statute or the legislative history that suggests that the purpose of the study was to identify the strongest State standard on each of the matters covered by those sections of the act and for FDA to implement that provision. Therefore, FDA rejects this comment.

2. One comment stated that the IOM had erred in failing to consider the level of FDA enforcement in determining whether a particular section has been adequately implemented.

The agency disagrees that its enforcement record is appropriately a factor in determining adequacy of implementation. There is nothing in the act or the legislative history that would indicate that it should be. Nor does it make any sense in light of the legislative history that level of enforcement is a relevant factor. Congress cited nutrition labeling and health claims as topics on which a strong Federal regulatory system is in place, even though the statutory provisions on these topics had never been enforced (136 Congressional Record H5840 (July 30, 1990)). Apparently, Congress did so because it anticipated that adoption of the regulations necessary in response to the 1990 amendments would establish such a strong regulatory system. Thus, it is appropriate to look to the regulatory systems in place for each of the sections in question—that is, to the regulations that effect those sections—to determine whether they are adequately being implemented.

3. One comment stated that IOM cannot legally determine whether a particular section is adequately being implemented without considering the level of industry compliance.

FDA disagrees. Because IOM received no information from FDA or the States concerning industry compliance, and because only anecdotal information exists, IOM concluded that there was no objectively verifiable data regarding compliance that could be used to evaluate adequacy of implementation of the misbranding sections. Therefore, IOM decided that to evaluate compliance on the basis of such limited data would be contrary to the intent of the 1990 amendments.

Again, there is nothing in the legislative history that would suggest that industry compliance was a factor that either IOM or FDA should consider in deciding whether the Federal regulations implementing the sections in question are adequate. If compliance is a problem, what the statute seems to contemplate is that FDA would establish a strong national standard that the States and the agency would then work together to enforce. As Congressman Waxman said: "Third, any preemption provision must recognize the important contribution that the State can make in regulation, and it must leave a role for the states." (136 Congressional Record H5840 (July 30, 1990)). Thus, FDA rejects this comment.

B. Preemption

4. One comment argued that IOM misinterpreted the 1990 amendments as to the extent of preemption by concluding that all State and local requirements, not just those that conflict with Federal law, should be preempted if FDA determines that the section under study has, as a whole, adequately been implemented. The comment argued that the national uniformity portion of the 1990 amendments was intended to ease the burden to industry by preempting inconsistent labeling requirements. The comment stated that, therefore, State and local requirements that serve consumer protection purposes should only be preempted if they conflict with FDA regulations.

The comment noted as an example that under IOM interpretation, a State requirement for a common or usual name for a particular product would be preempted even if there is no Federal requirement for a common or usual name for that product. The comment summarized its position by concluding that the IOM had incorrectly interpreted which State and local requirements were "of the type" or "related to" the six areas under study. As support for its position, the comment cited the FDA November 27, 1991, proposal entitled "State Petitions Requesting Exemption From Federal Preemption" (hereinafter referred to as the State petitions proposal) (56 FR 60528).

The agency disagrees with this comment. The comment misinterprets the extent of preemption that occurs under section 403A of the act.

FDA sought to address this issue in its proposal on State petitions for exemption from preemption. In that proposal the agency stated:

> Section 403A is only operative in matters where there is a Federal requirement applicable to the labeling addressed in the State requirement. If there is no applicable Federal requirement that has been given preemptive status by Congress, there is no competing claim of jurisdiction, and, therefore, no basis under the 1990 amendments for Federal preemption or grounds to justify the submission of a State petition for exemption.

(56 FR 60528 at 60530)

In discussing examples of State laws that would not be preempted, FDA listed the following:

> The examples included State laws pertaining to issues for which there is no national framework, such as open date labeling, unit price labeling, container deposit labeling, religious dietary labeling, and previously frozen labeling.

These examples do not include situations that are covered by the sections of the act that are given preemptive effect by section 6(b) of the 1990 amendments or regulations issued under those sections. With respect to those sections, however, the preemptive effect is quite broad. Section 403A(a)(3) of the act, for example, states that no State or political subdivision of a State may directly or indirectly establish or continue in effect as to any food in interstate commerce "* * * any requirement of the type required by section 403(b), 403(d), 403(f), 403(h), 403(403(i)(1), or 403(k) that is not identical to the requirement of such section." Thus, under this provision, as is discussed below in this document and as explained more fully in the final rule entitled "State Petitions Requesting Exemption from Federal Preemption," published elsewhere in this issue of the **Federal Register**, a State common or usual name regulation promulgated in conformance with the requirements of § 102.5 (21 CFR 102.5) for a food for which there is no specific Federal common or usual name would apparently be preempted. It would be a requirement of the type required by section 403(i)(1) of the act, but it would not be identical to the provisions that FDA has adopted under that section.

C. The Six Misbranding Sections Under Review

1. Section 403(b)—Offered for Sale Under the Name of Another Food

5. Four comments supported FDA's tentative determination that section 403(b) of the act is adequately being implemented. However, one comment argued that section 403(b) of the act is not adequately being implemented because FDA has issued no regulations under this section nor has it prosecuted many cases under this section. The comment also noted that IOM, while finding section 403(b) of the act adequately implemented, suggested that FDA should promote the development and introduction of new foods by pursuing more aggressively the regulatory options that will allow the formal naming of new nonstandardized foods.

Having considered the comments to the proposal, the IOM report, and other available information, the agency concludes that IOM was correct in its recommendation, and is finding that section 403(b) of the act is adequately being implemented. The agency notes, as did IOM, that it does have a regulation that implements section 403(b) of the act, § 101.18 *Misbranding of food* (21 CFR 101.18). Moreover, none of the comments pointed to State regulations that implement provisions that are similar to section 403(b) of the act that address matters not covered by FDA's regulations.

As to the enforcement, or lack thereof, of section 403(b) of the act, FDA agrees that there are not many actions brought against manufacturers solely under this general misbranding provision. Any such action taken by FDA against a manufacturer under section 403(b) of the act would almost always be brought in conjunction with counts that charge a violation of the more specific misbranding provisions of section 403, namely section 403(g) (standards of identity) and section 403(i)(1) (common or usual name). However, as discussed above, the level of enforcement is not relevant to the inquiry mandated by Congress.

The agency believes that IOM's suggestion that FDA actively pursue its regulatory options to allow the formal naming of nonstandardized foods was misinterpreted by the comment. IOM was simply offering a suggestion. There is no indication in IOM's report that IOM believed that there was a problem with the implementation of section 403(b) of the act, as evidenced by its recommended finding that this section is being adequately implemented. For these reasons, FDA rejects this comment.

2. Section 403(d)—Misleading Container

6. Two comments cited FDA's current requirements for net weight declaration and standards of fill regulations as evidence that section 403(d) of the act is adequately being implemented. One of the comments added that IOM's determination that section 403(h) of the act (fill of container) is adequately being implemented precluded the IOM from finding that section 403(d) is not adequately being implemented.

The agency disagrees with the comments. The suggestion that the provisions for net weight declaration (as provided by section 403(e) of the act) and standards of fill (as provided by section 403(h)(2) of the act) serve to implement section 403(d) of the act would basically serve to render section 403(d) of the act a nullity. Although there is clearly an interrelationship among the three sections, the agency believes that the presence of an accurate net weight statement or compliance with a standard of fill does not eliminate the misbranding that occurs when a container is made, formed, or filled so as to be misleading.

7. One comment argued that it would not be cost effective for FDA to implement section 403(d) of the act by promulgating detailed specific commodity and container regulations, such as those the agency has adopted in the past under section 401 of the act and enforced under section 403(h)(2) for all food products or specific food product classes. The comment also argued that further regulatory activity would be inappropriate in light of the IOM's failure to identify any State commodity and package regulations that should be adopted and of FDA's previous determination that the expenditures of agency resources that would be needed to implement such regulations would exceed potential benefits.

FDA disagrees. The fact that IOM was unable to identify any specific state law that FDA should adopt was not a basis for ending their consideration of whether a particular section is being adequately implemented. As noted above, the task was to determine the adequacy of Federal implementation by considering: (1) The extent of State regulation for each topic and the corresponding Federal regulation and (2) whether the States were doing anything that FDA should be doing. FDA notes that IOM did mention California's experience in this area suggested using the provisions of the Fair Packaging and Labeling Act (FPLA) as a guide for Federal regulations to implement section 403(d) of the act.

The agency's earlier decisions not to implement general or individual regulations concerning slack-fill or deceptive packaging were in relation to the efficient utilization of the agency's resources, not the adequate implementation of the intent of section 403(d) of the act. The provisions of the 1990 amendments require that the agency examine its implementation of section 403(d) of the act from a different perspective, i.e., not in terms of efficient use of resources but instead whether its regulations adequately implement the intent of section 403(d) of the act. Based upon the findings of IOM and its own review of the record, FDA concludes that section 403(d) of the act is not adequately being implemented.

8. One comment, without addressing whether the IOM recommendation concerning 403(d) of the act is correct, urged the agency to take whatever action is necessary to implement section 403(d) of the act adequately. The comment suggested that the agency consider using the definition for slack-fill that appears in section 5 of the FPLA. Another comment opposed the proposed determination that section 403(d) of the act is not being adequately implemented by FDA on the basis that the IOM report, in supporting its determination of inadequacy, does no more than suggest that FDA adopt some general regulations merely parroting the language of section 5(c)(4) of the FPLA which: (1) Authorizes FDA to adopt product-by-product regulations to prevent the nonfunctional slack-fill of packages when it finds such regulations are necessary to prevent the deception of consumers or to facilitate value comparisons, and (2) provides that a package shall be deemed to include nonfunctional slack-fill if it is filled to substantially less than capacity for reasons other than: (a) Protection of the contents of such package or (b) the requirements of machines used for enclosing the contents in such package. The comment argued that the adoption of a general regulation to implement statutory language of the FPLA would provide no further guidance to the agency, the public, or the industry than is now provided in the relevant case law under section 403(d) of the act and in the legal literature discussing nonfunctional slack-fill. Moreover, the comment argued, any attempt to write more specific requirements in a general slack-fill regulation would certainly founder on the widely different considerations that apply to different foods and different packages—as is graphically illustrated in the differing fill of container standards adopted by FDA.

The issue here is not how to adequately implement section 403(d) of the act, but whether it is being adequately implemented. Based on the evidence cited by IOM, FDA finds that the States have addressed fill of container matters that are not addressed by FDA's regulations. Therefore, FDA concludes that section 403(d) of the act is not adequately being implemented. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposal entitled "Misleading Containers; Nonfunctional Slack-fill" which is based on the FPLA definition for nonfunctional slack-fill but goes beyond it in ways that the agency has tentatively found to be appropriate to address the types of concerns that were raised by the latter comment. FDA urges that interested persons comment on that proposal.

3. Section 403(f)—Information of Appropriate Prominence

9. One comment stated that IOM was incorrect in recommending that FDA find that section 403(f) of the act is adequately being implemented. The comment stated that, although numerous regulations have been promulgated under this section, several important problems have not been addressed. For example, the comment cited the IOM report's concern that FDA's current regulations "do not provide as precise a definition of 'conspicuous' and 'prominent' as do some States." The IOM report had expressed concern that this lack of definition may place a greater enforcement burden on FDA. The comment submitted excerpts from "Guidelines for Document Designers," a product of the Document Design Project funded by the National Institute of Education as support for its concern on the readability of labels. The comment noted that there is no Federal regulation against obstructing important label information with, for example, price tags.

The agency disagrees with the comment. While FDA has not adopted as precise a definition for "conspicuous" and "prominent" as some States, the regulations adopted by FDA have specific requirements for placement of mandatory information such as product name, net weight, ingredients, and name and address of manufacturer with specifications for type size. FDA finds that these requirements adequately implement section 403(f) of the act. Although FDA has not explicitly enunciated definitions of "conspicuous" or "prominent", its regulations reflect the standard of prominence and readability in *United States* v. *46 Cases, More or Less, "Welch's Nut Caramels,"* 204 F. Supp. 321, 323 (D.R.I. 1962):

> * * * The Act prescribes no minimum specific standard as to how prominent such statements should be. It would seem that the requirements of said section 403(f) are met in a particular case if such statements are prominent enough to be seen and understood by the ordinary individual who is interested in discovering and learning the information disclosed thereby, and who makes the minimum examination of the package to determine its net weight and the ingredients of the candy contained in said package.

While studies on readability may suggest methods of highlighting label information, the question is whether or not the product meets the legal standard of being seen and understood by the ordinary individual. Section 101.1 requires that the principal display panel "shall be large enough to accommodate all the mandatory label information required * * * with clarity and conspicuousness and without obscuring design, vignettes, or crowding." Section 101.2 requires that all information that must appear either on the principal display panel or the information panel must be prominent and conspicuous, but in no case may the letters or numbers be less than one-sixteenth inch in height unless otherwise exempted. These requirements meet the legal standard by ensuring that the information can be seen and understood by the ordinary individual. Thus, while FDA has not chosen to implement section 403(f) of the act in the same way as some of the States, it has adequately implemented that section and established a strong standard.

As to the issue of obscuring label information, § 101.1 prohibits "obscuring design, vignettes, or crowding." The agency has not adopted more specific regulations regarding obscuring by price tags or other means because these tags are placed on the product at the retail level for the most part, and FDA does not have the resources to police individual food outlets across the nation. While the States do regulate at that level, FDA finds that the language of § 101.1 will give them an appropriate and adequate tool to address this problem.

4. Section 403(h)—Compliance With Standards of Quality and Fill

10. One comment set forth what it considered to be four major problems with IOM's conclusion that section 403(h) of the act is adequately being implemented. First, the comment argued that the statements that a product is substandard provided in § 130.14(a) and (b) (21 CFR 130.14(a) and (b)) do not adequately inform consumers of the reason the product is below standard. The comment suggested that FDA require an additional line in both statements to explain briefly the defect in quality or fill (e.g., similar to that which is provided in § 103.5(b) for bottled water, "contains excessive bacteria"). Secondly, the comment argued that the IOM's conclusion that section 403(h) is adequately being implemented should not be based on the fact that companies rarely use the statement "Below Standards in Quality," because it is equally plausible that companies are simply not complying with the requirement, or that there are insufficient substantive standards of quality, fill, and identity to make this determination. Thirdly, the comment stated that IOM's reliance on the lack of court cases involving section 403(h) of the act is not a valid criterion for determining whether the section is adequately being implemented because it is possible that FDA simply does not enforce this section. Finally, the comment argued that IOM did not consider the adequacy of the substantive standards themselves (i.e., the standards of identity, quality and fill) in determining whether section 403(h) of the act is adequately implemented.

Under section 403(h) of the act, a food is considered misbranded if it purports to be or is represented to be a food for which either a standard of quality or fill of container has been prescribed by regulations under section 401 of the act, and its quality or fill falls below such standards. The purpose of the disclosure requirements in § 130.14 (21 CFR 130.14) is simply to permit manufacturers, if they so choose, to sell a product that is not in compliance with section 403(h) of the act because of inadvertent manufacturing error.

The agency points out that the lack of an additional line in the disclosure statement explaining the defect in quality and fill is not germane to determining whether section 403(h) of the act is adequately being implemented for purposes of section 6(b) of the 1990 amendments. Under section 6(b) of the 1990 amendments, the standard that FDA is to use in determining the adequacy of its implementation of section 403(h) of the act is whether States or localities have adopted laws or regulations to implement requirements of this type that address matters not covered by FDA's regulations. Neither the comment nor the IOM report have shown that there are matters with respect to standards of quality or fill covered by States laws that FDA is not addressing.

With respect to the fact that companies rarely use the disclosure statements (e.g., "Below standard in fill"), the comment offered no evidence, nor is FDA aware of any such evidence, to substantiate that its claim that companies are not complying with section 403(h) of the act is in fact true. FDA's compliance efforts have not produced any evidence to this effect. Therefore, FDA can give no credence to this argument.

The agency notes that the lack of court cases involving section 403(h) of the act is not germane to determining whether this section is adequately being implemented. As noted elsewhere in this document, enforcement is not a criterion for making a determination of adequate implementation.

The last argument put forth by the comment is also not germane because the sufficiency of individual standards is not at issue in determining whether

the agency is adequately implementing section 403(h) of the act.

Therefore, FDA rejects the comment and concludes that section 403(h) of the act is adequately being implemented by its regulations.

5 Section 403(i)(1)—Common or Usual Name

11. One comment stated that the language of the IOM report contradicts IOM's conclusion that section 403(i)(1) of the act is adequately being implemented. The comment stated that the fact that the food industry continues to develop new foods for which no regulated common or usual name exists is evidence that section 403(i)(1) of the act is not adequately being implemented. The comment noted that the areas examined by IOM, i.e., bottled water, honey, fish, oriental noodles, Vidalia onions, and wild rice, are indicative of the fact that State standards offer more consumer protection than Federal standards.

The agency disagrees with the comment. The general regulation for common or usual names (§ 102.5 (21 CFR 102.5)) provides general principles that direct how to name any new food for which an individualized common or usual name regulation or standard of identity does not exist. Section 102.5 provides that:

> The common or usual name of any new nonstandardized food, which may be a coined term, shall accurately identify or describe, in as simple and direct terms as possible the basic nature of the food or its characterizing properties or ingredients. The name shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name.

In addition, § 102.5 requires that "each class or subclass of food shall be given its own common or usual name that states in clear terms, what it is in a way that distinguishes it from different foods." Section 102.5 also includes percentage labeling requirements for characterizing ingredients in certain foods. It provides that a common or usual name of a food may be established by regulation in 21 CFR part 102, Subpart B (Requirements for Specific Nonstandardized Foods), in 21 CFR part 104 (Nutritional Quality Guidelines for Foods), in a standard of identity regulation (21 CFR part 131 through 169), or in other regulations in Chapter I of Title 21 of the Code of Federal Regulations. It also states that a common or usual name of a food may be established by common usage.

The agency disagrees with the comment's statement that the specific common or usual name examples cited in the comment are indicative that State standards are stronger than Federal standards. The IOM report identifies several foods, including the six mentioned in the comment, for which States had common or usual name requirements but for which there were no Federal requirements. FDA finds, as did IOM, that each of IOM's examples represents a situation that either is not subject to section 403A of the act or calls for a state petition for exemption from preemption under section 403A(b), and that these examples do not demonstrate that the requirements of FDA's regulations do not adequately implement section 403(i)(1) of the act.

The agency notes that of the products cited by the comment, only three would be candidates for a common or usual name regulation. Wild rice, Vidalia onions, and fish. With respect to wild rice, IOM did state in its report that there was a potential for consumer fraud through substitution and blending of the more expensive wild rice with other cheaper rice products. However, the agency has no data, nor was any submitted, to confirm that this in fact is the situation in the marketplace. Moreover, the agency does not believe establishing a specific common or usual name regulation for wild rice would necessarily give the consumer any more protection than is currently provided by § 102.5 While the agency is not persuaded that there is a consumer fraud problem with wild rice, it would certainly entertain a citizen petition to establish a specific common or usual name regulation if a proper case is presented that demonstrates that there is a problem and a regulation is needed.

IOM also concluded that the Georgia State requirement for Vidalia onions appears to be predominantly protectionist in that no specific justification is provided for limiting the source to the defined producing locality The agency concurs with IOM's assessment and, therefore, concludes that a specialized Federal common or usual name regulation for this product is not necessary Again, while FDA believes that § 102.5 adequately provides for the naming of this product, it would have no objection to the State of Georgia or any other group or industry submitting a citizen petition to FDA to establish a specific common or usual name regulation for Vidalia onion based on measurable geographical, botanical, or quality criteria that differentiates it from other varieties or species of onion.

With respect to fish, FDA has issued "The Fish List FDA Guide to Acceptable Market Names for Food Fish Sold in Interstate Commerce 1988" to provide acceptable market, scientific, and common names for a wide range of common species. The agency believes, as did IOM, that The Fish List provides order to the marketplace. FDA also has Compliance Policy Guides (CPG's) for "red snapper" and for surimi-based (minced fish) imitation crab and other fish substitutes (CPG 7108.04 and 7108.16, respectively). The agency believes that The Fish List and the various CPG's more than adequately protect the consumer from fraud, while establishing specific common or usual name regulations for the many species of fish would be beyond the agency's resources and would not result in an appreciable reduction in consumer fraud. Anyone who believes a specific common or usual name regulation is needed for a particular species of fish may, of course, submit a citizen petition with appropriate justification as to why such action is warranted.

Bottled water, honey, and oriental noodles were also cited by the comment as products examined by IOM. Oriental noodles have compositional requirements, and, therefore, any regulations promulgated by FDA for this product would be in the form of a standard of identity regulation. Food standards are promulgated under the authority of section 401 and 403(g) of the act, not section 403(i)(1). The agency further notes that it has issued a compliance policy guide for oriental noodles (CPG 7102.02: Chow Mein Noodles, Chinese noodles, and other Oriental Noodles; Labeling). The agency believes that the CPG for oriental noodles more than adequately protects the public from consumer fraud. Again, the agency would not object to any interested persons submitting a citizen petition to establish a standard of identity for oriental noodles. The agency notes that it is currently considering a citizen petition from the International Bottled Water Association requesting that FDA regulate bottled water The agency hopes to take action on this petition by the end of this year

Thus, FDA concludes that it does have a strong and adequate regulatory system in place to implement section 403(i)(1) of the act. Therefore, the agency accepts IOM's recommendation and rejects the comment on this point.

6. Section 403(k)—Declaration That the Product Contains Artificial Flavoring, Coloring, or Preservatives

12. One comment argued that section 403(k) of the act is not adequately being implemented because there are several areas where FDA's current regulations fall short. As examples the comment

noted that current regulations: (1) Do not require all artificial flavorings in foods to be specifically identified on the label by their common or usual name (the comment stated that artificial flavorings can be listed as "flavorings"), (2) do not give consumers that are sensitive to monosodium glutamate (MSG) or sulfites sufficient label information to be able to avoid these substances, and (3) do not require labeling to reflect the percentage of each type of ingredient (e.g., the term "natural and artificial flavoring" can be used for a product which has 5 percent artificial and 95 percent natural flavoring and vice versa) when both natural and artificial coloring and flavoring are used in a food.

The agency disagrees with the comment. The premise of the comment is based upon a faulty interpretation of the requirements of section 403(k) of the act, of the agency's implementation of those requirements, and of IOM's report. The issues being raised by this comment would require fundamental statutory changes.

With regard to the first point, although they are separate requirements, section 403(i)(2) and (k) of the act must be read together. Section 403(i)(2) of the act requires the listing of the ingredients of a food by their common or usual names except that spices, flavorings, and color additives not required to be certified under section 706(c) of the act may be designated as spices, flavorings, and colorings without naming each (see also section 403(g)). Section 403(k) of the act provides that a food shall be deemed to be misbranded if it bears or contains any artificial flavorings unless it bears labeling stating that fact. FDA has implemented and amplified the requirements of section 403(k) of the act in § 101.22(h), which provides that the label of a food to which a flavor is added shall declare the flavor in the statement of ingredients as "artificial flavor" or "natural flavor" or any combination thereof, as the case may be.

Thus, contrary to the comment's assertion, FDA does not have the legal authority to require that artificial flavorings be listed by their common or usual name. However, again contrary to what the comment asserted, FDA has required that artificial flavorings be designated by the term "artificial flavoring."

The agency notes that the comment's concerns about the need for sensitive individuals to have sufficient label information to be able to avoid substances such as MSG and sulfites and the lack of percentage labeling of artificial and natural flavorings when both are used in food are not germane to whether section 403(k) of the act is adequately being implemented. To the extent that MSG, sulfites, or other substances that cause food sensitivities are flavorings, section 403(k) of the act would not require that they be declared in a way that would permit consumers to avoid them. FDA regulations do require that sulfites that are present in detectable amounts are declared on the food label (see § 100.100(a)(4) and the document on ingredient labeling published elsewhere in this issue of the **Federal Register**), however, FDA adopted this requirement under other provisions of the act. Similarly, percentage labeling requirements are outside the scope of section 403(k) of the act, which requires only that the presence of artificial flavorings (or artificial colors or chemical preservatives) be declared on the label. Section 101.22(h)(1) of FDA's regulations set forth how the addition of both articifial and natural flavorings to a food is to be declared. Therefore, the agency rejects the comment on this point.

Having considered the comments, the IOM report and other available information, FDA finds that section 403(k) of the act is being adequately implemented.

D. Procedural Issues

13. One comment argued that the agency's failure to present more than a conclusionary acceptance of IOM's recommendations did not provide the agency's views on the decision as to which sections were adequately being implemented.

The agency disagrees. The agency explicitly stated its tentative conclusions as to those sections that were adequately being implemented, and those that were not, were based on the recommendations of IOM and all of the information that IOM supplied to the agency as a result of the contract between FDA and IOM (57 FR 33283 at 33285). The July 28, 1992, proposal announcing the proposed lists discussed in detail the approach taken by IOM and the criteria that it used to determine adequate implementation. The notice summarized the basis for IOM's recommendations with respect to each section of the act (57 FR 33283 at 33284 through 33285). All the comments and other information considered by IOM, along with its draft final manuscript and final report, were placed on public display for all interested persons to review.

FDA's presumptive tentative acceptance of IOM's recommendations was fully consistent with the 1990 amendments and with the Administrative Procedure Act. Section 6(b)(3)(A) of the 1990 amendments directs the agency to publish the proposed lists as determined under the contract with a public or nonprofit private entity, which turned out to be IOM. This is eactly what the agency did. Moreover, § 10.40(b) (21 CFR 10.40(b)), FDA's regulation that implements the Administrative Procedure Act on informal rulemaking, states that the proposal shall act out the terms or substance of the proposed action and summarize the facts and policy that underlie it. Again, the July 28, 1992, proposal fully complies.

Thus, the agency finds that it provided adequate notice for all persons interested in this rulemaking as to the basis for its tentative determinations of adequacy of implementation.

III. Economic Impact

FDA has examined the economic implications of the final lists as required by Executive Orders 12291 and 12612 and the Regulatory Flexibility Act. Executive Order 12291 compels agencies to use cost-benefit analysis when making decisions, and Executive Order 12612 requires Federal agencies to ensure that Federal solutions, rather than State or local solutions, are necessary. The Regulatory Flexibility Act requires regulatory relief for small businesses where feasible. The agency finds that this final rule is not a major rule as defined by Executive Order 12291. In accordance with the Regulatory Flexibility Act (Pub. L. 96–354), FDA has also determined that this proposed rule will not have a significant adverse impact on a substantial number of small businesses. Finally, because these lists implement a statute that provides for preemption of State and local laws in specified circumstances, FDA finds that there is no substantial federalism issue that would require an analysis under Executive Order 12612.

A. Alternatives

The primary alternatives available to FDA were as follows:

1. Accept recommendation of IOM report
2. Reject recommendation of IOM report

B Costs

1 Accept Recommendation of IOM Report

By accepting the recommendation of the IOM report, FDA is legally required to publish regulations that ensure that section 403(d) of the act is adequately implemented. The compliance costs imposed by FDA's acceptance of this

legal obligation depend on the regulations that FDA promulgates to fulfill this obligation. One possible regulation that FDA might promulgate simply repeats the language of section 403(d) of the act. The compliance cost of this regulation would be zero because section 403(d) is already legally binding on food package manufacturers. If more restrictive regulations are promulgated, then compliance costs may occur. Potential compliance costs to industry include designing and manufacturing new packages. FDA has estimated the cost of implementing the regulations in the proposal on misleading containers that is published elsewhere in this issue of the **Federal Register**.

2. Reject Recommendation of IOM Report

If FDA had rejected the recommendation of the IOM report, then FDA could have made one of the following decisions: (1) Find that all sections of the act defining circumstances in which a food is misbranded are adequately implemented, or (2) find that one or more sections of the act defining circumstances in which a food is misbranded other than section 403(d) are not adequately being implemented.

If all relevant sections of the act had been found to be adequately implemented, then compliance costs would have been zero. If one or more sections of the act defining circumstances in which a food is misbranded other than section 403(d) had been found to be not adequately implemented, then compliance costs may have occurred. One possible regulation that FDA might have promulgated in the latter case would have simply repeated the language of the relevant sections of the act. The compliance cost of this regulation would have been zero because these sections of the act are already legally binding on food package manufacturers. If more restrictive regulations are promulgated, then some compliance costs may be incurred.

C. Benefits

1. Accept Recommendation of IOM Report

By accepting the recommendation of the IOM report, FDA is legally required to publish regulations that ensure that section 403(d) of the act is adequately implemented. One possible regulation that FDA might promulgate simply repeats the language of section 403(d) of the act. The benefit of this regulation would be zero because section 403(d) of the act is already legally binding on food package manufacturers. If more restrictive regulations are promulgated, then there may be positive benefits. The potential benefit of more restrictive regulations would be a reduction in consumer dissatisfaction with the fill of food containers. FDA has estimated the benefits of implementing regulations in the proposal on misleading containers that is published elsewhere in this issue of the **Federal Register**.

2. Reject Recommendation of IOM Report

If FDA had rejected the recommendation of the IOM report, then FDA could have made one of the following decisions: (1) Find that all sections of the act defining circumstances in which a food is misbranded are adequately implemented, or (2) find that one or more sections of the act defining circumstances in which a food is misbranded other than section 403(d) of the act are not adequately being implemented.

If all relevant sections of the act had been found to be adequately implemented, then benefits would have been zero. If one or more sections of the act defining circumstances in which a food is misbranded other than section 403(d) had been found to be not adequately implemented, then there may have been positive benefits. One possible type of regulation that FDA might have promulgated in this case would have simply repeated the language of the relevant section of the act. The benefit of this type of regulation would have been zero because these sections of the act are already legally binding on food package manufacturers. Thus the benefits of this alternative would have been estimated to be zero. If more restrictive regulations had been promulgated, then there may have been positive benefits.

D. Conclusion

In accordance with Executive Order 12291, the agency has analyzed the economic effects of this proposed rule and has determined that this rule, if promulgated, will not be a major rule as defined by that order.

In accordance with the Regulatory Flexibility Act, the agency has considered the effect that this regulation would have on small entities including small businesses and has determined that this final rule will not have a significant economic impact on a substantial number of small entities.

The costs and benefits of this final rule depend on the regulations that FDA produces in response to the requirement that it promulgate regulations ensuring the adequate implementation of sections of the act that it finds are not adequately being implemented. The costs and benefits of those regulations will be zero if those regulations simply repeat the language of the relevant sections of the act. As noted above, the costs and benefits of implementing regulations are considered in the proposal on misleading containers.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Final Lists

Based on its review of the IOM report, the comments to the July 28, 1992 proposal, and other available information, the agency is announcing its conclusions related to the adequacy of Federal implementation of sections 403(b), 403(d), 403(f), 403(h) 403(i)(1), and 403(k) of the act. FDA finds that the following sections are adequately implemented by FDA regulations: sections 403(b), 403(f), 403(h), 403(i)(1), and 403(k) of the act. Based upon the same considerations, FDA finds that section 403(d) of the act on misleading containers is not adequately being implemented by FDA regulations.

Having made these findings, FDA advises that section 403A(a)(3) of the act and section 6(b)(3)(B) of the 1990 amendments provide that no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce any requirement for the labeling of food of the type required by sections 403(b), 403(f), 403(h), 403(i)(1), or 403(k) of the act that is not identical to the requirement of such section, effective February 5, 1993.

Published elsewhere in this issue of the **Federal Register** is a proposal entitled "Misleading Containers; Nonfunctional Slack-Fill," in which FDA is proposing revisions of its regulations to ensure adequate implementation of section 403(d) of the act. Upon the effective date of the final regulations based upon that proposal, no State or local subdivision of a State may establish or continue in effect any requirement that is not identical to the requirements of section 403(d) of the act and regulations issued thereunder. If the agency does not issue final regulations in response to the proposal by May 8, 1993, the proposed regulations will be

considered the final regulations under the 1990 amendments, and preemption will become effective on the effective date of the rules that, on May 8, 1993, are considered final rules.

Dated: November 5, 1992.

David A. Kessler,

Commissioner of Food and Drugs

Louis W. Sullivan,

Secretary of Health and Human Services

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 20 and 101

[Docket No. 85N-0061]

RIN 0905-AB67

Food Labeling; General Requirements for Health Claims for Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is adopting general requirements pertaining to: (1) The use of health claims that characterize the relationship of a substance to a disease or health-related condition on the labels and in labeling of foods in conventional food form (conventional foods), and (2) the content of petitions regarding the use of such health claims pertaining to specific substances in such food. This action is being taken in response to provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) that bear on health claims for conventional foods. However, in the Dietary Supplement Act of 1992 (the DS Act), Congress imposed a moratorium on the implementation of the 1990 amendments with respect to dietary supplements with only very limited exceptions. Therefore, these final rules do not apply to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances. Elsewhere in this issue of the **Federal Register**, FDA is issuing final rules that respond, at least with respect to conventional foods and, to the extent that they would permit claims, with respect to dietary supplements, to the 1990 amendments' directive that the agency consider 10 topics associating substances with diseases or health-related conditions. Those final rules have been developed in accordance with the general principles of the requirements in this document.

EFFECTIVE DATE: May 8, 1993, except § 101 9(k)(1) which will become effective February 14, 1994, and §§ 101.14(d)(2)(vii)(B) and 101.14(d)(3) concerning restaurant firms consisting of 10 or less individual restaurant establishments for whom these sections will become effective on May 8, 1994.

FOR FURTHER INFORMATION CONTACT: Victor P Frattali, Center for Food Safety and Applied Nutrition (HFF-261), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4064.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 27, 1991 (56 FR 60537), FDA published a proposed rule to establish general requirements pertaining to: (1) The use of health claims that characterize the relationship of a substance to a disease or health-related condition on the labels and in labeling of both conventional foods and dietary supplements, and (2) the content of petitions regarding the use of such health claims pertaining to specific substances in food. The proposed rule was issued in response to provisions of the 1990 amendments (Pub. L. 101-535) that bear on health claims. With respect to health claims, the 1990 amendments amend the Federal Food, Drug, and Cosmetic Act (the act) by adding a provision (section 403(r)(1)(B) of the act (21 U.S.C. 343(r)(1)(B))) that provides that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition, unless the claim is made in accordance with section 403(r)(3) or (r)(5)(D).

Congress enacted the health claims provisions of the 1990 amendments to help U.S. consumers maintain healthy dietary practices and to protect these consumers from unfounded health claims. The House Report of June 13, 1990, states, "Health claims supported by a significant scientific agreement can reinforce the Surgeon General's recommendations and help Americans to maintain a balanced and healthful diet" (Ref. 1). Senator Orrin Hatch, one of the primary authors of the 1990 amendments, noted that diet has been implicated as a factor in the three leading causes of death (heart disease, cancer, and stroke) (Ref. 2). In addition, the statement of the House Floor Managers noted that "There is a great potential for defrauding consumers if food is sold that contains inaccurate or unsupportable health claims" (Ref. 3). The House Report characterized the need for regulation as "compelling" (Ref. 1).

FDA's first step in support of the congressional goals of the 1990 amendments appeared in the form of the proposed health claims regulation. The proposed regulation contained: (1) Definitions to clarify the meaning of specific terms used in the regulation; (2) preliminary requirements that a component of food must meet to be eligible to be the subject of a health claim; (3) a scientific standard for assessing the validity of claims both for dietary supplements and for conventional food, general labeling requirements for health claims that are permitted by regulation, and prohibitions on certain types of health claims; and (4) the required content of petitions for health claims.

In response to the proposed rule, FDA received over 6,000 letters, each containing one or more comments, from consumers, health care professionals, universities, State and local governments, foreign governments, trade organizations, consumer advocacy organizations, research institutes, industry, and professional organizations. In addition to receiving these written comments, the agency held a public hearing on January 30 and 31, 1992 (57 FR 239, January 3, 1992), on a number of food labeling issues, including the requirements for health claims. Some of the comments agreed with one or more provisions of the proposed rule without providing further grounds for support other than those presented by FDA in the preamble to the proposal. Other comments disagreed with one or more provisions of the proposed rule without providing specific grounds for the disagreement. A few comments addressed issues outside of the scope of the regulations and will not be addressed in this document. Most of the comments provided specific grounds in support of their positions concerning provisions of the proposed regulations. The agency has summarized and addressed the issues raised in the sections of this document that follow.

In October 1992, the DS Act was enacted. This statute states that, with certain limited exceptions, the Secretary (and FDA, by delegation) may not implement the 1990 amendments with respect to dietary supplements earlier than December 15, 1993. As a result, this final rule applies only to conventional food (Ref. 34). The DS Act establishes a timetable for the adoption of final rules implementing the 1990 amendments with respect to dietary supplements by December 31, 1993. One exception to the moratorium on the implementation of the 1990 amendments is a provision (section 202(b)) that states that FDA may, earlier than December 15, 1993, approve claims with respect to dietary supplements that are claims described in clauses (vi) and (x) of section 3(b)(1)(A) of the 1990 amendments. FDA is responding to this provision in the documents on the 10 specific substance-disease topics that accompany this final rule.

II. Definitions

FDA proposed definitions for "health claim," "substance," "nutritive value," and "dietary supplement" to serve as tools for clearly establishing the scope of the types of claims that would be

subject to the regulations promulgated under section 403(r)(1)(B) of the act. In addition, the agency proposed a definition for "disqualifying nutrient levels" to establish limits on the amounts of certain nutrients that are known to increase the risk of disease that can be in a food if that food is to bear a health claim in its labeling.

A. Definition of a Health Claim

As proposed, § 101.14(a)(1) stated:

Health claim means any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including "third party" endorsements, written statements (e.g., a brand name including a term such as "heart"), symbols (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition. Implied health claims include only those statements, symbols, vignettes, or other forms of communication that a manufacturer intends, or would be likely to be understood, to assert a direct beneficial relationship between the presence or level of any substance in the food and a health or disease-related condition.

(56 FR 60537 at 60563)

As was explained in the preamble of the proposal (56 FR 60542), FDA derived this definition almost directly from the provisions of section 403(r)(1)(B) of the act. The proposed definition establishes that a claim must have at least two basic elements for it to be regulated as a "health claim." First, the claim must be about a "substance" as that term is defined in proposed § 101.14(a)(2). Secondly, the claim must characterize the relationship of the substance to a "disease or health-related condition." If a claim has one of these elements without the other, it would not be a "health claim," although it may still be subject to regulation under other provisions of the act (e.g., the requirement of section 403(a)(1) of the act that a label statement be truthful and not misleading).

Although FDA attempted in the proposed definition of a "health claim" to draw clear lines between health claims and other types of claims about diet and health, comments raised significant questions about the applicability of one or both of the elements highlighted in the definition. Many of these questions resulted because, at the time that it issued the proposal, FDA had not itself decided on the precise coverage of the definition. For example, in the proposal (56 FR 60537 at 60542), FDA stated:

While the act focuses on the substance-disease relationship, it is clear that the Congress was concerned about any disease claims that are made on food (Ref. 1). In reviewing the evidence on the 10 topic areas, however, FDA has become aware that there may be certain relationships between foods and diseases that are supported by the available evidence but that cannot be attributed to a particular nutrient. For example, the scientific evidence shows that diets high in whole grains, fruits, and vegetables, which are low in fat and rich sources of fiber and certain other nutrients, are associated with a reduced risk of some types of cancer. The available evidence does not, however, demonstrate that it is total fiber, or a specific fiber component, that is related to the reduction of risk of cancer. The question is thus whether, to fulfill Congress's intent in the 1990 amendments, FDA should regulate claims about apparent food-disease relationships and, if so, how it should do so.

In response to comments questioning the meaning of the proposed definition of a "health claim," the agency has sought to clarify this definition as well as the meaning of the terms "substance" and "disease or health-related condition."

B. Substance—The First Basic Element

As proposed, § 101.14(a)(2) stated:

Substance means a component of a conventional food or of a dietary supplement of vitamins, minerals, herbs, or other nutritional substances.

1. Some comments maintained that because section 403(r)(1)(B) of the act specifically addresses only a claim that characterizes the relationship of any nutrient required to be on the label of a food to a disease or health-related condition, claims about other types of nutrients or about foods are not subject to the provisions of section 403(r). Many of these comments contended that claims about foods and other types of claims must be controlled under the general regulatory regime that requires that a label be truthful and not misleading, and they maintained that FDA could not therefore require preapproval of such claims.

However, other comments stated that Congress intended to control claims about foods as well as nutrients. One comment pointed out that people do not eat nutrients as such; they eat foods that contain (or do not contain) those nutrients. Another comment advised that consumers would more readily understand claims about foods than about nutrients, and that where food claims were appropriate, consumers might be more likely to improve their diets. One comment stressed that FDA has historically defined "substance" expansively, asserted that this policy should not be changed, and suggested that the definition of "substance" should be consistent with the wording of § 170.3(g) (21 CFR 170.3(g)), which defines "substance" as including "a food or food component consisting of one or more ingredients." A few comments pointed out that an understanding of Congress' intent can be obtained by considering the legislative history of the 1990 amendments. One comment advised that, before the enactment of these amendments, Congress considered a great deal of testimony about how health claims should be related to an overall diet of various foods. For example, a representative from one professional organization told the House of Representatives in a hearing on the bill that ultimately became the 1990 amendments (Ref. 24) that health claims should be compatible with the dietary recommendations of the National Research Council's (NRC's) report "Diet and Health: Implications for Reducing Chronic Disease Risk" (the Diet and Health report) (Ref. 6). That NRC report recommends that people eat five or more servings per day of vegetables or fruits and increase their intake of starches and complex carbohydrates. This recommendation is tied to the conclusion that "Diets high in plant foods—i.e., fruits, vegetables, legumes, and whole-grain cereals—are associated with a lower occurrence of coronary heart disease and cancers of the lung, colon, esophagus, and stomach."

In addition, the comment stated that this theme was echoed by the American College of Physicians, which told the House in a prepared statement that the NRC, the Surgeon General, and other organizations "recommend a reduction in fat and an increase in complex carbohydrates and fruits and vegetables in order to reduce the risk of these cancers." Further, the comment advised that the Senate hearing held on November 13, 1989, before the Committee on Labor and Human Resources (Ref. 25), also included significant testimony about the overall health benefits of foods. For example, an official with the American Dietetic Association told the Senate that that organization supported the dietary recommendations of NRC and the Surgeon General, and that health claims should reflect those recommendations and "should assist the public to integrate specific food products into a well-balanced diet." Thus, the comment maintained that both the House and the Senate had before them a record in which various private and public health organizations endorsed the linking of health claims to foods consumed as part of an overall diet, an endorsement validated by repeated references to the dietary recommendations of the NRC and the Surgeon General, sources that FDA has considered authoritative.

Another comment stated that the congressional debates reveal an equal, if not a greater, concern for the health benefits of foods, as opposed to nutrients, and that this concern makes sense when one considers that many public and private health organizations recommend obtaining an adequate nutrient intake through the consumption of a variety of foods. The comment pointed out that it is clear that during the debates over the 1990 amendments, Congress drew no distinction between foods and nutrients. The comment cited a variety of statements from the Congressional Record to substantiate its contention. For example, the comment pointed out that Senator John Chafee of Rhode Island, cosponsor of S. 1425 (the Senate's version of the bill that became the 1990 amendments), said that the proposed legislation would provide definite guidelines governing "the claims and statements that can be made about food" (Ref. 26). Similarly, Senator Orrin Hatch of Utah, cosponsor of the Senate amendments to the House's version of the 1990 amendments, viewed the bill as covering health and diet-related claims about food products (Ref. 2).

FDA does not agree that section 403(r)(1)(B) of the act addresses health claims for only those nutrients required to be on the label of a food and does not include claims about other types of nutrients. The language of section 403(r)(1)(B) of the act is clear in that it pertains to a claim that "* * * characterizes the relationship of any nutrient which is *of the type* required by paragraph (q)(1) or (q)(2) to be in the label or labeling of a food * * *" (emphasis added). Section 403(q)(1) of the act lists specific nutrients that are required for food labeling as part of nutrition labeling. Section 403(q)(2) of the act permits the Secretary of Health and Human Services (the Secretary) to include by regulation any other nutrient not required to be listed by section 403(q)(1) if information about the nutrient will assist consumers in maintaining healthy dietary practices. Moreover, section 403(r)(5)(D) of the act relates to vitamins, minerals, herbs, or other similar substances. Thus, claims relating to a broad range of substances are potentially subject to regulation under section 403(r)(1)(B) of the act, and claims about a nutrient-disease relationship are not outside the coverage of section 403(r) simply because the nutrient in question is not required to be listed in the nutrition label. For these reasons, FDA is retaining the broader term "substance" in the regulations and will use it in this preamble.

In fact, FDA agrees with the comments that contended that the proposed rule interpreted the 1990 amendments too narrowly with respect to the regulation of claims about foods. The agency has reviewed the legislative history of the 1990 amendments and concluded that this history does indeed contain evidence to support the conclusion that Congress intended that foods could be the subject of claims that are regulated under section 403(r) of the act. However, this legislative history also makes clear that, to be subject to section 403(r) of the act, a claim about a food must be, at least by implication, a claim about a substance in the food. The House Report (Ref. 1) states:

> The requirement applies to any disease claim that is made with respect to required nutrients and other nutrients in food. However, a statement about the importance of good nutrition which does not make a direct or implied connection between any nutrient in the food and a particular disease is not necessarily a disease claim that will be covered by this section.

Thus when a consumer could reasonably interpret a claim about the relationship of a food to a disease or health-related condition to be an implied claim about a substance in that food, that claim would satisfy the first element of a health claim.

However, a claim about the benefits of a broad class of foods that does not make an express or implied connection to any of the substances that are found in foods that comprise that class would not constitute an implied claim. Such claims about classes of foods (e.g., fruits and vegetables) are not health claims because they are not about a substance.

Accordingly, FDA has revised the definition of "substance" in new § 101.14(a)(2) to include a specific food as well as a component of food. Although, the agency's tentative view is that the term "substance" has the same meaning regardless of whether the food is a conventional food or a dietary supplement that includes vitamins, minerals, herbs, or other nutritional substances, in response to the DS Act, FDA is not reflecting this view in the final regulation. FDA will decide whether to do so in the rulemaking it will undertake in response to the DS Act. For consistency with the revised definition of "substance," new § 101.14(d)(2)(vii) has also been revised, as explained in section V.E. of this preamble, to provide guidance for identifying the appropriate dietary intake of a specific food necessary to achieve the claimed effect.

FDA has not modified new § 101.14(a)(2) to be identical to § 170.3(g). However, new § 101 14(a)(2) and § 170.3(g) are fully consistent, and any differences in their wording reflect the different contexts to which they apply. The definition of "substance" in § 170.3(g) is specific to the definition of the term "food additive," and in that context it is appropriate because of the statutory definition of "food additive" as "any substance the intended use of which results or may reasonably be expected to result * * * in its becoming a component or otherwise affecting the characteristics of any food." (See section 201(s) of the act (21 U.S.C. 321(s))). Proposed § 101.14(a)(2) was drafted to reflect the broad coverage of section 403(r)(1)(B) of the act. Importantly, a substance under § 170.3(g) would also be a substance under new § 101.14(a)(2) and vice versa.

Under the revised definition of a substance that FDA has included in new § 101.14(a)(2), phrases on labeling such as "eat apples to ———," "eat low sodium foods to ———," "eat fruits high in fiber to ———," or "cook with garlic to———" would constitute references to a substance and would thereby satisfy one of the two essential elements of a health claim. However, phrases on labeling such as "eat a variety of foods to ———," "eat a variety of fresh fruits and vegetables to ———," or "follow the food pyramid to ———," without any reference, either express or implied, to a substance that might be in the foods, would not satisfy this element. The latter types of claims would not be subject to regulation as health claims. Of course, such claims would still be subject to the requirement in section 403(a) of the act that they be truthful and not misleading.

C. Disease or Health-Related Condition—Second Basic Element

As mentioned previously in this preamble, the proposed definition of "health claim" contains two basic elements, "substance" and "disease or health-related condition," that must be present for a claim to be a "health claim." FDA did not define the phrase "disease or health-related condition" in the proposal. This omission raised many questions and concerns in the comments.

2. Many comments objected that FDA's interpretation of the phrase "health-related" could be too broad. One comment was concerned that FDA might interpret the phrase to apply to statements pertaining to general good health. The comment noted that food itself sustains life, so the mere

identification of a product as a food is to that extent a "health-related" claim.

Another comment argued that such phrases as "invigorating," "relaxing," "stimulating," "feel better," "enjoy a good night's sleep," and "perform at your best" should be exempt from regulation because they do not refer to a disease. A few comments contended that claims about relationships between nutrients and the structure or function of the body (e.g., "this calcium fortified product helps build strong bones") should not be considered health claims.

Some of the comments suggested that the definition of a "health claim" should refer only to "disease" or "disease-related" claims because such a characterization more accurately reflects the nature of claims regulated by section 403(r)(1)(B) of the act. One comment asserted that the statutory phrase "a disease or health-related condition" does not set up two categories and maintained that the phrase "health-related" as used in the law appears to be nothing more than an expansion of the word "disease." The comment submitted a definition of the word "disease" from "Stedman's Medical Dictionary," (25th ed., p. 444, 1990), which states that a disease is "a morbid entity characterized by at least two of the following criteria: (1) Recognized etiologic agent(s), (2) identifiable group of symptoms, or (3) consistent anatomical alterations."

Although the legislative history of the 1990 amendments gives clear direction that Congress intended that health claims do include disease-specific claims, this history is not as explicit concerning what kind of claims are claims about a "health-related condition." As FDA pointed out in its response to the previous comment, Congress did, however, give clear direction that a statement about the importance of good nutrition that does not make a direct or implied connection between any substance in the food and a particular disease is not necessarily a disease claim that will be regulated as a health claim (Ref. 1). Thus, it is clear that Congress did not intend that all claims pertaining to general good health be considered health claims.

However, the inclusion of the phrase "health-related condition" in section 403(r)(1)(B) of the act in addition to the term "disease" leaves no question that Congress intended that claims about conditions other than diseases be regulated under this provision. Further, the legislative history of the 1990 amendments confirms this fact. In hearings before the Senate and the House of Representatives preceding the passage of the 1990 amendments, many references were made to two texts, the Diet and Health report by the NRC (Ref. 6) and "The Surgeon General's Report on Nutrition and Health" (the Surgeon General's report) (Ref. 5). In the former text (Ref. 6), a section entitled "Hypertension and Hypertension-Related Diseases" states the following:

> Deaths related to hypertension have been variously classified over recent years. They have either been considered as a separate entity or combined with such classes of atherosclerotic cardiovascular diseases as CHD and stroke. Thus, it is not useful to consider vital statistics alone in discussing the epidemiology of hypertension. Hypertension is treated here primarily as a risk characteristic of atherosclerotic cardiovascular diseases rather than a disease entity in itself.

Elsewhere in the Diet and Health report (Ref. 6), hypertension is defined as sustained, elevated arterial blood pressure measured by an inflatable cuff and pressure manometer. The text goes on to say:

> It [hypertension] has been clearly shown to increase the risk of developing stroke, coronary heart disease, congestive heart failure, peripheral vascular disease, and nephrosclerosis.

Further, the Surgeon General's report identifies high blood pressure as a common, chronic medical problem in the United States responsible for a major portion of cardiovascular disease. It then states that public health efforts have increased public awareness and knowledge of the risks and treatment of this condition (Ref. 5).

The repeated references in the legislative history to texts that place significant importance on the control of risk factors as a means of reducing the risk of disease persuades FDA that the agency should include such factors in any definition of a "health-related condition." In view of the explicitly stated intention of Congress to help Americans maintain a healthful diet (Ref. 1), Congress intended that the 1990 amendments facilitate communication to consumers of information about risk factors such as hypertension, which is a risk characteristic or factor for several diseases, including coronary heart disease and stroke. Accordingly, the agency concludes that the inclusion of "a health-related condition" in the coverage of section 403(r)(1)(B) of the act means that claims about risk factors related to disease, as well as claims about a disease, can be health claims.

Having reached this conclusion, FDA finds that one limitation on the coverage of the phrase "disease or health-related condition" is appropriate. The limitation is for claims about nutrient deficiency diseases. In the legislative history, Congress focused only on those health claims that related to chronic diseases affected by diet, such as cancer, heart disease, and osteoporosis. There is no indication that it intended to cover classical deficiency diseases (diseases resulting directly from a deficiency of a vitamin, essential mineral, or other essential nutrient). The relationships between nutrients and classical deficiency diseases are well-established. Moreover, such diseases are of little public health significance in this country. Under such circumstances, FDA believes that it would not be appropriate to subject such relationships to the health claims regime. Claims about such classical nutrient deficiency diseases are adequately regulated under the provisions of section 403(a) of the act and thus must be truthful and not misleading. However, as discussed in more detail further in this document, a claim about the benefits of vitamin D in preventing vitamin D deficiency, for example, would be misleading where the claim does not explain that few individuals in the United States are at risk of such a deficiency. Of course, some claims about such diseases may result in a product being regulated as a drug. Thus, claims about the administration of a nutrient either intravenously or nasally will be regulated as drug claims. This position is consistent with the position that the agency took in the February 13, 1990, proposal (55 FR 5176) with respect to nutrient deficiency diseases.

Therefore, to assist affected parties in clearly understanding what the second element of a health claim encompasses, FDA is adopting the following definition of "disease or health-related condition" in new § 101.14(a)(6):

> *Disease or health-related condition* means damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition (claims pertaining to such diseases are thereby not subject to §§ 101.14 or 101.70).

This definition does not differentiate between a "disease" and a "health-related condition." The two states are often so closely related that no bright-line distinction is practicable. Further, both states are regulated under section 403(r) of the act. Thus, there is no reason to separate one state from the other as long as both are covered.

FDA structured this definition primarily after the common sense definition of "disease" that appears in

the second edition of "Random House Dictionary of the English Language" (Random House, Inc., New York, NY, copyright 1987) without referring to examples of the causes of the dysfunctioning that were cited in that definition. For purposes of this rule, the agency did not pattern the definition after the one suggested in the comment because the clinical nature of the suggested definition would not be readily understandable. Thus, it is not suitable for use in a regulation.

The definition of "disease or health-related condition" would not generally encompass terms or phrases such as "invigorating," "relaxing," "stimulating," "feel better," and "perform at your best." Such terms would be covered under the regulatory regime of a label needing to be truthful and not misleading. Moreover, they may also subject the product to regulation under the structure or function of the body aspect of the "drug" definition (section 201(g)(1)(C) of the act). However, the definition would clearly encompass terms such as "osteoporosis," "heart disease," "cancer," and "high blood pressure."

For further clarification, the definition of "disease or health-related condition" is not considered by FDA to include a change in a biological parameter, such as a decrease in platelet (a type of blood cell that promotes blood coagulation) aggregation time or an increase in serum cholesterol, unless the parameter is associated with a disease or health-related condition, and there is evidence that altering the parameter can improve the condition. Of the two examples cited, high serum cholesterol is generally accepted as a predictor of risk for coronary heart disease, and there is evidence that decreasing high serum cholesterol can decrease that risk. For the health claim in new § 101.73, published elsewhere in this issue of the **Federal Register**, which associates dietary lipid intake with an increased risk of coronary heart disease, it may be appropriate, then, to permit as optional information a discussion of how dietary saturated fat, cholesterol, or both, affect blood cholesterol levels and, thereby, the disease that is the subject of the claim. Nevertheless, the agency considers it is inherently misleading for the claim to be articulated as an association between dietary lipids and serum cholesterol because of the potential to confuse consumers about the relevant disease for which the claim is authorized. It is not the biological indicator that is the disease or health-related condition for which the claim is authorized. Where there is no well-documented association or specificity between a biological parameter and a disease or health-related condition and some evidence that improving the parameter improves the condition, the agency will be disinclined to consider a petition for a health claim for that parameter because it fails to meet the definition of a disease or health-related condition.

3. Some comments asked if FDA intended to regard any statements that describe the "special dietary uses" of foods (e.g., hypoallergenic, lactose-free, wheat gluten-free, and dietetic foods) as health claims. The comments were concerned that health claim disqualifying levels would bar many such foods from disclosing dietary information. One of the comments requested that FDA revise the definition of a "health claim" to include advice that a statement in the labeling of a food subject to part 105 (21 CFR part 105) shall not be deemed to be a health claim solely because it represents the food to be for special dietary use.

FDA advises that any statement that appears on the label or in the labeling of a food intended for "special dietary use" that is consistent with provisions of the regulations promulgated under section 403(j) of the act will not be regulated as a health claim by the agency. Thus, such foods will not be subject to health claim disqualifying levels. However, FDA cautions firms that information not specifically provided for by specific regulations for foods for special dietary use may create an express or implied health claim and thereby subject such a food to the provisions of new § 101.14, including the disqualifying levels.

FDA has not revised the final rule to address foods subject to part 105 in the definition of "health claim." The requested revision is unnecessary in view of the agency advice in the previous paragraph. Further, the agency believes the requested revision might mislead some firms to assume that such foods would be exempt from the health claim provisions regardless of the nature of claims appearing in labeling where the claims are not specifically authorized in part 105. In addition, if FDA were to revise the final rule with respect to part 105, the rule should also be revised with respect to other provisions in the act and the regulations promulgated thereunder (e.g., infant formula subject to section 412 of the act (21 U.S.C. 350a)), and the agency does not believe that it would be appropriate to have the rule reference every other similar situation in the regulations in Title 21, Code of Federal Regulations.

D. Implied Health Claims

The agency proposed to define "implied health claim" as:

> * * * those statements, symbols, vignettes, or other forms of communication that a manufacturer intends, or would be likely to be understood, to assert a direct beneficial relationship between the presence or level of any substance in the food and a disease or health-related condition.

The agency then provided some examples of such claims—"third party" endorsements, written statements such as a brand name including a term such as "heart," and symbols such as a heart symbol.

1. General

4. Comments varied widely on whether FDA should regulate implied health claims. Some comments, noting the difficulty in specifically defining an implied health claim, suggested that implied health claims should not be regulated under the proposed regulations. One of these comments asserted that FDA could regulate implied health claims only under the general requirement that a label must be truthful and not misleading. However, other comments urged FDA to strictly regulate implied health claims because they have the potential to undermine the sound regulatory approach for explicit health claims.

FDA advises that there is no basis under the act for it not to regulate implied health claims. Regulation of such claims is specifically mandated. Under section 403(r)(1)(B) of the act, a food is misbranded if "* * * a claim is made in the label or labeling of the food which expressly *or by implication* * * *" (emphasis added) characterizes the relationship of any substance to a disease or health-related condition unless the claim is made in accordance with the health claims provisions of the act. Thus, FDA must reject the comments that suggested that it not regulate implied health claims.

5. While a number of comments encouraged FDA to take a broad view of what constitutes an implied claim, other comments argued that any "bright-line" definition of an implied health claim would be too inflexible to enforce fairly because labeling displays can have different meanings in different contexts. Some comments urged that both manufacturers' intent and consumer perception be considered in determining whether an implied claim has been made. One comment proposed that if vendor intent is not considered, then the test should be whether consumers acting reasonably under the circumstances would interpret language on labels or labeling in a particular

fashion and noted that such a test has been applied by the Federal Trade Commission (FTC) in the context of misleading advertising claims. The comment contended that the fact that a few credulous people may perceive a claim in a particular manner should not suffice if the vast majority perceive it otherwise.

FDA agrees that no "bright-line" definition can be established for implied health claims. Labeling claims need to be considered in their entirety and in context to determine if the elements of a health claim are present. FDA has therefore revised the definition of an implied health claim in new § 101.14(a)(1) to clarify that the claim will be evaluated within the context of the total labeling to determine if an implied health claim has been made.

FDA has also revised the list of the types of claims that may be implied claims. The agency has substituted the term "'third party' references" in place of the term "'third party' endorsements" because it has become clear that a third party endorsement is only one type of reference to a third party that may constitute a health claim in the context of the entire labeling. Further, FDA has corrected the phrase "health or disease-related condition" in the definition of an implied health claim in the last sentence in new § 101.14(a)(1) to "disease or health-related condition." FDA had intended to consistently use this latter phrase throughout proposed § 101.14(a)(1), but the terms "disease" and "health" inadvertently were interchanged in the proposal.

In the case of implied claims, FDA will evaluate all of the labeling to determine whether, within the context in which a claim is presented, both basic elements of a health claim are present. Where both elements are present in a product's labeling, the product bears a health claim, regardless of whether one or both of the basic elements are explicit or implied.

In making an evaluation of a claim within the context of the labeling, FDA agrees that it should consider both manufacturer's intent and consumer perception. However, the agency notes that intent means more than the manufacturer's subjective intent. Therefore, the agency concludes that the focus of its determination as to whether a claim is an implied claim should be on what the claim is saying. To be consistent with the definition of "implied nutrient content claim" in new § 101.13(b)(2) in the nutrient content claims document published elsewhere in this issue of the **Federal Register**, the agency is striking the phrase "* * * a manufacturer intends, or would be likely to be understood, to assert * * *" and is replacing it with the word "suggest" in the definition of a health claim in new § 101.14(a)(1). Section 101.14(a)(1) now reads:

> *Health claim* means any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including "third party" references, written statements (e.g., a brand name including a term such as "heart"), symbols (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition. Implied health claims include those statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition.

The agency believes that this will clarify what the agency's inquiry will be when it determines whether a claim is an implied claim.

FDA has not used the comment's proposed "reasonable person" test for deciding when a claim is implied. The regulation reflects the fact that courts have construed the act as protecting not just the reasonable person but also the "ignorant, the unthinking and the credulous." (See *United States* v. *an article * * * consisting of 216 cartoned bottles * * * "Sudden Change,"* 409 F.2d 734, 741 (2d Cir. 1969).) Given relevant case law construing the act, it is unnecessary to look to the standard applied by FTC for guidance.

2. Brand names

6. A number of comments asserted that all brand names containing words such as "heart" are inherently misleading and therefore should be banned. Other comments urged FDA to permit the use of words such as "heart" in the brand names of foods only when the food qualifies for an approved heart-related health claim. Other comments maintained that some brands that incorporate the word "heart" (e.g., Sweetheart) have been used for decades in a nonmisleading manner to convey an old-time, homey feeling and therefore should not be banned or construed to be an implied health claim.

FDA does not agree that all brand names containing words such as "heart" are inherently misleading. Certainly where this term is placed on a product that qualifies for an express health claim on cardiovascular disease that is provided for in part 101, subpart E, and where such a claim is appropriately included elsewhere in the labeling, consumers would not be misled by the term "heart." In addition, there may be situations in which, when considered within the context of the full labeling, the term cannot be reasonably understood to be a health claim (e.g., "sweetheart" or "from the heartland of America," where no claims about the fat, cholesterol, or sodium content of the food are made).

However, comments from several consumer, health professional, and regulatory organizations demonstrate that the use of the word "heart" in the brand name of a food may lead consumers to believe that the specific food bearing that brand name has properties deriving from a substance that it contains that are beneficial for reducing the risk of developing a disease or health-related condition, specifically cardiovascular disease. Both basic elements of a health claim may be implied in a brand name containing the term "heart." Therefore, any product bearing such a brand name is subject, depending of course on the full content of the labeling, to be viewed by FDA as bearing an implied health claim. Thus, FDA has retained the term "heart" as an example of what may be an implied claim in the definition of "health claim" in new § 101.14(a)(1) to alert firms to the agency's position on this matter. However, FDA will review the context in which this term is presented and consider how the term would be understood in deciding whether a particular use of the term "heart" or a use of a heart symbol on a particular label is a health claim.

3. Other written statements

7. A number of comments suggested that any statement on a label, including nutrient content claims such as the word "healthy" or other terms that may lead consumers to believe that a food has health benefits, should be regarded as implied health claims. Comments suggested that FDA use broad latitude in considering such words as health claims.

As FDA advised earlier in this preamble, the agency will evaluate all of the labeling to determine whether, within the context in which a claim is presented, both basic elements of a health claim are present. Thus, FDA will take a flexible case-by-case approach to assessing whether labeling contains a health claim.

In the case of the word "healthy," the agency does not believe that the use of this word would normally be a health claim. "Healthy" has a wide variety of meanings in addition to ones that would satisfy the second basic element of a health claim. For example, "healthy" can certainly imply general nutritional well-being. Thus, while a claim such as "Eat a diet low in fat for a healthy heart" may be a health claim, "Eating

five fruits or vegetables a day is a good way to a healthy lifestyle" is not. Moreover, as explained in the document concerning nutrient content claims that appears elsewhere in this issue of the **Federal Register**, FDA may also regulate the term "healthy" in certain circumstances as an implied nutrient content claim. A proposal on how to define the term in such circumstances appears elsewhere in this issue of the **Federal Register**. The varied uses of the term "healthy" demonstrate the need for FDA to take a flexible case-by-case approach in deciding whether a claim is an implied health claim.

4. Third party references

8. Some comments requested that FDA explain its interpretation of the term "third party endorsement" and clarify when such an endorsement constitutes a health claim. One comment observed that the courts have been careful not to define the concept of "endorsement" too broadly and noted that disclaimers can be used where the perception of endorsement may be construed. Other comments asserted that the mere presence of endorsements should not automatically constitute health claims. One suggested that regulatory limits concerning such endorsements should be set.

FDA agrees that third party endorsements do not automatically constitute health claims. "Funk & Wagnall's Standard Dictionary," Harper Paperbacks, New York, 1980, defines the term "endorse" as "to state one's personal support of (a product) to promote its sale." FDA views third party endorsements as references, made through a name or logo, to a person or organization such as a professional society or association that is independent of the product's manufacturer or distributor, on product labeling or advertising, to promote that organization's approval of a product.

In response to the comments addressing the term "third party endorsements," as explained in the agency's response to comment 5 of this document, the codified language of new § 101.14(a)(1) has been revised to refer to "'third party' references." This term, which includes third party endorsements, better describes the type of information from an organization or individual not directly associated with the manufacturer that may be included in a label and that could constitute an implied or express health claim.

Third party references on food labels include a wide variety of information about diet and general health that is disseminated by reputable public or private organizations. Such information will be regulated as a health claim if, within the context of the total labeling, the third party reference can be reasonably understood to characterize the relationship between a substance and a disease or health-related condition. Thus, an endorsement by the American College of Nutrition or the National Nutritional Foods Association would not, of itself, cause a product to be considered to bear a health claim, even if these organizations were promoting the consumption of a specific food or nutrient, if the resultant claim did not include reference to a disease or health-related condition.

However, a third party endorsement would constitute an implied health claim if the endorsement references a particular food or substance, and the name of the endorsing organization references a particular disease (e.g., American Heart Association). In such an endorsement, both basic elements would be present. As a result, a link would be created between the food/substance and the specific disease that could be reasonably understood by consumers as asserting that the product is useful in reducing the risk of developing that disease.

The following illustration using the National Cancer Institute's (NCI's) Five-a-Day Program (Ref. 27) exemplifies how the context of the label will determine whether a statement is a health claim or dietary guidance. A cereal label that says "The National Cancer Institute recommends that you eat five servings daily of fruits and vegetables" is not a health claim because the information cannot be reasonably understood to be about a substance. There is neither a nutrient nor a product-specific element in the claim, and there is therefore no characterization between a substance and the disease included in the name or the organization. However, if the statement said "The National Cancer Institute recommends that you eat five servings daily of fruits and vegetables to increase your intake of fiber," it would be a health claim because of the reference to a specific nutrient, fiber, and to a disease, cancer.

9. Several comments questioned the status of the American Diabetes Association's "Exchange Lists for Meal Planning." One comment questioned the status of the American Diabetes Association's "Self-Test" public awareness program printed on the back of certain cereal boxes, which is designed to enable consumers to recognize diabetes based on warning signs and symptoms of the disease. The comments expressed the belief that these situations should not be interpreted as either an endorsement or a health claim because no claim is made about a specific nutrient in the foods, and no link is created between the products and diabetes. Comments also requested clarification of FDA's position on fund raising activities conducted with the cooperation of manufacturers using organizational logos and messages such as: "A proud sponsor of the American Diabetes Association" or "A contribution from the sale of this product has been made to the American Diabetes Association." The consensus of these comments was that these situations should not be interpreted as endorsements because no claim is made about the nutrient content of the foods, and there is no association between the products and the disease, diabetes mellitus.

FDA recognizes the value that providing exchange lists on food labeling has for certain consumers and advises that the mere inclusion of that information on a food will not, of itself, subject the labeling to the health claim regime. Reference to the exchange lists lacks the substance element of the "health claim" definition because it relates to many foods rather than to a specific food or a nutrient. Such information is instead subject to section 403(j) of the act and, more specifically, to § 105.67 relating to foods for use in the diets of diabetics. Of course, the labeling would be subject to regulation under section 403(r) of the act if the labeling bears any implication that a substance in the food is helpful in reducing the risk of diabetes or any other disease.

In the absence of an explicit or implied reference to a substance in food labeling, the "Self-Test" program and sponsorship/fund raising information also are outside the coverage of section 403(r)(1)(B) of the act. However, labeling for both of these programs would be subject to section 403(a) of the act, which requires that a label be truthful and not misleading, and section 201(n) of the act which describes the circumstances in which labeling is misleading.

10. Some comments requested that paid third party endorsements be prohibited. These comments stated that such references often give the public the impression that endorsed products are superior in terms of health, safety, or nutrition to other foods not bearing the same endorsement, when, in fact, they are not.

FDA has no authority under the act to prohibit either paid or unpaid third party endorsements or references, provided that, when such statements e included on food labeling, the

statements are made in a manner that is in compliance with all applicable provisions of the act. However, the agency recognizes that endorsements made for compensation by private organizations or individuals may be misleading to consumers. The agency is advising that when such endorsements are made, a statement should be included in close proximity to the claim, informing consumers that the organization or individual was compensated for the endorsement. Failure to divulge this information on a label that bears a paid endorsement would cause the product to be misbranded under sections 403(a) and 201(n) of the act for failure to reveal a fact that is material.

11. A number of comments suggested that all unpaid endorsements be regarded as explicit health claims.

FDA disagrees, because the issue of whether an endorsement is made in exchange for monetary compensation is not germane to the issue of whether the endorsement or other third party reference constitutes a health claim. As discussed in the response to comment 8 of this document, for a third party reference to be a health claim, two criteria must be met. There must be an implied or explicit reference to both a substance and to a disease or health-related condition. In the absence of these elements, a third party reference is not a health claim, regardless of any financial arrangement that may have been entered into before making the endorsement.

12. Other comments urged FDA to allow the use of third party endorsements of specific products. Many of these comments asserted that references from credible health organizations reduce or eliminate consumer confusion about specific products, provide useful and relevant information about products, and assist consumers in making healthy food choices. The comments also argued that the use of third party endorsements and references should also encourage the development of new products that attract such endorsements.

FDA has no basis in principle for objecting to the use of third party endorsements and other third party references for specific products, provided that such references are made in compliance with all applicable provisions of the act, including the nutrient content claims and health claims requirements of the 1990 amendments and sections 403(a) and 201(n) of the act. The agency is aware of the potential impact of the 1990 amendments on the development of more healthful products that will appeal to consumers and encourage people to improve their eating habits. In the Congressional Record of October 24, 1990, Senator Hatch (Ref. 2) stated:

> * * * manufacturers should have the economic incentives they need to be creative and innovative so that more and more low-fat, reduced sodium, and high-fiber foods come into the market. We should not deter such benefits for the consumer.

FDA is very much in favor of product innovation as a means of bringing more healthful products to the American public and recognizes that appropriate and lawful third party endorsements may have some potential to stimulate innovation and play a useful role in educating consumers about the importance of developing diets that will improve their health.

13. A number of comments recommended that FDA selectively designate which governmental and nongovernmental organizations are allowed to make third party endorsements. One comment suggested that FDA require organizations that grant endorsements to have the expertise in the area in question as well as a formal product approval process. The organization should actively disseminate additional explanatory information concerning the meaning of the endorsement and manner of its use. Other comments recommended that third party endorsements be considered to be misleading unless the reason for the presence of the endorsement is clearly explained (including but not limited to disclosure of financial arrangements).

With the exception of disclosing the fact that an endorsement has been paid for, as discussed in comment 10 of this document, FDA believes that it lacks the factual and legal basis at this time for imposing such requirements on third party endorsements. FDA recognizes, however, that third party references have significant potential to be abused or to be misleading if, for example, they come from organizations or programs that exist primarily for commerical or marketing purposes, they are not based on sound nutritional criteria, or they appear on products that are not appropriate in light of the actual or implied nutritional purpose underlying the endorsement. Therefore, the agency will closely monitor the use of endorsements on food labels. Interested persons should submit their views on the need for additional regulatory controls to the Center for Food Safety and Applied Nutrition. FDA intends to consider in a future rulemaking proceeding whether additional criteria or controls are necessary.

In the meantime, any labeling generated with a third party endorsement or reference would be subject to regulation under sections 201(n) and 403(a) of the act and must, therefore, be truthful and not misleading. Further, if the reference meets the definition of a nutrient content claim or a health claim, such a claim must be consistent with FDA's regulations.

14. A number of comments suggested that all written health claims be banned in favor of third party endorsements. One of the comments favored allowing third parties, such as the American Heart Association and the American Dental Association, to independently review products and to place their logos on the labeling if they determine that use of the product would be helpful in reducing the risk of their specialty disease.

FDA has an obligation under the act to ensure that health claims comply with section 403(r) of the act, and that they are truthful and not misleading under section 403(a). Delegation of this responsibility to private organizations associated with specific diseases would not be consistent with the act. Such organizations are free to submit well-supported petitions pertaining to the health benefits of any substance to FDA, as provided for in new § 101.70. However, FDA will always have the obligation of ensuring compliance with the act.

5. Symbols

In the preamble to the proposed rule (56 FR 60537 at 60542), FDA recognized that there is often ambiguity in the message conveyed by a symbol or logo and solicited comments on the appropriate meaning to be attributed to a heart symbol and other currently used logos and symbols. The agency also invited comments on the issue of how logos should be regarded: as nutrient content claims, health claims, or both? The comments, which are summarized below, ranged from those that wanted strict regulation of symbols to those that felt symbols should not be regulated as health claims. Many comments took an intermediate position, arguing that symbols should be evaluated within the context of total labeling.

15. Many comments supported FDA's proposal to regulate symbols as health claims. These comments stated that the uncontrolled use of medical symbols (e.g., a heart or an electrocardiogram (EKG)) should not be permitted. Some comments suggested that symbols be allowed only when the food qualifies for the health claim implied by the symbol, and then only if they are not misleading

and increase consumers' comprehension of the claim.

Many industry comments argued that symbols cannot practicably be included in the definition of a health claim. One comment pointed out that candy packages bearing a heart symbol near Valentine's Day should not be regulated as an implied health claim. Another comment cited examples where the heart symbol may do nothing more than operate as a design motif with no implicit health claim (e.g., the combination of a heart symbol plus the statement "Hey Fudge Lovers! More Fudge Filling!"). The comments maintained that any analysis of how the symbol is construed must focus on the entire label, not on an isolated aspect of it.

FDA agrees that a determination as to whether a symbol constitutes a health claim must be made based on the entire food label. As explained in the response to comment 5 of this document, FDA has provided for such flexibility by revising new § 101.14(a)(1) to state:

> Implied health claims include those statements, symbols, vignettes, or other forms of communication that a manufacturer intends, or that would be reasonably understood in the context in which they are presented, to assert a relationship between the presence or level of a substance in the food and a disease or health-related condition.

"Funk & Wagnall's Standard Dictionary" defines the term "symbol" as "something chosen to represent something else; esp., an object used to typify a quality, abstract idea, etc." Determining whether a symbol on a label represents an implied health claim requires an evaluation of all of the labeling to ascertain whether, within the context of that labeling, the presence of that symbol results in both basic elements of a health claim being present in the labeling.

Because of the abstract nature of symbols, they have considerable potential for conveying a wide variety of meanings on labeling. As the comments pointed out, the same symbol on a food label may have a multitude of meanings for the same food as the context of the labeling is changed from one label to another. Certainly, the combination of a heart symbol and the statement "Hey Fudge Lovers!" on a food containing fudge adequately explains the meaning of the heart symbol and prevents consumers from being misled about its meaning. Under such circumstances, the heart symbol would not convey either of the basic elements of a health claim. The statement "Hey Fudge Lovers!" clarifies that the symbol does not refer to a substance in the specific food bearing the symbol or to any health benefits from consuming that food.

However, if the statement "Hey Fudge Lovers!" does not appear on the product, and no other explanation of the heart symbol appears on the labeling, the context of the labeling no longer explains the meaning of the symbol. Under such circumstances, the symbol may well be perceived by consumers in a wide variety of ways, many of which would not be true. FDA believes that most of the perceptions about heart symbols fall under the regulatory regime of a health claim. For example, consumers may logically assume that the symbol is equivalent to the term "heart." Under such circumstances, these consumers may conclude that the symbol means that the food has properties that are beneficial for reducing the risk of developing a disease or health-related condition, specifically cardiovascular disease. Thus, the second basic element (i.e., disease or health-related condition) would be conveyed by the symbol. Further, the first basic element (i.e., substance) would also be present. In the absence of an explanation for the symbol, consumers would likely infer that the symbol pertains to the specific food bearing the symbol and to the substances that it contains. Thus, both basic elements of a health claim can be implied through the unexplained presence of a heart symbol on a label.

Even if the heart symbol is not perceived by some as a health claim, the symbol would still be misleading within the meaning of section 403(a)(1) of the act because the context of the labeling would not explain what the symbol means and thus would fail to disclose a material fact. Accordingly, FDA advises that the use of health-related symbols in food labeling without some clarification of their meaning in context is likely to cause the food to be misbranded.

Similarly, an EKG (a record of the electrical current produced by the action of the heart muscle) also constitutes a health claim where the context of the labeling does not explain the meaning of the EKG. Although it is unlikely that most consumers would be able to interpret an EKG reading as representing a healthy or unhealthy heart, most consumers would probably make a connection between an EKG graph and heart function. Under such circumstances, the symbol alone could lead consumers to believe that a substance in the product is related to the risk of cardiovascular disease and thereby constitute a health claim.

Of course, symbols with specific reference to nutrients may also constitute health claims. For example, a heart on a label that also makes a claim that the product is low in fat would be an implied health claim. The explicit nutrient content claim would satisfy the substance basic element, and the disease or health-related basic element would be provided by the symbol because it implies that the low level of fat has a beneficial effect relative to a disease of the heart. (This decision assumes the label does not contain sufficiently clarifying information to change the meaning of the heart symbol, so that the symbol would not constitute a basic element.)

However, in some circumstances, the context of the labeling may make it obvious that there is no connection between the symbol and a substance in the food or between the symbol and a disease or health-related condition. In such a situation, the symbol would not constitute an implied claim. For example, a heart shaped box of candy or a heart shaped candy, whose label does not include an explicit or implied reference to a disease or health-related condition, would not be an implied claim.

In addition, some symbols, such as the U.S. Department of Agriculture/Department of Health and Human Services (USDA/DHHS) Health Pyramid, a symbol for the American Heart Association, or a symbol for the American Cancer Society, may not constitute health claims when the labeling contains no other references to a substance or a disease or health-related condition. In all of these situations, the organizations provide general dietary guidance for good health. Thus, consumers should not assume from the name of the organization that the symbol implies an association with the disease or health-related condition basic element.

When symbols constitute a health claim, they should only be used on foods that qualify for the express claim they represent. Since it is unlikely that a symbol alone can convey all the information necessary as part of a health claim, health claims implied by symbols must be accompanied by a written message that includes the essential elements of the claim authorized by FDA's regulations in part 101, subpart E. To prevent misinterpretation of the claim by consumers, this message should be located in close proximity to the symbol but could be located in other labeling provided that a reference statement appears next to the symbol. The appropriate content of health claims reference statements is discussed subsequently in section V.C. of this preamble. FDA has revised the

provision of the final rule addressing reference statements in new § 101.14(d)(2)(iv) to provide that such statements shall appear in immediate proximity to the graphic material (e.g., symbol). Anyone wishing to use a symbol alone to deliver a health claim may submit a petition with supporting data that demonstrate that the essential elements of the health claim are conveyed to consumers by the proposed symbol.

FDA recognizes that symbols are an important means of conveying information to consumers, and that they are useful when used in a truthful and nonmisleading manner. The agency will continue to protect the interests of the public by monitoring the use of symbols and will take appropriate action under either section 403(a) or (r) of the act when symbols are used to mislead consumers.

16. Some comments proposed that, if symbols such as a heart are to be regulated as implied health claims, products that bore such symbols before the implementation of the regulation should be exempted from the health claims regime.

Although the statute provides very explicit guidance regarding grandfathering of nutrient content claims in sections 403(r)(2)(C) and (r)(2)(D) of the act, it is silent with respect to any such provision regarding health claims. In light of this omission, it is clear that Congress did not intend to provide such relief for labeling making either implied or explicit health claims (see *Andrus* v. *Glover*, 446 U.S. 608 (1980)). Further, grandfathering of labels that do not qualify to bear an implied health claim would result in confusion on the part of consumers and reduce the credibility of symbols on food labels that are eligible to bear such claims. Therefore, FDA is rejecting this proposal.

17. Several comments suggested that the final rules should make some provision for the use of FDA standardized symbols and logos on products that would qualify for health claims. The comments stated that such logos and symbols would help individuals with poor reading skills plan a more healthful diet, although they did not make clear whether the use of symbols and logos should be optional or mandatory.

As stated above, FDA recognizes the value that symbols and emblems have in promoting good health and dietary guidelines to consumers. However, at this time the agency feels that it is inappropriate to permit an emblem alone to deliver the substance of a health claim, and it would be difficult for FDA to design standardized symbols or logos in a manner that would be in compliance with the statute. Section 403(r)(3)(B)(iii) of the act requires that a health claim be accurate and comprehensible within the context of the daily diet. New § 101.14(d)(2)(iii) requires the inclusion of factors other than consumption of the substance when such factors affect the substance-disease relationship (e.g., exercise).

Further, under section 201(n) of the act, labeling can be misleading based on what is omitted as well as on what appears on the label. Designing an emblem that would deliver the message required by the act while also meeting the criterion of being truthful and not misleading, as mandated by section 403(a)(1) of the act, would be extremely difficult.

However, the agency will consider petitions for use of a symbol or emblem for approved claims or as part of a new health claim petition, provided that appropriate data are submitted that provide the agency with some assurance that consumers accurately interpret the claim. Such data should include the results of tests using the suggested symbol.

6. Dietary guidance

As FDA explained earlier in this preamble, when the proposal was issued, FDA had not yet decided how certain types of claims should be regulated when they pertain to truthful information about health and diet and are not in the form of an explicit health claim. FDA referred to "dietary guidance" as a class of claims that might not be regulated under section 403(r) of the act. The agency cited the NCI "Five-A-Day" program as an example of dietary guidance that is not a health claim. Unfortunately, use of that program as an example created confusion because, even though most of the messages in the program only encouraged consumers to eat fruits and vegetables, a small number of the messages refer to nutrients (e.g., fiber) and disease (cancer).

Further, use of the term "dietary guidance" to describe claims that do not constitute "health claims" is also confusing because "health claims" themselves provide a form of dietary guidance. In addition to "health claims" and "dietary guidance," there is a broader class of claims that encompasses all other truthful information about diet and health as well as drug claims. In view of the overlapping nature of these categories of claims, it is understandable that there was considerable confusion among the comments about "dietary guidance."

For the sake of clarity in this preamble, FDA will use the term "dietary guidance" to refer to claims that do not contain both basic elements of a health claim and are therefore not "health claims." However, use of this term in the comments may, or may not, have encompassed a "health claim." FDA will attempt to clarify the use of the term by the comments in the summaries to the comments.

18. Some comments asserted that dietary recommendations that relate to a specific disease but provide guidance concerning general food choices without unduly emphasizing a particular substance, or recommendations that emphasize a particular substance but are related to a variety of diseases or to a healthy lifestyle in general, should not constitute implied health claims.

As discussed in the response to comment 1 of this document, claims that do not satisfy either the substance element or the disease or health-related condition element of the "health claim" definition are not health claims. Accordingly, claims that provide guidance about a general food choice or about how to achieve a healthy lifestyle would not be health claims. Claims that are related to a variety of diseases are likely to be health claims, although a specific determination will be made based on the context in which a claim is made and on its specific content.

19. A number of comments contended that the agency unjustly regulated accessibility to recommendations from authorities, such as the National Institutes of Health and USDA. Most comments felt that such dietary guidance should not be regulated as health claims on food labeling because such regulation would discourage education of the public on sound nutrition practices. One comment suggested that the furtherance of consumer information was mandated under the 1990 amendments and asserted that industry and FDA need to focus more attention on the education authority provided therein. This comment and others stated that public health organizations, such as NCI, can more effectively reach consumers with valuable advice if products that fit into their recommendations are free to display this information on their labels, and that consumers are more likely to notice and appreciate recommendations from a respected source. Other comments felt that nongovernmental sources (e.g., the American Dietetic Association and the American Heart Association) also provide credible dietary guidance.

FDA has reconsidered the tentative position that it took in the proposal (56

FR 60537 at 60555) that references to programs sponsored by such organization as the American College of Nutrition, the American Heart Association, the American Medical Association ("Campaign Against Cholesterol"), and the American Medical Women's Association would always be regulated as implied health claims. The comments have convinced the agency that it would not be appropriate to establish by regulation the specific types of statements that may be used on food labeling concerning either Federal programs or private sector programs because the guidance offered by such organizations may not include a reference to a substance or to a disease or health-related condition. The agency has therefore concluded that publicly available dietary information provided to consumers by Federal or private programs and used in food labeling by manufacturers may be either dietary guidance or a health claim depending upon the content of the information and the context in which it is presented in the labeling.

In taking this position, FDA hopes to encourage the dissemination of information to consumers regarding nutrition and health that has been provided by such sources as the U.S. Surgeon General, the National Academy of Sciences, USDA/DHHS Dietary Guidelines, NRC, and the National Cholesterol Education Program. However, information from such programs presented in labeling in a context that includes explicit or implicit references to both elements of a health claim is subject to the health claims provisions of the act.

20. Many consumers asserted that dietary supplements, including supplements containing herbs, should be permitted to include all types of nutritional and dietary guidance in their labeling, including information based on folklore and historical use, provided that the claims are made truthfully. These comments maintained that such information is essential to making informed choices of such alternatives to conventional drug therapies.

Manufacturers of dietary supplements are free to provide dietary guidance within the regulatory framework discussed above. However, if a product's labeling characterizes the relationship between a disease or health-related condition and a substance, the product will be subject to the provisions of section 403(r) of the act, although in the case of dietary supplements they will not be subject to section 403(r) of the act until the expiration of the moratorium established by the DS Act. If the claim reveals that the product is intended to be used in the diagnosis, cure, mitigation, treatment, or prevention of a disease, the product, like any other product that does so, is a drug under section 201(g)(1)(B) of the act. When the moratorium expires, and subject to the regulations in place at that time, supplement and herb manufacturers, like all other food manufacturers, will be welcome to submit health claim petitions that establish the validity of claims that characterize the relationship of a substance to a disease or a health-related condition.

E. Definition of Nutritive Value

21. A number of comments asserted that FDA's definition of "nutritive value" in proposed § 101.14(a)(3) is unduly restrictive and does not fully recognize the important role that nutrients play in helping to reduce the risk of chronic disease. Other comments requested that FDA state in the definition that the list of processes cited is not all-inclusive. Another comment asked that the proposed rule be modified to specifically recognize the nutritive value of fat substitutes (triglycerides and other substances that contain fatty acids but are modified in ways that limit the bioavailability of those acids).

FDA recognizes that certain substances can play a major role in reducing the risk of certain chronic diseases and may confer their benefits through a number of processes. Accordingly, the agency has worded the definition of "nutritive value" in new § 101.14(a)(3) to provide significant flexibility in determining whether a substance possesses such value. FDA used the phrase "such * * * as" in the definition to insure that the three referenced processes will be understood to be general examples of the ways in which a substance may legitimately confer nutritive value, rather than as an all-inclusive list.

The agency believes that it is inappropriate to codify findings of nutritive value for specific substances. Such findings would only serve to undermine the intended flexibility of the definition because an extended listing of those substances that possess nutritive value could be interpreted as an exclusive list.

FDA considers it more appropriate for the agency to evaluate the nutritive value of substances that are the subjects of health claim petitions on a case-by-case basis. This approach will best ensure that the definition retains its intended flexibility and does not become an unintentional barrier to the approval of legitimate health claims.

F. Definition of Dietary Supplement

22. A number of comments suggested that the proposed definition of "dietary supplement" in proposed § 101.14(a)(4) should be revised to include foods as well as components in foods (e.g., herbs as well as components in herbs).

FDA advises that the proposed definition of "dietary supplement" already covers foods. Reference to a "component" with nutritive value encompasses the specific portion of the food, that is, of the dietary supplement, responsible for this value. Under section 201(f)(3) of the act, a component of a food is itself a food. However, because of the provisions of the DS Act, FDA is not adopting § 101.14(a)(4) at this time. FDA will reach a final decision on the appropriate definition of this term following in accordance with the provisions of the DS Act.

G. Definition of Disqualifying Nutrient Levels

As proposed, "disqualifying nutrient levels" was defined in proposed § 101.14(a)(5) as:

> *Disqualifying nutrient levels* means the levels of total fat, saturated fat, cholesterol, or sodium in a food above which the food will be disqualified from making a health claim. These levels are 11.5 grams (g) of fat, 4.0 g of saturated fat, 45 milligrams (mg) of cholesterol, or 360 mg of sodium, per reference amount commonly consumed, per label serving size, and per 100 g. Any one of the levels, on a per reference amount commonly consumed, a per label serving size or a per 100 g basis, will disqualify a food from making a health claim.

For consistency with the final rule on serving sizes published elsewhere in this issue of the **Federal Register**, the word "commonly" in the term "reference amount commonly consumed" in the definition above is corrected to read "customarily."

1. Consistency with statute

23. Most industry comments contended that the proposed definition of "disqualifying nutrient levels" in proposed § 101.14(a)(5) is either overly restrictive or inconsistent with the statutory provision of section 403(r)(3)(A)(ii) of the act. The comments based their arguments on the language of the provision that provides that a health claim cannot be made by a food that contains "any nutrient in an amount which increases * * * the risk of a disease or a health related condition." Several comments stated that the agency correctly acknowledged that there are no generally recognized levels at which nutrients in an individual food pose an increased risk of disease, although there are

recommended levels associated with decreased risk of disease for dietary intake of total fat, saturated fat, cholesterol, and sodium. A number of these comments argued that the acknowledgment by FDA of a lack of recognized risk levels in an individual food should prevent the agency from establishing any disqualifying nutrient levels because the 1990 amendments require FDA to consider whether the individual food for which the claim is made contains a nutrient at a level that increases to persons in the general population the risk of a diet-related disease, taking into account the significance of the food in the total daily diet.

The comments argued that single foods, even when their significance in the total daily diet is considered, do not increase disease risk because only total diets consisting of many foods consumed over time have that potential. Thus, these comments argued that FDA cannot reasonably take the position that the analysis upon which the proposed disqualifying levels are based constitutes a credible scientific determination that the specific levels are the levels that, if exceeded in an individual food, increase the risk of disease in the general population. Other comments stated that if the agency believes that it has in fact determined levels that will increase the risk of diet related disease when present in individual foods, then either the marketing of such foods should be disallowed under the act by virtue of their being injurious to health under section 402(a)(1) of the act (21 U.S.C. 342(a)(1)), or warning labeling should be required on all foods containing such levels regardless of whether they contain health claims.

Some comments asserted that Congress intended for FDA to disallow a health claim on the basis of disqualifying nutrient content only if there exists an actual risk as determined by the analysis of actual consumption data for the specific food, and not as determined from models based on theoretical diets and extrapolation. Therefore, these comments argued that disallowing health claims on the basis of theoretically-derived nutrient disqualifying levels is contrary to the legislative intent of section 403(r)(3)(A)(ii) of the act, which reads, "If the Secretary determines * * *" and not "The Secretary shall determine * * *." These comments maintained that FDA had failed to show that a person exposed to foods with levels of fat, saturated fat, cholesterol, and sodium above the disqualifying levels were actually at an increased risk for various diseases and maintained that such an actual risk must be shown for FDA to legally establish disqualifying levels for these nutrients.

One comment noted that FDA's proposed model health claims emphasize the role of the total diet in reducing the risk of various diseases and do not allow manufacturers to claim that an individual food will reduce the risk. The comment stated that it was ironic and inappropriate, then, that FDA would single out individual foods as increasing the risk of those same diseases, and set disqualifier levels for those foods. Other comments agreed, saying that an individual food could no more cause a disease than prevent one.

FDA disagrees that the 1990 amendments require that FDA consider whether the individual food for which the claim is made contains a nutrient at a level that increases to persons in the general population the risk of a diet-related disease. There is nothing in the legislative history of the 1990 amendments that would support such a contention. To the contrary, the legislative history and the language of the statutory provision that ultimately resulted suggest that Congress intended that the risk of diet-related disease be considered in a far broader context than that of an individual food. Section 403(r)(3)(A)(ii) of the act states that the risk of a disease or health-related condition be considered "* * * taking into account the significance of the food in the total daily diet * * *." Thus, FDA must consider the role that a particular food plays in the total diet, and the effect that its nutrient levels will have on a person's ability to structure a healthy diet in making a determination under section 403(r)(3)(A)(ii) of the act. That provision contains no language implying that risk should be considered in terms of the immediate impact of consuming the particular food at issue.

Further, if Congress had been concerned about the impact of consuming a nutrient in a particular food, it would not have provided an exemption to disqualification in section 403(r)(3)(A)(ii) of the act when FDA finds that a claim will assist consumers in maintaining healthy dietary practices. Under the comment's view of this provision, no such circumstances could exist. Similarly, Congress would not have elected to provide for nutrient content claims with only disclosure requirements for such nutrients in section 403(r)(2)(B) of the act if the risk from a particular food was the concern that it was addressing. Further, if risk from a particular food was its concern, Congress would not have exempted nutrient content claims on restaurant foods from these disclosure requirements (see section 403(r)(5)(B) of the act).

Congress intended that health claims would not merely provide information on particular substance-disease relationships, but that they would help individuals to maintain healthy dietary practices. The House Report (Ref. 1) states:

> * * * Health claims supported by significant scientific agreement can reinforce the Surgeon General recommendations and help Americans to maintain a balanced and healthful diet * * *.

Health claims on foods with levels of fat, saturated fat, cholesterol, or sodium that exceed the disqualifying levels will make it much more difficult for consumers to follow the Surgeon General's recommendations and to construct a healthy diet. An increase in risk in a diet-related disease follows as a result. All references in the legislative history concerning the meaning of section 403(r)(3)(A)(ii) of the act show that Congress was concerned with general levels of nutrients in broad food classes that could increase risk rather than levels of nutrients that could increase risk from individual foods. For example, the House Report (Ref. 1), in addressing the meaning of this provision, states:

> By requiring the Secretary to decide this issue in the total daily diet, the bill permits the Secretary to differentiate between different foods which have the same level of a nutrient. For example, a particular level of fat in a frozen dinner might not trigger the provision [disqualification], whereas the same amount of fat in a snack food product might trigger it.

Further, in testimony presented before the House of Representatives on a predecessor bill to the 1990 amendments (Ref. 24), a consumer organization identified ways by which health claims on products in the U.S. marketplace can deceive consumers. One such way was for a product to highlight a characteristic that may help reduce the risk of a disease but remain silent about another characteristic that may affect the risk of the same, or another, disease. An example cited in the testimony was a breakfast cereal bearing a health claim approved by NCI on the association between dietary fiber and cancer while containing 4 g of fat per serving—an amount characterized as quite high for a breakfast cereal. In testimony presented before the Senate on a predecessor Senate bill to the 1990 amendments (Ref. 25), another consumer organization stated that a health claim on a product must provide consumers with the assurance that the

product does not also contain properties that are potentially harmful to health. The testimony continued:

> But a health claim on whole milk, promoting its calcium content [relative to osteoporosis], could encourage consumption of a product high in saturated fat. Low-fat milk has all the benefits of whole milk, without the accompanying risks, and would be a more appropriate vehicle for health claim labeling.

Congress obviously recognized the fact that, as pointed out in some of the comments, single foods, when their significance in the total daily diet is considered, do not generally increase disease risk. It is the total diet, consisting of a number of foods consumed over time, that has the potential to increase disease risk. Thus, FDA believes that the purpose of section 403(r)(3)(A)(ii) of the act is to ensure that FDA establishes appropriate disqualifying levels for those nutrients that have the potential, at high levels of consumption, to increase disease risk so that consumers who rely on health claims will be consuming foods that will assist them in meeting dietary guidelines in constructing their total daily diet, and not foods that make it more difficult to do so.

FDA also does not agree that Congress intended that section 403(r)(3)(A)(ii) of the act only prohibit health claims where the level of risk from a nutrient is sufficient to invoke the adulteration provisions of the act. Disqualifying levels in no way should be construed as nutrient levels that FDA believes are harmful in an individual food. The House Report (Ref. 1) explains that this provision pertains to nutrients required to appear on the label and specifically points out that certain levels of fat in foods may trigger this provision. Foods that are 100 percent fat are still safe and lawful under the act. FDA believes that fat was cited to make it obvious that the provision is intended to provide a measure of control for diet-related diseases that are influenced by excessive consumption of safe and lawful nutrients.

In appropriate amounts, such nutrients have a necessary or useful place in the total daily diet. In fact, where the only safety issue is an increased risk of a chronic disease from excessive consumption, the safety provisions of the act would not provide regulatory sanctions against such components of foods, at least if they have not been added to foods. For such components, FDA must show that the component is a poisonous or deleterious substance that would ordinarily render the food injurious to health. If Congress had intended that section 403(r)(3)(A)(ii) of the act to prohibit health claims only where the level of risk from a nutrient is sufficient to invoke regulatory sanctions, the provision would have been unnecessary. Clearly, Congress had something else in mind.

The agency also disagrees with the comments that argue that FDA developed disqualifying nutrient levels based on a misconstruction of the statutory language and intent of section 403(r)(3)(A)(ii) of the act. That section does not read, as one comment stated, that disqualifying nutrient levels may be established * * * "if the Secretary determines * * *." Instead, it states that a health claim may only be made "* * * if the food for which the claim is made does not contain, as determined by the Secretary by regulation, any nutrient in an amount that increases to persons in the general population the risk of a disease or health-related condition which is diet related * * *." FDA believes that the most straightforward reading of this provision is as an instruction to the agency to establish a list of levels of nutrients in food that, taking into account the makeup of the total daily diet, increase to persons in the general population the risk of diet-related diseases or health-related conditions.

In addition, the agency disagrees with the contention that the definition of "disqualifying nutrient levels" is either overly restrictive or based on an inappropriate scientific basis. The agency stated in the November 1991 proposal that although there are well-established recommendations for dietary intake for fat, saturated fat, cholesterol, and sodium that are consistent with maintaining good health, there are no levels for these nutrients in an individual food generally recognized by the health community to pose an increased risk of disease. However, this statement was intended to point out that scientists have not developed a scheme for transposing quantitative information on the nutrient content of a diet to comparable quantitative information for the broad array of individual foods as they may fit within the context of a healthful diet. Because of this fact, the agency stated in the November 1991 proposal that it did not know of an established or accepted approach for identifying levels for fat, saturated fat, cholesterol, and sodium in an individual food that would increase the risk of a diet-related disease and that would, therefore, disqualify that food from bearing a health claim. In the absence of an established approach, FDA arrived at an approach in which the amounts of fat, saturated fat, cholesterol, and sodium that the agency proposed as disqualifying nutrient levels were the amounts that, in a single food, would make it difficult to construct a diet that meets dietary guidelines, particularly if consumption of the food is encouraged and emphasized by a health claim. Because the guidelines identify dietary levels for specific nutrients (e.g., saturated fat) for which higher levels of intake are linked to an increased risk for a diet-related disease (e.g., heart disease), failure to meet them can reasonably be expected to increase the risk of a disease. Indepth discussions of the agency's conclusions about risk inherently associated with each of the disqualifying nutrients appear elsewhere in this issue of the **Federal Register** in the preambles of the final rules for health claims for dietary lipids and cardiovascular disease, dietary lipids and cancer, and sodium and hypertension.

Accordingly, the definition for disqualifying nutrient levels is fully consistent with the information contained in the legislative history of the 1990 amendments.

2. Disclose rather than disqualify

24. Several comments suggested that Congress sought through the exception process permitted by section 403(r)(3)(A)(ii) of the act to limit the disqualifying effect of nutrient levels to only those nutrients that have a direct effect on the disease that is the subject of the health claim. Some comments suggested that the agency should have utilized the flexibility accorded by Congress to opt for disclosure of nutrients that are not directly related to the disease mentioned in a claim, rather than disqualification of the product from bearing any health claim. In support of their position, the comments cited the discussion on section 403(r)(3)(A)(ii) of the act contained in the House Report on the 1990 amendments (Ref. 1). Comments argued that even though sodium is linked to hypertension, which is a risk factor for heart disease, a product with high sodium content should not be disqualified from bearing a claim about dietary lipids and heart disease because of the lack of major linkage between sodium as a causative factor for heart disease. Another comment, which asserted that prohibiting an osteoporosis claim for whole milk would be misleading because none of the disqualifying levels have any relevance to osteoporosis, also maintained that FDA had made no room for the disclosure permitted by section 403(r)(3)(A)(ii) of the act for a food

containing a nutrient exceeding the disqualifying level.

The agency disagrees with these comments. Section 403(r)(3)(A)(ii) of the act states that a health claim "may only be made if the food for which the claim is made does not contain * * * *any* nutrient in an amount which increases to persons in the general population the risk of *a* disease or health-related condition which is diet related * * *" (emphasis added). That language is clear in that it does not permit a claim for a product containing a nutrient that increases the risk of any diet-related disease or condition and is not limited to a substance that is associated only with the subject disease. The provision then goes on to state that exceptions to this requirement may be made by regulation in the interest of providing consumers with information in maintaining healthy dietary practices. Contrary to the assertion by one comment, FDA provided for the disclosure permitted by section 403(r)(3)(A)(ii) of the act for a food containing a nutrient exceeding the disqualifying level in proposed § 101.14(e)(3).

Because of the time constraints for issuing regulations on health claims, the agency did not exercise the option to develop exceptions to disqualifying nutrient levels. Nevertheless, the changes made in the disqualifying levels that are explained in response to comments 29 and 32 of this document will reduce, but may not eliminate, any need to develop exceptions to disqualifying levels. With those changes, the number of foods that would be disqualified from making a claim will decrease significantly.

Even though § 101.14(e)(3) provides for exceptions from disqualifying levels and the use of an appropriate referral statement, FDA believes that the use of disqualifying levels will be clearer if § 101.14(a)(5) also reflects the fact that exceptions are possible. Thus, FDA has revised this section to state that exceptions to the disqualifying levels may be provided in the specific health claim regulations in part 101, subpart E. The agency will be receptive to petitions that present the reasons that, and the circumstances in which, an exception to disqualification would assist consumers in maintaining a healthy diet.

3. Additional disqualifiers

25. Several comments recommended that health claims be prohibited in labeling for candies, soft drinks, and other sugars-containing foods on the basis of added sugars content. Some comments stated that a Daily Reference Value (DRV) of 50 g for added sugars should be established, and they recommended a disqualifying nutrient level of 8 g of added sugars. This disqualifying level would represent 15 percent of the DRV recommended by the comments. The comments noted that sugars have been associated with the development of plaque, dental caries, and periodontal disease and further noted that the Dietary Guidelines for Americans (Ref. 7) urges the public to consume sugars only in moderation. Another comment asserted that health claims should not be allowed on the label or labeling of a food when more than 15 percent of the food's total calories is contributed by added sugars.

The agency finds that it would not be appropriate to limit health claims on foods on the basis of added sugars either in terms of an absolute amount per serving or as a function of percent of calories per serving. In determining the disqualifying nutrient levels for fat, saturated fat, cholesterol, and sodium, the agency used an approach based on the DRV's for these nutrients. As explained in the proposal to establish DRV's (55 FR 29476), the values for fat, saturated fat, cholesterol, and sodium were based on recommendations that American consumers limit or reduce dietary intake of these nutrients in order to lower their risk of a number of diet-related diseases whose incidence in the general population is considered by the vast majority of public health experts to be unacceptably high. Such recommendations were derived from two publications: The Surgeon General's report (Ref. 5) and the Diet and Health report (Ref. 6) and are reflected in "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 7). One of these recommendations, for example, is for Americans to reduce dietary fat intake from about 37 percent of total energy intake to 30 percent or less. Accordingly, the DRV for total fat is derived from the recommendation that daily total fat intake not to exceed 30 percent of calories. This and other recommendations are believed to have the potential for a substantial reduction in the risk of diet-related chronic diseases in the general population.

Of the comments recommending a DRV of 50 g of added sugars as the basis for a disqualifying level of 8 g, only one provided a rationale for the suggestion. The comment arrived at its recommendation by first estimating in a nonrigorous fashion that the current consumption level is about 100 g per day. The comment then offered that, because FDA concluded in a 1986 report (Ref. 28) that the average American consumes 53 g of added sugars per day, one-half of their 100 g estimate is close to 53 g which should be rounded to 50 g to become the DRV. It offered that, if the agency sets the DRV for added sugars at what the agency considers to be a current consumption level, it would be difficult to argue that the agency has restricted sugars intake too severely.

FDA does not believe that a disqualifying level for sugars can presently be established because of the lack of suitable criteria in the aforementioned comment on which to base a DRV. Even if the comment's estimate of current consumption is scientifically sound, it is significant that no other DRV has been established with average daily consumption as the criterion. Moreover, the public health community has not identified a dietary level above which consumption of sugars has been demonstrated to increase the risk of a disease. Thus, the agency finds that there is no sound basis on which to establish the requested DRV for sugars. Accordingly, the agency is declining to set a disqualifying level for added sugars at this time. Nevertheless, the agency points out that the criteria established in response to comment 87 of this document for limiting health claims based on the nutritional value of a food will provide at least some of the relief requested in that a food fabricated with sugars and few other nutrients will not qualify for a claim.

26. A few comments recommended that FDA prohibit health claims on foods containing any "unnecessary substances," food or color additives or flavor enhancers. One of these comments justified the recommendation by stating that saccharin is associated with a major disease.

FDA does not believe it is appropriate for it to judge whether use of an ingredient is necessary, or to make the mere presence of a food additive disqualify foods from bearing health claims unless the use of the food additive has not been listed by FDA for use in food under section 409 of the act (21 U.S.C. 348). When it passed the Food Additives Amendment in 1958, Congress concluded that use of food additives is in the public interest, provided that their use is safe and not deceptive. For those comments concerned about the safety of food and color additives, the agency advises that the act requires that the use of these additives be shown to be safe before they are listed for use in food. Other ingredients that may be added to food are limited to those that are generally recognized as safe (GRAS) by the scientific community by virtue of their history of use or other scientific knowledge (i.e., GRAS), or whose use

was sanctioned by FDA or USDA before the enactment of the Food Additives Amendment (i.e., prior sanctioned ingredients).

With respect to the comments that specifically mentioned saccharin, FDA did propose on April 15, 1977 (42 FR 19996), to ban its use, based on its interpretation of evidence available from animal studies at that time. However, Congress decided that the additive should be permitted in food and blocked the proposed ban through enactment of the Saccharin Study and Labeling Act. Therefore, unless there is a change in its legal status, the use of saccharin in compliance with § 101.11 (21 CFR 101.11) and § 180.37 (21 CFR 180.37) must be treated the same as any other legally authorized use of an ingredient.

4. Fifteen Percent of the DRV

a. *Criticism of approach.*

27. A number of comments stated that, despite FDA's assertions to the contrary, a total ban on health claims for foods exceeding a disqualifying level would create a good food/bad food image in the minds of consumers. The comments claimed that consumers may turn away from foods that provide significant amounts of essential nutrients simply because the foods do not carry a health claim. One comment noted that whole milk would be prohibited from making a claim about calcium and osteoporosis in spite of the fact that it is recommended as a source of calcium for children 1 to 2 years of age. The comment cautioned that parents may inappropriately substitute skim and low fat milk because of an assumption that whole milk is inferior.

Other comments proposed that if FDA decides to establish disclosure/disqualifying levels for nutrients, the agency should employ extreme care in informing consumers that individual foods do not increase the risk of disease, because it is the total daily diet that must be taken into account.

FDA disagrees with the contention that if foods that exceed a disqualifying level are ineligible to bear a health claim, consumers will perceive those foods as bad. A food without a claim, even if it does not exceed a disqualifying level, may not have the appropriate level of a nutrient to qualify for a claim. For various reasons, a food manufacturer may decide not to label a product with a claim even if the product qualifies. On the other hand, a product bearing a claim is required to provide the consumer with sufficient information to understand how the product may be useful to achieve the claimed effect within the context of the total daily diet. The agency believes that there are sufficient safeguards within section 403(r) of the act that are fully implemented in the final rules on health claims to prevent consumers from being misled about the value of any food based on whether it does or does not bear a health claim.

The agency acknowledges, however, that the full array of all of the new labeling regulations effected by the 1990 amendments may not be immediately understood by consumers. To deal with this, FDA will conduct an education program to effectively communicate how this new food labeling can assist consumers to maintain a healthy diet through informed food selection.

In response to the last group of comments, the agency reiterates that the disqualifying levels represent the amount of these nutrients in a single food that would make difficult the construction of a diet that meets dietary guidelines. They in no way represent a finding by the agency that these levels will cause diet-related disease or that foods that contain nutrients at these levels are unsafe, dangerous, or bad.

28. Other comments contended that an across-the-board disqualifying level based on a set percentage of the DRV for a nutrient could not be justified. One comment stated that it could not support the food composition analysis the agency used in developing the proposed disclosure/disqualifying levels because that approach does not fully meet the requirements of section 403(r)(3)(A)(ii) of the act. Specifically, the comment asserted that FDA's approach to disclosure/disqualifying levels ignores the legal requirement of accounting for the "significance of the food in the total daily diet." The comment claimed that this requirement implies a food consumption analysis that considers how a food is customarily used in the context of a daily diet. Further, the comment said that only a careful examination of food consumption data, in which foods are inherently related to their use in daily diets, can properly address the requirements of the law. The comment offered that the agency's proposed disclosure/disqualifying levels have some basis in daily consumption because of the use of DRV's. However, it said that the evaluation of individual foods in the agency's model is based on food composition values compared to food consumption values derived from DRV's. The comment argued that the composition of a food has no meaning in the context of the daily diet until its customary use is considered. The comment concluded that FDA did not do this, and that this error invalidates the agency's analysis.

The food composition methodology used by the agency in arriving at the proposed disclosure/disqualifier nutrient levels is fully consistent with section 403(r)(3)(A)(ii) of the act. As FDA explained earlier in this preamble in its response to comment 23 of this document, Congress intended that FDA establish these levels by considering the role of the nutrients in food in a way that will enhance the chances of consumers constructing total daily diets that meet dietary guidelines. The focus of this provision was clearly not on consumption of the individual food. Thus, references to "the significance of the food in the total diet" in that section does not imply that a food consumption analysis of how individual foods are used in a daily diet should be made. Instead, that section requires that FDA consider consumption in a far broader context. As explained in the subsequent paragraphs of this response, FDA's approach considers daily food consumption through use of the DRV's.

The DRV's were developed from recommendations in, for example, the Surgeon General's report (Ref. 5) and Dietary Guidelines for Americans (Ref. 7). They reflect current and established scientific evidence related to overall nutrient intake and risk of diet-related diseases. They also reflect total dietary intake from foods in general, but not intake from individual foods. Thus the disclosure/disqualifying nutrient levels are also based on food consumption in general, not just food composition.

Further, in arriving at the numerical value for the disclosure/disqualifying levels, the agency looked at the daily diet as being composed of approximately 20 servings of food and the likely distribution of the subject nutrients in the diet. The agency concluded that such nutrients were likely to be found at significant levels in as many as 10 of those 20 foods. Thus, while the agency did not consider the role of specific individual foods in the diet in arriving at the disclosure/disqualifying levels, the significance of particular types of food, such as those that contain a significant amount of fat, were considered. In sum, FDA's approach considers consumption in a broad manner that enhances the chances of consumers constructing total daily diets that meet dietary guidelines. Accordingly, contrary to the point made in the comment, the agency concludes that it did effectively consider food consumption data in which foods were related to their use in the diet in establishing the disclosure/disqualifying nutrient levels.

b. *Fifteen percent should increase to 20 percent.*

29. A number of comments, mostly from consumer organizations, agreed with the agency's rationale for selecting 15 percent of the DRV as the disclosure/disqualifying level for a specific nutrient; however, many comments from industry objected. In lieu of the 15 percent level chosen by FDA, the latter comments recommended 20 percent of the DRV because that is the amount the agency proposed as a "high" or "major source" nutrient content claim. Other comments strongly urged FDA to raise the disqualifying level to 20 percent of the DRV for cholesterol and sodium.

In addition, comments from industry and a Federal agency expressed concern that the disqualifying levels for fat, saturated fat, cholesterol, and sodium would prevent manufacturers from making potentially beneficial health claims on food that could assist consumers in making dietary changes. Some of the comments claimed that 99 percent of the food items in the categories of poultry, meat, and fish are disqualified from mentioning the health reasons for changes in consumption, despite recommendations from dietary authorities to substitute lean chicken and fish for meat. Similarly, the comments argued that the disqualifying levels would prevent nearly 90 percent of the items in mixed foods (grain), ready-to-eat cereal, and cheese categories and over 80 percent of the items in bread and crackers/salty snacks categories from making health claims. One comment concluded that the disqualifying levels would preclude many foods that could contribute to a better diet from mentioning truthful health reasons for making desirable substitutions, even where there is general scientific agreement on the desirability of these changes.

The agency agrees that the disqualifying levels for fat, saturated fat, cholesterol, and sodium should not serve as impediments to providing consumers with important information on diet and health by precluding health claims for major food groups, such as fish and whole grain cereals, that can be significant foods in a balanced and healthy diet. As FDA explained earlier in this preamble in its response to comment 23 of this document, Congress intended that FDA establish disqualifying levels by considering the role of the nutrients in food in a way that will enhance the chances of consumers constructing total daily diets that meet dietary guidelines. Thus it would not be appropriate for FDA to establish disqualifying nutrient levels that would be so stringent that major food groups that have an appropriate place in a healthful diet would not qualify for health claims.

In concert with the Surgeon General's recommendations, USDA and DHHS provided the American consumer with food guide information on food selection to achieve a healthy diet in the current edition of "Nutrition and Your Health, Dietary Guidelines for Americans" (Ref. 7). Most recently, USDA published "USDA's Food Guide Pyramid" (Ref. 29), which is intended to assist consumers in putting these dietary guidelines into action. The pyramid booklet provides information on dietary moderation, proportionality, and variety to ensure that consumers get the nutrients they need without too many calories or too much fat, saturated fat, cholesterol, sodium, sugar, or alcohol. The pyramid booklet suggests a range of daily servings from five major food groups, one of which includes meat, poultry, fish, dry beans, eggs, and nuts. As the comments indicate, a very large proportion of the items in this food group would exceed one or more of the disqualifying nutrient levels. Consequently, products in this group would not be permitted to bear health claims despite recommendations from dietary authorities to choose, for example, fish, lean meat, and poultry without skin as a way to reduce dietary fat intake. Accordingly, the agency has decided to revise the disqualifying nutrient levels to make it possible for a greater variety of foods in all food groups that are consistent with dietary guidelines to bear health claims.

FDA developed the disclosure/disqualifying levels for fat, saturated fat, cholesterol, and sodium to ensure that health claims are not made for foods that contain a nutrient in an amount that makes it difficult for consumers to comply with dietary guidelines. In developing these levels, FDA found no ready guidance on how to calculate them. The legislative history of section 403(r)(3)(A)(ii) of the act does not suggest what amount of a nutrient in a food should be considered as the limit to ensure compliance with dietary guidelines. Furthermore, current dietary guidance is presented in terms of daily nutrient intake rather than intake from individual foods.

Thus, in the absence of an accepted means for deriving the levels of nutrients in food that could be considered to increase the risk of disease, FDA, after considering the language of the act and its legislative history and based on the agency's scientific expertise, arrived at a tentative approach that was based on the proposed DRV's and available information on food composition and dietary intake patterns. The agency considered that a consumption pattern of individual foods that allowed for the intake of 100 percent of the DRV's would not increase the risk of diet-related disease, but that intakes resulting in the consumption of 200 percent of the DRV would do so. Therefore, an amount of a nutrient that would not increase the risk of disease would fall somewhere between 100 percent and 200 percent of the DRV. Based on the assumptions that diets generally include approximately 20 food/beverage items per day (Refs. 8 through 10), and that, given the uneven distribution of nutrients among the food categories, only about half of the foods consumed during a day will contain the nutrients of concern, the agency tentatively concluded that an increase in risk from an individual food was likely to result if it contained between 10 and 20 percent of the DRV per serving of fat, saturated fat, cholesterol, or sodium.

Based on food composition data available to the agency, FDA evaluated the kinds and types of foods that would be disqualified from bearing a health claim on the 10, 15, and 20 percent levels. Based on this evaluation, FDA tentatively concluded that 15 percent of the DRV represented the amount of the nutrients in question that increases to persons in the general population the risk of a diet-related disease or health-related condition.

After reviewing additional information on food composition (Ref. 30) and the comments recommending that the disclosure/disqualifying levels be raised from 15 to 20 percent of the DRV's, FDA is persuaded that its approach to calculating this level should be modified. FDA acknowledges that its primary concern in its initial development of these criteria was that foods that contain levels of nutrients that are not consistent with dietary recommendations be precluded from making a health claim. However, comments on this approach strongly urged that FDA also ensure that types of foods that are consistent with dietary recommendations—or, more specifically, types of foods whose increased consumption has been promoted in dietary recommendations—be able to bear claims if they meet the specified definition for the claim. In other words, comments argued that the disclosure/disqualifying levels should be sufficiently liberal so as to maximize the number of foods that bear claims and to allow claims on foods that are generally regarded as desirable components of an overall healthy diet,

assuming that the food meets the basic definition for the claim.

Based on consideration of foods highlighted by the comments as well as on a review of the food composition data available to the agency, FDA agrees that the use of a 20 percent DRV criterion will permit foods that are appropriately included in an overall healthy diet, for example a greater variety of bran and oat breakfast cereals or legume and vegetable products, to bear a health claim, even though they would not have been permitted to do so under the 15 percent DRV criterion. Furthermore, FDA finds compelling the argument made in comments that the criterion for "high" levels of a nutrient in a food can be applied not only as proposed (i.e., to emphasize the presence of a nutrient when it is considered desirable) but also can provide a consistent and appropriate basis for defining the levels at which the presence of a nutrient may be undesirable.

FDA acknowledges the debate on the issue that an exact level is not readily identifiable for a nutrient in a food that increases the risk of a disease or health-related condition to persons in the general population. With levels set at 20 percent of the DRV's for fat, saturated fat, cholesterol, and sodium, the question arises as to whether there are foods included among those containing 20 percent or less of a DRV that may lead to a diet inconsistent with dietary guidelines for maintaining good health. On reconsideration, the agency believes that the answer is no. Since the primary consideration from dietary guidance for avoidance of disease risk focuses on nutrient composition of the diet, and since there is no generally accepted way to extend that risk to the multiplicity of foods that may be selected in a daily diet while remaining consistent with dietary guidance, the agency finds that, taking into account the significance of the foods in question (that is, foods with 20 percent or less of the DRV for fat, saturated fat, cholesterol, or sodium) in the total daily diet, it is appropriate to adjust the disqualifying levels to the higher value of 20 percent of a DRV. In doing so, the agency is balancing the availability of valid information against the probability that food with that information will result in diets that increase the risk of a disease or health-related condition. FDA believes that, in the 15 to 20 percent range for establishing disqualifying levels, the importance of providing health claim information is greater than the possibility that risk of disease will be increased. Above 20 percent, however, the agency believes that that risk will increase and thus section 403(r)(A)(ii) of the act should be brought to bear. Therefore, FDA finds that, if a food contains more than 20 percent of the DRV for fat, saturated fat, cholesterol, or sodium (i.e., more than 13 g of fat, 4 g of saturated fat, 60 mg of cholesterol, or 480 mg of sodium) per reference amount customarily consumed or per label serving size it may not bear a health claim because these levels in an individual food can lead to a diet inconsistent with dietary guidelines for maintaining good health. Moreover, as explained in the response to comment 32 of this document, if a food that has a reference amount of 30 g or less or of 2 tablespoons or less contains more than 20 percent of the DRV for any of these nutrients per 50 g of food, it may not bear a health claim because claims on such nutrient-dense foods would be inconsistent with dietary guidelines.

c. *Increase for meals and meal replacements.*

30. Some comments suggested that FDA establish separate disqualifying levels for meal-type products at 25 percent of the DRV. They contended that products ordinarily consumed as meals contribute much more to the total diet than do individual foods. The comments argued that the single-food disqualifying levels for these meal-type items is too strict. A disqualifying level of 25 percent DRV for saturated fat, total fat, sodium, and cholesterol would ensure that persons eating three meals a day plus a snack would not exceed 100 percent DRV of any nutrients of concern.

The agency agrees that single food disqualifying levels are too strict when applied to meal-type products, which contain multiple servings of food. Because disqualifying levels for health claims are the same as disclosure levels for nutrient content claims, and because both are derived from the same statutory standard regarding nutrient levels in amounts that increase the risk of a diet-related disease in the general population, the definition for disqualifying levels in new § 101.14(a)(5) has been revised to be consistent with comparable requirements in new § 101.13 on disclosure levels for nutrient content claims for meal-type products published elsewhere in this issue of the **Federal Register**.

FDA is now providing for the definition of "meal product" in new § 101.13(l) and "main dish product" in new § 101.13(m) within the context of providing for nutrient content claims. As described in the nutrient content claims final rule, the agency is adopting different criteria for nutrient content claims for these products as compared with individual foods. The definition for a "meal product," which is described in more detail in the nutrient content claims final rule, is that: (1) It is represented as, or commonly understood to be, a dinner, lunch, breakfast, or other meal; and (2) it makes a major contribution to the diet by weighing at least 10 ounces (per labeled serving), containing at least 3 different foods from at least 2 of 4 food groups, and containing not less than 40 g of each of the 3 different foods. The definition for a "main dish product" is that: (1) It is represented as or is in a form commonly understood to be a main dish, and (2) it weighs at least 6 ounces per labeled serving, contains at least 2 different foods from 2 of 4 food groups, and contains not less than 40 g of a food from each of 2 food groups.

FDA has considered the appropriate disclosure/disqualifying level for main dish and meal products. As mentioned above, comments have suggested that the criterion be based on the amount per 100 g of product. Using this approach, the amounts used for individual foods (i.e., 13 g of total fat, 4 g of saturated fat, 60 mg cholesterol, and 480 mg sodium) would be the amount per 100 g of a meal or a main dish. FDA however notes that, on this basis, a meal weighing 10 ounces (280 g) would be subject to disclosure/disqualification if it contained approximately 36 g of fat or 55 percent of the DRV. A single meal product weighing 12 ounces (336 g)—not an uncommon weight for a meal—would be subject to disclosure/disqualification if it contained approximately 44 g of fat or about 67 percent of the DRV for total fat. If it is assumed that a "meal" constitutes one-fourth of a total day's nutrient/calorie intake, which, if anything understates the contribution of a meal, this criterion is seen to be too high because a meal could contribute more than half of the total amount of one of the nutrients in question (i.e., fat, saturated fat, cholesterol, or sodium) generally recommended as a total daily intake and yet still bear a health claim.

The comments received offered no approaches other than use of the "per 100 g" basis relative to disclosure/disqualifying levels for main dishes and meals. FDA, therefore, has developed an approach that extends the rationale used for individual foods to main dishes and meals. Specifically, given that main dishes and meals constitute a larger portion of the diet than individual foods, the criterion for disclosure/disqualification for main dishes and meals should be a greater percentage of the DRV than for individual foods.

FDA has determined that criteria of 30 percent of the DRV as a disclosure/disqualifying level for main dishes and of 40 percent of the DRV as that level for meals are appropriate. Assuming a typical consumption of three meals and a snack, each of which contain 40 percent of the DRV for a particular disclosure/disqualifying nutrient, and foods that sometimes accompany meals such as beverages, bread, and desserts that contribute an additional 40 percent of the DRV for the nutrient, 200 percent of the DRV would be consumed during the day. As discussed in the response to comment 29 of this document, FDA has concluded that on balance, given the benefits and the probabilities that risk of disease will be increased, a disqualifying level based on a total dietary intake of 200 percent of the DRV is appropriate.

Disclosure/disqualifying levels for main dishes are appropriately placed at 30 percent because it is likely that consumption levels of these products is between the level for individual foods and the level for meals. Therefore, FDA has set the criterion at 30 percent which is between the 20 percent criterion for individual foods and the 40 percent criterion for meals. Finally, FDA's review of available data suggests that these criteria have practical application in that the criteria of 30 and of 40 percent of the DRV would not be overly restrictive (Ref. 35). Accordingly, the definition of disqualifying nutrient levels in new § 101.14(a)(5) has been revised to incorporate these changes for meals and main dish products.

31. One comment from a manufacturer of foods for special dietary uses suggested that the proposed disqualifying provisions of proposed § 101.14(a)(5) should not apply to a formulated product presented as a meal replacement where a serving provides one-fourth to one-third of the daily nutrient intake based on calories. Rather, the comment suggested that the disqualifying levels should be based on the amount of total fat, saturated fat, cholesterol, or sodium when the amount of any of these substances exceeds the equivalent portion of the DRV on a caloric basis. For example, according to the comment, a meal replacement that provides 25 percent of the daily caloric intake in a single serving should have the disqualifying levels set at or above 25 percent of the DRV's. The comment said that such a provision would provide a standard for these products consistent with the regulation. Each "serving" of the formulated product would represent an entire meal and would replace several servings of conventional food. Establishing disqualifying levels on this basis, the comment said, would allow consumers access to important health information. The comment suggested that the proposed regulation be modified to read as follows:

> Formulated meal replacement products that provide 25% to 33–1/3% of the daily caloric intake shall be disqualified when the level of fat, saturated fat, cholesterol, or sodium exceeds, on a caloric basis, the equivalent portion of the Daily Reference Value [21 CFR 101.9(c)(12)(i)].

The agency acknowledges the point made by this comment that a meal replacement product, particularly one that is a food for special dietary use, may be sufficiently different from a serving or amount of a conventional food to warrant a different criterion for disqualifying nutrient levels. Nevertheless, the agency does not believe that it is appropriate to modify the codified language as recommended because of a lack of essential information needed to implement the change. Specifically, where the proposed codified language applies to "formulated meal replacement products," there is no definition or other characterizing information that identifies this class of products.

The agency published proposed regulations on June 14, 1974, to establish a nutritional quality guideline and a common or usual name for formulated meal replacements (39 FR 20905). Subsequently, however, those proposals were withdrawn. Although they may serve as a basis to reconsider what had been proposed, a significant number of changes have occurred in the intervening 18 years with regard to the regulations and policy on the nutrient content of foods.

For example, the proposed nutrition quality guideline regulation defined a formulated meal replacement, in part, as a product that supplies a minimum of 700 kilocalories per serving (the term "calorie" has the same meaning as "kilocalorie" in the text that follows), unless the product is represented for use in a reduced calorie diet (39 FR 20905, June 14, 1974). On the presumption that a meal should provide at least 25 percent of daily caloric intake, the value of 700 calories per serving was derived from a proposed intake standard of 2,800 calories per day. Subsequently, as reflected in the current fortification policy (21 CFR 104.20), the energy intake standard has been lowered to 2,000 calories per day. This value is the same as the reference caloric intake that FDA used in determining the DRV's, published elsewhere in this issue of the **Federal Register**. Accordingly, the agency advises that with the necessary steps to establish a definition and nutrient composition and nutrition quality requirements for the class of "meal replacement products," particularly those that are foods for special dietary use, consideration may be given to providing an exception to disqualifying levels for that class of products.

The agency has examined several products currently in the marketplace promoted for use, among other things, as either a "meal replacement" or as a "balanced meal" that included a formulated ready-to-consume fluid product and dry mixes for addition to fluid milk to produce an "instant breakfast drink." The former, but not the latter, type product bore other labeling for use of the product to either lose or gain weight, thus classifying the product as a food for special dietary use. A single serving of the ready-to-consume product provides 360 calories, whereas the dry mixes provide 220 calories when combined with 8 fluid ounces of skim milk. From nutrition labeling information, neither type of product exceeds the disqualifying levels for fat and sodium defined in new § 101.14(a)(5) for an individual food. From the list of ingredients and nutrient content information from standard data bases, it is also unlikely that either product would exceed the disqualifying levels for saturated fat or cholesterol. Further, it appears that if a serving of the ready-to-consume meal replacement were adjusted to increase the caloric yield from 360 to 470 calories per serving, the disqualifying levels for fat, saturated fat, cholesterol, and sodium would still most likely not be exceeded. Although this assessment, admittedly, is extremely limited in scope, the agency concludes that the disqualifying levels in new § 101.14(a)(5) for an individual food will apply to a product promoted as a meal replacement until a more appropriate requirement is established by regulation.

d. *Per 100 grams.*

32. A number of comments from industry and from other Government agencies objected to the part of the proposed definition for "disqualifying nutrient levels" in proposed § 101.14(a)(5) that tied such levels to the amount of fat, saturated fat, cholesterol, or sodium "per 100 g." One comment asserted that 100 g means nothing to the public and suggested that standardized serving sizes should be the basis of labeling. Others agreed that the "per 100 g" criterion is unnecessary with the adoption of standardized serving sizes, which, the comments asserted, effectively eliminate the agency's concern that manufacturers may

manipulate serving sizes to make their products appear more attractive. One comment cautioned that using both the 100 g and serving size requirements risks substantial confusion.

FDA does not agree that a weight-based criterion is unnecessary. The agency notes that section 403(r)(3)(B)(iii) of the act states that a claim should enable the public to comprehend the information in a claim and understand the relative significance of that information in the context of a total daily diet. Because certain foods are consumed in small amounts and thus have small serving sizes, it is possible that a food dense in a nutrient such as fat or sodium could qualify for a health claim because the serving size of the food is so small that there is not a sufficient amount of the nutrient present to disqualify the food. Accordingly, the nutrient density, or weight-based, criterion was developed to deal with foods with small serving sizes that may be consumed more frequently than once a day.

However, the food itself could be inconsistent with dietary guidelines in that it has been identified as a food to be limited in the diet. "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 7) states that certain types of foods high in fat, for instance, should be limited in the diet without regard to the amounts typically consumed in a single serving. Furthermore, the recommendations provided in "USDA's Food Guide Pyramid" (Ref. 29) are consistent with the guidance to limit the intake of certain types of foods regardless of serving size. Claims on such foods would promote their consumption and, thus, fail to set the food in its proper dietary context.

Therefore, FDA has concluded that criteria for health claims based solely on serving size would be inconsistent with dietary guidance and would fail to respond to section 403(r)(3)(B)(iii) of the act, which requires that the claim set the food properly in the context of the diet. This conclusion is supported by the comments to the docket discussed in the response to comment 87 of this document, which stated that health claims should be prohibited on foods that are inconsistent with a sound dietary pattern. Moreover, claims intended to promote the consumption of a food that appear on a food that is inconsistent with dietary guidelines could be misleading to consumers under section 403(a) of the act and, thus, such claims are inappropriate.

However, the agency has concluded that the weight-based criterion is only needed for foods with small serving sizes that include those foods with reference amounts of 30 g or less or 2 tablespoons or less. For foods with reference amounts above 30 g or 2 tablespoons, the per label serving size or per reference amount customarily consumed criteria are sufficient to prevent nutrient-dense foods from bearing health claims.

Accordingly, FDA has provided for a weight-based criterion in addition to the criterion that specifies the amount of nutrient present per reference amount customarily consumed and per label serving. The weight-based criterion precludes claims on nutrient-dense foods and would qualify for a health claim solely because they have very small serving sizes.

A weight-based criterion for foods with small serving sizes is also used with nutrient content claims, which are discussed in a final rule published elsewhere in this issue of the **Federal Register**. As discussed in that document, comments to the nutrient content claims proposal stated that basing the criterion on per 100 g may be overly restrictive. These comments pointed out that the per 100-g criterion precludes claims on foods that are consistent with dietary guidelines, such as whole grains and cereals. Alternative and less restrictive criteria were suggested including a criterion based on 50 g rather than 100 g. As discussed in the nutrient content claims final rule, FDA has been persuaded that it is appropriate to use 50 g rather than 100 g as the weight-based criterion.

To ensure that its treatment of disqualifier and disclosure levels is consistent, FDA has reexamined the 100-g criterion for use with health claims. Data analyses (Ref. 31) demonstrate that changing from 100 g to 50 g and applying the criterion only to foods with small serving sizes allows a number of foods that would otherwise have been precluded from bearing a claim and that are consistent with dietary recommendations, such as certain cereals and whole grains as well as fish and milk products, to qualify for health claims. Moreover, such a change would allow only a few foods that are inconsistent with dietary guidelines to bear claims. Therefore, to provide for claims that are consistent with dietary guidance, FDA is providing for a weight-based criterion for foods with small serving sizes based on per 50 g rather than per 100 g. In addition, for dehydrated foods that must have water added to them prior to typical consumption, the per 50-g criterion refers to the "as prepared" (that is, hydrated) form.

The agency also disagrees that using three criteria, nutrient density, reference amount customarily consumed, and label serving size, to determine disqualifying levels runs the risk of confusing consumers. The determination as to whether a food contains a disqualifying level of a nutrient is not discussed on the label or in labeling. Thus, there is no basis on which a consumer could be confused.

e. *Relevant nutrients.*

i. *Fat and saturated fat.*

33. One comment recommended that in conjunction with the health claim on skim milk and 1 percent lowfat milk, the agency requires that the products display a statement that "whole milk is more appropriate for the growth and development of children under two years who are drinking milk." The comment noted that children in this age group require an adequate amount of fat in their diet for proper growth and development.

FDA does not believe that skim and lowfat milk should be required to bear the suggested statement. The health claim about calcium and osteoporosis is directed primarily to those individuals with known family histories of osteoporosis and to adolescent and young adult Caucasian and Asian American women. Such claims are not directed to children. In fact, health claims are prohibited, except in very limited circumstances, wherever a food is represented or purports to be for infants and toddlers less than 2 years of age. Therefore, FDA rejects the request in this comment.

34. Some comments asserted that the disqualifying levels for fat and saturated fat were too high and should be lowered.

The agency disagrees with this contention. Absent a showing to the contrary, and the comments did not contain such a showing, the agency has no basis to find that levels in a food of fat and saturated fat of less than 15 percent of the respective DRV's increase the risk of a diet-related disease. Further, as explained above, FDA has reassessed the issue and concluded that the disqualifying levels for fat and saturated fat should be raised to 20 percent of their DRV's. The agency finds that this decision is consistent with dietary recommendations to limit energy intake from fat and saturated fat to 30 and 10 percent of calories, respectively. Accordingly, the agency rejects the comment's recommendation.

35. One comment stated that the disqualifying regulations for fats and saturated fats should be adjusted to reflect the use of reduced calorie novel fats and fat replacers. The comment

explained that products employing novel fats should be eligible to display a lipid and cardiovascular health claim consistent with other requirements for this claim. The comment asserted that the identity of fat should be limited to those materials that do in fact provide measurable bioavailable fatty acids and calories. The comment asserted that fatty acid containing fat substitutes that are essentially nondigestible do not qualify as fats and should be treated separately. The comment stated that the quantity of fat should be determined by the amount of bioavailable fatty acids that such a fat substitute contains. This approach, the comment said, would provide a common basis for quantifying the fat equivalence of novel fats as well as mono- and diglycerides, phospholipids, and "natural" fats of limited digestibility. Under it, total fat could be quantified, and fatty acid type could be expressed as the triglyceride equivalent of the bioavailable fatty acid fraction. For the novel fats, the average characterizing bioavailability could be established by the manufacturer and submitted to FDA as part of a petition for regulatory food-use approval. Application of a "bioavailability" index for fats would be similar to the use of the Protein Digestibility Corrected Amino Acid Score or Protein Efficiency Ratio used to characterize proteins and of the bioequivalence values assigned to vitamin products.

The agency does not disagree with the comment's main point that the quantity of fat in a product, which determines whether a claim can be made, should be determined by the amount of bioavailable fatty acids that the product contains. Total fat content is a part of nutrition information mandated by section 403(q)(1)(D) of the act. Thus, any claim (i.e., a health claim or nutrient content claim) based on fat content must be based on the amount of fat declared in the nutrition label. How total fat content is determined is addressed in the regulation on mandatory nutrition labeling, new § 101.9, published elsewhere in this issue of the **Federal Register**. Thus, the agency sees no need to provide for a separate method in the health claims regulation for purposes of declaring whether a food contains a disqualifying, or a qualifying, level of fat.

The agency advises that any proposal to modify the methods for determining the total fat and fatty acid content of a food may be submitted as a petition to amend new § 101.9. Moreover, as explained in the final rule on mandatory nutrition labeling, when seeking approval from the agency for use of a fat replacer or novel fat in food, the petitioner should include information on the caloric value and macronutrient content of the ingredient. Nutrient content requirements for health claims will be subject to the appropriate requirements for nutrition labeling and any other related regulation.

ii. *Cholesterol.*

36. Many comments expressed support for the proposed cholesterol disqualifying levels. One Federal agency objected to the proposed cholesterol disqualifying level which, it contended, appears to be based on behavioral assumptions about consumption patterns that are not borne out by USDA data. Another comment urged that FDA raise the disqualifying level for cholesterol to one-third of the DRV.

As discussed in detail above, FDA has reassessed the disqualifying levels for cholesterol, fat, saturated fat, and sodium. The agency has concluded that the levels for all 4 can be set at 20 percent of the DRV's. Accordingly, having concluded, for the reasons set out previously, that a nutrient level in excess of 20 percent of the DRV for each of the 4 disqualifying nutrients is associated with an increased risk of a diet-related disease or health-related condition, the agency rejects the recommendation that the disqualifying level for cholesterol be raised to one-third of the DRV.

iii. *Sodium.*

37. Some comments challenged FDA's decision to set a disqualifying level for sodium. One of these comments noted that it was FDA and not Congress that identified sodium as a nutrient of concern because sodium, like fat, saturated fat, and cholesterol, has been "associated with increased risk of disease." Several comments asserted that there is a lack of significant scientific agreement on a link between dietary sodium and hypertension.

One comment cited reports by the Surgeon General and others as proof of the divided and inconclusive opinions of experts in the field. Furthermore, the comment charged that FDA had failed to independently analyze the results of the INTERSALT study, which, the comment alleged, refutes the traditional sodium-hypertension hypothesis.

Another comment submitted published studies that it claimed supported the comment's position that there is no rational basis for concluding that any single food contains sodium "in an amount which increases to persons in the general population the risk of a disease or health-related condition which is diet related," and that "FDA has absolutely no statutory or scientific basis by which to establish any disqualifying level for sodium." One comment warned that a final decision by FDA to set such a level without proper regard to conflicting scientific data would not meet the statutory requirements of sections 403(r)(3)(A)(ii) or 403(r)(2)(B)(ii) of the act governing the establishment of disqualifying and disclosure nutrient levels and would clearly constitute arbitrary and capricious rulemaking.

The agency disagrees with the contention that sodium has not been associated with increased risk of disease. As explained in detail in the specific health claim document on this subject that is published elsewhere in this issue of the **Federal Register**, the available data, including the INTERSALT study, establish that dietary sodium intake is associated with hypertension. This discussion is referenced. For example, "Dietary Guidelines for Americans" (Ref. 7) states:

> Many American diets have too many calories and too much fat (especially saturated fat), cholesterol, and sodium. * * * Such diets are one cause of America's high rates of obesity and certain diseases—heart disease, high blood pressure, stroke, diabetes, and some forms of cancer.

FDA is convinced not only of the scientific soundness of the sodium/hypertension health claim but also of the appropriateness of a disqualifying level for sodium.

38. One comment suggested that it would be appropriate to include on the label of a food, in immediate proximity to any health claim, information on the sodium content (such as that required by new § 101.13(h) published elsewhere in this issue of the **Federal Register**), thus benefitting the small segment of the population for which sodium may be of concern, while providing a health message that could potentially benefit a much larger population.

FDA recognizes that there may be a number of different ways to display selected information, like sodium content, to meet various consumer needs or preferences. Although a display of sodium content information like that recommended by the comment may benefit a certain segment of the population, the 1990 amendments do not provide the agency with authority to require for health claims the type of nutrient disclosure required for nutrient content claims by new § 101.13(h). That regulation derives from section 403(r)(2)(B)(ii) of the act which states that if a food that bears a nutrient content claim that increases to persons in the general population the risk of a disease or health-related condition, the claim shall also identify such nutrient. Under those same circumstances,

however, the 1990 amendments do not permit a health claim to be made. The regime by which nutrient content claims are made is different than that for health claims.

The agency points out, nevertheless, that any food with a health claim will also bear nutrition information listing sodium and other nutrient content. Although the information on sodium content may not be displayed as conveniently or prominently as that recommended by the comment, it will, nevertheless, be readily accessible on a product's label.

39. Other comments called for a higher disqualifying level for sodium. One comment argued that the decision to set the sodium disqualifying level at 15 percent of the DRV is not as solidly based as the disqualifying levels for fat, saturated fat, and cholesterol. The comment further concluded that because much of the sodium in the American diet is concentrated in a few products, a product containing 20 percent of the DRV for sodium (480 mg) could easily be incorporated into a diet without increasing the risk of hypertension. Another comment agreed that the proposed sodium disqualification levels are too strict and noted that many breads would be restricted from making any health claims if the proposed level is adopted.

Another comment urged that FDA raise the disqualifying level for sodium to one-third of the DRV. The comment warned that setting such a low disqualifying level as 15 percent of the DRV for sodium would discourage manufacturers from producing lowfat products, because salt is required to improve the taste, and thus the marketability, of many such lowfat products.

As discussed previously in this section, FDA has reassessed its analysis for defining disqualifying levels and determined that the levels can be set for sodium and the 3 dietary lipids at 20 percent of the DRV's. Having concluded that nutrient levels greater than 20 percent of the DRV's, including that for sodium, increase the risk of diseases or health-related conditions that are diet related, FDA rejects the recommendation that the disqualifying level for sodium be set at one-third of that nutrient's DRV.

f. *Exception from disqualification.*

40. Some comments stated that exceptions to the disqualifying levels should not be granted. Other comments urged FDA to consider requests for exemptions from the disqualifying levels only on a case-by-case basis, and only when virtually all foods containing significant levels of the nutrient would otherwise be disqualified. One of these comments asserted that none of the currently proposed health claims would warrant an exception. Furthermore, many of the comments suggested that if FDA did grant an exception, a statement disclosing the level of the disqualifying nutrient should appear prominently next to the health claim.

The agency disagrees with those comments recommending that exceptions to the disqualifying levels should not be granted. Similarly, it is not convinced that the only basis to permit exceptions is when virtually all foods containing significant levels of the health claim nutrient would be disqualified. Section 403(r)(3)(A)(ii) of the act provides the Secretary (and FDA, by delegation) discretionary authority to permit a claim for a food that would otherwise be disqualified if the Secretary determines that the claim would assist consumers in maintaining healthy dietary practices. The agency is prepared to consider whatever arguments may be brought to bear with respect to a particular claim or with respect to a particular nutrient as to why an exception to a disqualifying level should be granted. Thus, the agency is not prepared to limit its discretion in the manner suggested by several of the comments.

If an exception to the disqualifying levels is authorized, section 403(r)(3)(A)(ii) of the act specifies that the label of the product contain a disclosure of the type required by section 403(r)(2)(B)(ii) of the act. Thus, the disclosure will have to be made prominently and in immediate proximity to the claim. It will have to identify the nutrient, and it will have to refer the consumer to the labeling panel where nutrition information may be found.

41. Other comments urged the use of discretion in permitting health claims for foods in cases where such claims would assist consumers in maintaining healthy dietary practices. Oils and margarine were cited as examples of foods for which exceptions should be made to provide consumers with information on the health reasons for choosing oils that are lower in saturated fat, because all oils exceed the disqualifying level of 11.5 g of fat. One comment emphasized the importance of focusing on the type of fat in the fats that are consumed and concluded its comment by suggesting that FDA could address its concern about total fat by requiring a clear message on such products that consumers should consume less fat.

The agency intends to use discretion in permitting health claims that encourage certain dietary practices generally recognized by the public health community as being consistent with guidelines for maintaining and promoting good health. FDA acknowledges that "Dietary Guidelines for Americans" (Ref. 7), while recommending that diets low in fat be chosen, also provides advice on how certain fats and oils used sparingly can assist the consumer in maintaining a relatively low saturated fat intake. Although fats and oils obviously exceed the disqualifying level for fat, section 403(r)(3)(A)(ii) of the act does permit exceptions, as discussed previously. Accordingly, FDA is willing to consider a petition that provides a basis for excepting certain fats and oils based on compositional or other characteristics from being disqualified from bearing a particular health claim.

42. A number of comments asked that FDA exempt milk and other dairy products from the disqualifying levels for fat and saturated fat. One comment noted that dairy products contribute 76.8 percent of the dietary calcium in the food supply, yet contribute only 20 percent of the saturated fats and 12 percent of the total fat. The comment contended that allowing only fat-reduced dairy products to make a calcium/osteoporosis claim would be misleading to those individuals who prefer whole milk to reduced-fat milk.

While milk and other dairy products do in fact contribute a large percentage of the daily supply of calcium, the agency noted in the preamble to the proposed regulations that lowfat and skim milk will be able to bear a health claim under proposed § 101.14(a)(5), as will many products made from these reduced-fat milks. FDA, therefore, cannot conclude that an exception for whole milk and other dairy products that exceed the fat disqualifying level would assist consumers in maintaining healthy dietary practices.

III. Preliminary Requirements for a Claim

FDA proposed several criteria in proposed § 101.14(b) that would have to be met before a substance would qualify to be the subject of a health claim. These criteria reflect not only the requirements of section 403(r) of the act but also the fact that FDA is charged with ensuring that the food supply is safe, and that the food label is not misleading. Given that agency evaluations of the validity of a health claim will be resource intensive, FDA proposed not to make such an evaluation unless a petition for a health claim demonstrates that the preliminary requirements are met.

A. Effect on General Population

As proposed, § 101.14(b)(1) stated:

The substance must be associated with a disease or health-related condition for which the general U.S. population, or an identified U.S. population subgroup (e.g., the elderly) is at risk, or, alternatively, the petition submitted by the proponent of the claim otherwise explains the prevalence of the disease or health related-condition in the U.S. population and the relevance of the claim in the context of the total daily diet and satisfies the other requirements of this section.

43. Several comments endorsed, or advised that there was no objection to, the agency's preliminary requirement in proposed § 101.14(b)(1). Some of these comments stressed that the agency should always interpret this provision with flexibility. One comment asked for clarification as to whether a proven substance-disease claim would be allowed if the affected population was few in number or not readily identifiable as a subpopulation (e.g., vitamin D insufficiency in an undefined population group).

FDA intends to apply a flexible approach in interpreting this provision. The proposed alternative aspect of the provision, which would permit petitioners to explain the prevalence of the disease or health-related condition in the U.S. population and the relevance of the claim in the context of the total daily diet, evidences a determination by FDA to disqualify as few proposed claims as possible under this provision. However, if a proposed claim is ultimately authorized by FDA that involves an affected population that is few in number, that fact will have to be declared in the labeling in conjunction with the claim. Where the affected population is not readily identifiable, information about the prevalence of the disease or health-related condition in the U.S. population will be a material fact and thus will have to be provided in conjunction with the claim if the claim is not to misbrand the product.

As explained previously in this preamble (see comment 2 of this document), FDA does not believe that the 1990 amendments pertain to claims about diseases resulting solely from classical deficiencies of vitamins and essential minerals. Thus, for example, a claim about the benefits of vitamin D in reducing the risk of rickets, if not representing the product as a drug, needs no preclearance under the provisions of new § 101.14. However, such claims must be truthful and not misleading. In view of the fact that very few people are at risk of vitamin D deficiency disorders, a claim about the benefits of vitamin D in preventing vitamin D insufficiency would be misleading where the claim does not explain that few individuals in the United States are at risk of such insufficiency. Further, the claim would need to be more specific about the affected population to be adequately informative. For example, the claim might advise that although the vast majority of the U.S. population is not at risk for vitamin D deficiency disorders, the vitamin may be effective in reducing the risk of vitamin D deficiency problems in some segments of the elderly who are house-bound for prolonged periods and are not exposed to sunlight.

B. Components of Food within the Context of a Daily Diet

New § 101.14(b)(2) and (b)(3)(i) contain provisions requiring that the substance be a component of food. If the substance is present at decreased dietary levels, under new § 101.14(b)(2), it must be a nutrient that is required to be included in nutrition labeling (e.g., cholesterol, total fat). If the substance is present at other than decreased dietary levels, under new § 101.14(b)(3)(i), it must contribute taste, aroma, or nutritive value, or any technical effect listed in § 170.3(o) to the food, and must retain that attribute when consumed at levels that are necessary to justify a claim.

1. General

44. One comment suggested that FDA predetermine for each nutrient appearing in an approved health claim a level below which the nutrient is considered to be present in the context of the total daily diet and above which the nutrient is considered to be present at therapeutic levels.

FDA does not believe that it is practicable or appropriate for the agency to attempt to identify any single nutrient level as a boundary between those levels that are within the context of the daily diet and those which are therapeutic. The agency simply does not have sufficient resources to devote to the suggested determinations without unduely sacrificing resources from other high priority regulatory matters. Instead, FDA believes that it is more appropriate that the burden be upon the petitioner to demonstrate that the claimed effect actually can be achieved through consumption of dietary levels of the substance. At such levels, the presence of therapeutic effects should not be at issue.

2. Section 101.14(b)(3)(i)

45. Some comments stated that the eligibility restrictions on the term "substance" in proposed § 101.14(b)(3)(i) are too restrictive and asked that they be removed. One comment asserted that the agency is creating needless procedural confusion by having a broad definition of the term "substance" in proposed § 101.14(a)(2), which it then immediately narrows in proposed § 101.14(b)(3)(i). A few comments contended that, if FDA retains the food eligibility restrictions in the final rule, the agency should permit a broader interpretation of what constitutes food. Another comment stated that although the phrase "taste, aroma, or nutritive value" is borrowed from the Seventh Circuit's opinion in *Nutrilab Inc.* v. *Schweiker*, 713 F.2d 335, 338 (7th Cir. 1983), the court noted in that decision that these food characteristics were only the primary reasons why people consume food. The court, according to the comment, did not intend to give an all-inclusive list. One comment stated that not all of the other possible food characteristics are encompassed in the listing provided in § 170.3(o). Some comments asserted that food should include everything that can be consumed.

FDA does not believe that it is overly restrictive to require, as it does in proposed § 101.14(b)(3)(i), that a substance be a food or a component of food for it to be the subject of a health claim. Section 403(r) of the act describes the circumstances in which a food will, and will not be, misbranded if it bears a health claim. Thus, it is appropriate for the agency to make it incumbent upon the proponent of a health claim to demonstrate that the substance that is the subject of the claim is a food or component of food.

FDA believes that the framework that it has created in its regulations is appropriate and fully consistent with the act. Under it, manufacturers will be able to make claims that characterize the relationship between any substance and a disease or health-related condition so long as the substance achieves its effect through its use as a food, that is, through its nutritional value.

FDA disagrees with the comments' interpretation of the *Nutrilab* decision and believes that the agency's reliance on the case is justified. The *Nutrilab* court adopted a "common sense" definition under section 201(f)(1) of the act: "When the statute defines 'food' as 'articles used for food,' it means that the statutory definition of 'food' includes articles used by people in the ordinary way most people use food—primarily for taste, aroma, or nutritive value." *Nutrilab*, 713 F.2d at 338. Other courts have followed suit. (See *United States* v. *Undetermined Quantities of Cal-Ban*

3000, 776 F. Supp. 249, 254–55 (E.D.N.C. 1991); *American Health Products Co.* v. *Hayes*, 574 F. Supp. 1498, 1508–09 (S.D.N.Y. 1983), aff'd, 744 F.2d 912 (2d Cir. 1984).) By describing taste, aroma, and nutritive value as the "primary" reasons for consuming food, the *Nutrilab* court acknowledged that a food consumed for one of these reasons might sometimes also be consumed for an additional purpose. 713 F.2d at 338 (giving prune juice and coffee as examples of foods that "may be consumed on occasion for reasons other than taste, aroma, or nutritive value"). Under *Nutrilab*, a substance whose uses do not include taste, aroma, or nutritive value is not a food.

FDA does not believe that the word "food" should be defined any more broadly than it is in the proposed regulation, and the agency specifically rejects the proposal to define "food" as "any substance that is consumed by people for any purpose other than the treatment of disease." Under such an expanded definition, the parenthetical exception for food to the definition of drug in section 201(g)(1)(C) of the act would swallow the rule. Section 201(g)(1)(C) of the act states that "articles (other than food) intended to affect the structure or any function of the body of man or other animals" are drugs. Under the definition of food suggested in the comment, the only products consumed by people that would be considered drugs under section 201(g)(1)(C) of the act would be those intended both to affect the structure or function of the body and to treat a disease. Substances taken to treat a disease are already drugs under section 201(g)(1)(B) of the act, regardless of whether they are foods. The suggested definition of "food" would thus render section 201(g)(1)(C) of the act meaningless. It is a basic principle of statutory construction that a statute should not be construed in such a way as to render certain provisions superfluous or insignificant. *United States* v. *Leonard*, 868 F.2d 1393, 1395–96 (5th Cir. 1989), cert. denied, 496 U.S. 904 (1990).

46. Numerous comments from producers and consumers of dietary supplements expressed concern that the proposed provision represents an attack by the agency against dietary supplements. Some comments maintained that FDA lacks the legal authority to restrict approved health claims on nutritional supplements that are beyond daily diet limits. Other comments asserted that FDA intends to use regulations based on the proposal to ban health claims on dietary supplements wherever the supplements contain a substance above the context of an ordinary daily diet. Other comments stated that the agency would ban the supplements themselves by making them available only by prescription or by limiting the potency of the supplements. A few comments believed that FDA would also ban supplements where they lack a therapeutic effect at levels within the context of an ordinary daily diet. While most of the comments did not specify any particular proposed provisions that could lead to these actions, they strongly protested that any restriction on dietary supplements would infringe on consumers' freedom of choice and would be in conflict with the Proxmire Amendment (21 U.S.C 350) and the 1990 amendments.

As stated above, the DS Act imposed a moratorium on the implementation of the 1990 amendments with respect to dietary supplements. Thus, nothing in these final rules will affect dietary supplements in any way. However, FDA disagrees with the comments' characterization of its proposal and disagrees with the statement that the proposed regulations were in conflict with section 411 of the act (21 U.S.C. 350) (the Proxmire Amendment). Nothing in the proposed regulations would have affected the availability of dietary supplements. Rather, these regulations were intended to regulate claims that may be made for all foods, including dietary supplements.

Nothing in the regulations would necessarily prevent a supplement from bearing a health claim when that supplement contains a level of a substance that exceeds the level achievable in the context of the daily diet. To the contrary, the final rule concerning calcium (where health benefits are provided within the context of the daily diet), for example, which is published elsewhere in this issue of the **Federal Register**, permits a calcium health claim for dietary supplements and requires only that the supplement labeling advise consumers that there is no known benefit from consuming more than 200 percent of the U.S. Recommended Dietary Allowance (U.S. RDA) for calcium.

Section 411 of the act does not authorize health claims for dietary supplements or in any way affect FDA's authority under section 403(r)(5)(D) of the act to regulate such claims. Under section 411(a)(1)(B) of the act, FDA may not classify a dietary supplement as a drug solely because it contains vitamins or minerals exceeding the level of potency that the agency determines is nutritionally rational or useful. Nothing in the proposed regulations would have done so. Absent a claim, FDA will not consider a dietary supplement to be a drug simply because it contains vitamins or minerals at levels above those normally found in food. However, a claim on a product may indicate the product's intended use. If a claim reveals that the product is intended to be used in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body (other than food), the product is a drug. (See 21 U.S.C. 321(g)(1)(B) and (g)(1)(C)).

47. Another comment asked for assurance that approved health claims appearing on dietary supplements will not automatically be considered drug claims. The comment noted that section 201(g)(1)(B) of the act exempts approved health claims on foods from consideration as drug claims and stated that dietary supplements should be afforded the same exemption under FDA regulations.

Section 202(b) of the DS Act does permit FDA to approve health claims with respect to dietary supplements. FDA advises that, as provided in section 201(g)(1)(B) of the act, any food, including dietary supplements, for which an authorized health claim is made in accordance with the requirements of section 403(r) of the act, and of the regulations that FDA has adopted to implement that section of the act, is not a drug under section 201(g)(1)(B) solely because its label or labeling contains such a claim. FDA considers this provision to provide the same type of assurance as that in sections 406, 408, and 409 of the act that foods containing substances used in accordance with regulations issued under those sections of the act are not subject to regulatory action under section 402(a)(1) of the act. This provision does not create an exception to the "drug" definition. Thus, a product whose intended use is as a drug will continue to be regulated as a drug.

3. Drugs

48. One comment contended that FDA should permit the use of health claims on over-the-counter (OTC) antacid products containing only calcium carbonate. The comment noted that the preamble to the proposed regulations cited the potential for confusion if health claims were allowed for bulk-fiber laxatives that have not been shown to be useful in lowering cholesterol and for which appropriate labeling for that claim does not exist. The comment asserted that while health claims may be inappropriate for laxatives, such claims would be appropriate for antacids. The comment stated that calcium has been

identified as an essential nutrient which, unlike psyllium, has a defined intake requirement as well as a claim that FDA has proposed to authorize relating to the role of calcium in helping to reduce the risk of developing osteoporosis. The comment asserted that FDA's objection to OTC drugs bearing health claims is not appropriate in the case of calcium-based antacids because antacids have been labeled for years with both food and drug labeling. The comment explained that many antacids bear calcium nutrient content claims with directions for using the products as calcium dietary supplements as well as antacids.

Further, the comment pointed out that, in addition to calcium carbonate, there are several multiple use products currently in the marketplace (e.g., sodium bicarbonate). The comment stated that sodium bicarbonate, marketed under the name "baking soda," is labeled as a baking ingredient, a deodorizer, and an antacid. The comment suggested that FDA approve health claims on drugs under the following conditions: (1) The drug is properly labeled; (2) a health claim has been approved by FDA for an ingredient in the drug; (3) the OTC product meets or exceeds the requirement for a minimum recommended intake of "the natural supplement" as established by regulation; and (4) all labeling is in compliance with the authorizing regulation.

Multiple use products that are both foods and drugs present a difficult set of competing concerns for the agency. Such products are likely to be, like the product that is the subject of the comment, both an OTC drug and a dietary supplement.

Most OTC drug products are developed to address some type of acute physical problem that is expected to be of short duration. If the problem persists, it is important that the person with the problem know that it may be more severe than he or she otherwise thought, and that he or she seek medical attention. Labeling on such products, therefore, includes instructions to use the product for a limited period of time and, if the problem persists, to seek medical intervention. Thus, the time limits on use of the product are important to the health of the users.

Dietary supplements, on the other hand, are developed for inclusion in a daily diet at levels that are consistent with dietary use and may often be consumed throughout most of a person's lifetime. Labeling on dietary supplements contains no instructions for seeking medical intervention or for limiting the duration of consumption of the supplement. Rather, under the 1990 amendments (subject to the DS Act), they will be able to bear nutrient content and health claims, which focus the consumer's attention on the advantages that consuming the product will have in helping the consumer to maintain a healthy diet. Moreover, where the supplement bears a health claim, the claim will contain information about how long-term ingestion of the supplement may promote health.

The comment's reference to baking soda (sodium bicarbonate) as an example of a dual labeled drug/food is not apposite. As a food, baking soda is consumed only as an ingredient in other foods, and it is unlikely that labeling would result in increased consumption of this product. Baking soda is not labeled with either a nutrient content claim or a health claim. Thus, there is little opportunity for consumer confusion presented by this product.

Where dietary levels and therapeutic levels differ (as is generally the case and is in fact the case with antacids and calcium supplements), an apparent conflict is created when both food and drug labeling appear on the same product. In the case of the drug labeling, consumers are given directions for use that involve high consumption during a limited time period. In the case of the food labeling, consumers are given directions for lower consumption with no time constraints. Even though label instructions may identify those directions for food and drug use in separate locations, FDA is concerned that consumers will incorrectly assume that the therapeutic dosage is appropriate for dietary use, and that the directions for food use will undercut the warning in the drug labeling to seek medical care if use persists. Where the labeling is not properly followed, significant adverse consequences may result.

The agency knows of no broad approach that it can use to harmonize a nutrient content claim or a health claim with drug labeling. A drug that is labeled with instructions for use that both limit and do not limit consumption would be misbranded under section 502(a) of the act (21 U.S.C. 352(a)) if it failed to contain a material fact—that is, how to reconcile these conflicting instructions. Therefore, FDA advises that it will tend to view dual claims as misbranding the product.

However, FDA does not believe that it would be appropriate to preclude such claims under all circumstances. Such claims may be permissible if a firm can demonstrate that dual claims can be made in a manner that will neither misbrand the product nor create a safety problem. The agency suggests that anyone desiring to make a health claim or a nutrient content claim that complies with section 403(r) of the act on a product that is both a food and a drug contact the Center for Drug Evaluation and Research, OTC Compliance Branch (HFD-312), FDA, 7500 Standish Pl., Rockville, MD 20855, to discuss whether it would be possible to put such a claim on the product and still comply with the drug provisions of the act.

49. Some comments asserted that FDA should permit the use of health claims on herbs whose only known use is for medicinal effects. A few of these comments objected that the herbs that FDA cited in the preamble of the proposal also have food uses.

As FDA explained fully in the preamble of the proposal (56 FR 60554), Congress clearly intended that the health claim provisions of the 1990 amendments apply only to foods. A product that is intended for medicinal effects, that is, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, is a drug and not a food. Thus, there is no basis under the act for FDA to permit health claims for herbs whose only known use is for medicinal effects. Health benefits of such herbs may appear in the labeling only in accordance with the drug provisions of the act. Where herbs have a history of use both as foods and drugs, the context of all of the available information on the intended use of the product will determine whether FDA will regulate the herbs as foods, as drugs, or as both foods and drugs.

In this regard, the agency points out that the relationship of a food or a food component to a disease is quite different from that of a drug. The Surgeon General's report (Ref. 5) points out that, apart from classic disorders resulting from dietary deficiencies of essential nutrients (e.g., pellagra and niacin), it has proved difficult to demonstrate causal associations between specific dietary factors and chronic or other diseases (e.g., dietary fiber and cancer). The report states:

> Development of the major chronic disease conditions—coronary heart disease, stroke, diabetes. or cancer—is affected by multiple genetic, environmental, and behavioral factors among which diet is only one—albeit an important—component. These other factors interact with diet in ways that are not completely understood. In addition, foods themselves are complex; they may contain some factors that promote disease as well as others that are protective. The relationship of dietary fat intake to causation of atherosclerotic heart disease is a prominent example. An excess intake of total fat, if

characterized by high saturated fat, is associated with high blood cholesterol levels and therefore an increased risk for coronary heart disease in many populations. A higher proportion of mono- and polyunsaturated fats in relation to saturated fats is associated with lower blood cholesterol levels and, therefore, with a reduced risk for coronary heart disease.

Because of these complexities, definitive scientific proof that specific dietary factors are responsible for specific chronic disease conditions is difficult—and may not be possible—to obtain, given available technology.

(Ref. 5). Thus a claim that a substance can be used in the prevention, diagnosis, cure, mitigation, or treatment of a disease or symptom is inappropriate on a food. (See § 101.9(k)(1).)

C. Safety

Proposed § 101.14(b)(3)(ii) would require that to justify a claim for a substance that is to be consumed at other than decreased levels, the use of the substance must be shown by the proponent of the claim, to FDA's satisfaction, to be safe and lawful under the applicable food safety provisions of the act.

The preamble of the proposed rule stated further:

* * * This showing can be based on: (1) A demonstration that the substance is generally recognized as safe (GRAS) within the meaning of 21 CFR 170.30; (2) a listing of the substance as GRAS in 21 CFR part 182 or as affirmed as GRAS in 21 CFR part 184; (3) a food additive regulation; or (4) a sanction or approval granted by FDA or the United States Department of Agriculture prior to September 6, 1958. If the safety and lawfulness of the substance is not expressly recognized in an FDA regulation, the burden will rest on the claim's proponent, as a prerequisite to FDA's evaluation of the health claim, to submit all the scientific data and other relevant information required to demonstrate safety and lawfulness in accordance with applicable petition requirements. FDA will withhold review of the health claim until it is satisfied on these points.

(56 FR 60537 at 60546 through 60547)

50. Many industry comments objected to the safety provisions as proposed. Some of these comments asserted that the 1990 amendments do not require a separate showing of safety for nutrients that are the subject of disease-related claim petitions, and that FDA should not add such a requirement to its regulation. Many comments particularly disagreed with the application of FDA's preliminary safety requirement to dietary supplements and herbs. The comments pointed out that many herbs and supplements have been used for thousands of years with no known ill effects. Requiring further evidence of safety for these products, the comments contended, would be superfluous and expensive. However, other comments agreed with FDA that it would be inappropriate to allow a health claim on a product that contains a substance that is not GRAS, is not the subject of a food additive regulation, or has not received a prior sanction of approval.

FDA believes that the preliminary requirement that substances must be components of food that are safe and lawful must be included in the health claims final rules. Sections of the act enacted by the 1990 amendments cannot be implemented independently of the remaining portions of the act. The act must be considered as a whole, and FDA's responsibility for ensuring the safety of foods is explicitly provided for in other sections of the act (see sections 201(s), 402(a)(1) and (a)(2), and 409 of the act).

This fact is particularly significant because the agency will be specifically providing for the health claims that will be made. In view of this affirmative action, FDA authorization of a health claim places the agency's imprimatur on the claim. It would be a violation of the agency's responsibility under the act to authorize a health claim about a substance without being satisfied that the use of the substance is safe. Furthermore, safety considerations are also of unique importance in the case of health claims because such claims will inevitably change consumption patterns of many Americans.

Even though there is no explicit provision in the 1990 amendments requiring a separate showing of safety, it must be kept in mind that the act "* * * is designed to ensure the safety of the food we eat * * *." Les v. Reilly, ——— F.2d ——— (9th Cir. 1992). This requirement is implicit in the 1990 amendments. Section 403(r)(3)(A)(ii) of the act states that a health claim may be made only for a food that does not contain any nutrient in an amount that increases the risk of a disease or health-related condition that is diet related to persons in the general population, taking into account the significance of the food in the total daily diet. FDA believes that, in addition to requiring establishment of disqualifying levels, this provision evidences a concern by Congress that a substance that is the subject of a health claim be used in a manner that is safe. This concern was reflected in the statements of the sponsors in both the House and the Senate (Refs. 2 and 3).

Further, section 9 of the 1990 amendments states that the amendments "shall not be construed to alter the authority of the Secretary of Health and Human Services * * * under the Federal Food, Drug, and Cosmetic Act * * *." Thus, FDA's responsibility for ensuring the safety of foods has in no way been diminished by the passage of the 1990 amendments.

As a result of the DS Act, herbs and other substances in dietary supplements are generally not subject to the provisions of this final rule. However, to the extent that these substances bear an approved health claim under section 202(b) of the DS Act, they will also bear the agency's imprimatur. To that extent, they will be treated in the same manner as other substances that bear such claims. Other issues with respect to the safety of substances in dietary supplements will be addressed in the rulemaking provided for in the DS Act.

51. Some comments argued that the agency should give full weight to manufacturers' private GRAS determinations in instances where food manufacturers seek to use substances that are not listed by FDA as safe. Some of these comments asserted that if FDA does not recognize private GRAS determinations for fulfilling the preliminary safety requirement, the agency will frustrate Congress' intent to permit health claims, because the GRAS petition procedure is usually quite lengthy, and many GRAS affirmation petitions are pending that are more than 10 years old. Some of the comments requested that if the agency does not recognize private GRAS determinations, FDA should shorten the timeframe for making its GRAS determination or establish an alternate procedure. One suggested that FDA relinquish responsibility for making GRAS determinations to USDA. Another comment suggested that FDA recognize the findings of an independent panel of experts, pending the results of the formal review process.

FDA acknowledges that the GRAS affirmation and food additive listing process can be lengthy. Thus, FDA designed new § 101.14(b)(3)(ii) to provide flexibility with respect to the type of showing of safety that is necessary to make a substance eligible to be the subject of a health claim. GRAS affirmation and food additive listing are but two of the procedures by which a substance may meet this preliminary requirement.

FDA intends to consider the basis of manufacturers' independent GRAS determinations where such determinations are submitted with petitions for health claims and may use its discretion to accept, without formal affirmation, the independent determination of GRAS where FDA believes that such action would be

appropriate. As FDA pointed out in the previous comment, however, the agency would not be fulfilling its responsibilities under the act if it were to permit a substance to be the subject of a health claim without satisfying itself that the use of that substance is safe.

Although FDA will consider all manufacturers' independent GRAS determinations where the bases for such determinations are submitted with petitions for health claims, the agency advises that it will generally not be possible for FDA to judge whether GRAS determinations based on complex scientific evidence are valid within the short timeframes mandated under the 1990 amendments for health claims petitions. Instead, agency agreement with an independent determination that a substance is GRAS will be most likely where the substance is an ingredient, or a component of a food ingredient, that was in common use in food prior to January 1, 1958, in a similar context. However, where such agreement occurs, the agreement does not constitute GRAS affirmation. Instead, the history of common use in food, coupled with the fact that FDA knows of no reason to question the safety of the food ingredient, means that the substance will be treated as if it is an unlisted GRAS substance (as provided for in §§ 170.30(d) and 182.1(a) (21 CFR 170.30(d) and 182.1(a))) in the manner provided for in the food ingredient list in 21 CFR part 182.

In response to comments requesting that FDA relinquish responsibility for making GRAS determinations to USDA, or that FDA recognize the findings of an independent panel of experts pending the results of the formal review process, the agency advises that neither course of action would be appropriate. FDA is charged under the act with the responsibility of protecting interstate commerce from adulterated foods. There is no basis under the act for delegation of this responsibility to other Federal agencies or to individuals outside of FDA.

IV. Validity Requirements for a Claim

A. The Scientific Standard

As proposed, the scientific standard in § 101.14(c) stated:

> * * * FDA will promulgate regulations authorizing a health claim only when it determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.
>
> (1) It must be supported by the totality of publicly available scientific evidence (including evidence from welldesigned studies conducted in a manner which is consistent with generally recognized scientific procedures and principles); and
>
> (2) There must be significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims that this support exists.

(56 FR 60537 at 60563)

In the preamble of the proposal (56 FR 60547), FDA advised that this standard embodies the language in the statutory requirements for conventional food in section 403(r)(3)(B)(i) of the act that there be significant scientific agreement about the support for the claim and the mandate provided in the legislative history of the 1990 amendments that FDA have "a high level of comfort that the claim is valid" (Ref. 1). Thus, the agency will authorize a claim when the evidentiary and review components of the scientific standard are met. However, FDA also stated in the proposal:

> It has been suggested that FDA should allow claims that reflect more preliminary * * * scientific findings so long as such claims are qualified in a way that appropriately reflects the state of the scientific evidence. For example, under this suggestion, FDA would allow a claim such as "Preliminary data show that diets rich in fiber reduce the risk of heart disease," so long as there is significant scientific agreement that this is in fact what the evidence shows. FDA has significant reservations about these types of claims, however, because of their potential to be misunderstood by consumers and therefore to be misleading. The agency is also concerned that such claims will undercut the credibility of the food label. This concern exists despite the fact that because such claims arguably do not assert a [causal] relation between diet and diseases they can never by disproved. FDA requests comments on whether it should authorize these types of claims in implementing the health claim provisions of the act.

(56 FR 60537 at 60552)

52. A number of comments objected that the wording of proposed § 101.14(c)(1) and (c)(2) changes the meaning of the scientific standard presented in section 403(r)(3)(B)(i) of the act. One comment asserted that the proposed provisions treat the totality of publicly available scientific evidence as a separate evidentiary element in showing that the claim is sound, thus distorting Congress' clearly-expressed intent. Similarly, the comment asserted that the language "supported by" in proposed § 101.14(c)(1) "eviscerates" the provisions of the statute because the level of support called for by this requirement is not consistent with the "significant scientific agreement" that the act prescribes. Some comments appeared to interpret the basis of the standard proposed in section 403(r)(3)(B)(i) of the act as being primarily or exclusively the review component, which incorporates the criterion of "significant scientific agreement."

FDA did not intend to change the meaning of the scientific standard presented in section 403(r)(3)(B)(i) of the act through the inclusion of paragraphs (c)(1) and (c)(2) in proposed § 101.14(c). The agency merely intended to clarify that, in accordance with the language of the 1990 amendments, the scientific standard does, in fact, include both a body of evidence component and a review component. However, the agency now recognizes that this attempt to provide greater clarity within the regulatory language itself was unnecessary and, to the extent that it has been interpreted as an attempt to change the meaning of the scientific standard, undesirable. The agency is therefore deleting proposed § 101.14(c)(1) and (c)(2). Without these paragraphs, the wording in new § 101.14(c) is virtually identical to that in section 403(r)(3)(B)(i) of the act.

The wording in section 403(r)(3)(B)(i) of the act and in new § 101.14(c), as amended, clearly establishes two components within the scientific standard. The evidentiary component arises from the inclusion of the phrase "evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles" in the statutory qualification of "the totality of publicly available scientific evidence." This aspect of the standard clearly mandates that the claim be based on a body of sound scientific evidence. The requirement that there be "significant agreement among experts qualified by scientific training and experience to evaluate such evidence * * * that the claim is supported by such evidence" constitutes the separate and distinct review component of the standard.

53. Some comments objected to the standard and suggested modifications. Several comments stated that Congress intended the scientific standard to be one of substantial evidence (i.e., "more than a scintilla and less than a preponderance"). The comments asserted that the 1990 amendments require that FDA adopt such a standard. The comments contended that a standard of substantial scientific evidence, even in the absence of significant scientific agreement, would be in accordance with sound scientific

principles and prevention of consumer fraud. They argued that such a standard would better serve public health through the prompt communication of the health and disease information. Further, other comments objected that the requirement of significant scientific agreement in the proposed standard expands FDA authority beyond legislative intent.

A number of comments maintained that, instead of "significant scientific agreement," FDA should use a scientific standard encompassing different degrees of certainty for different types of health claims. Most industry comments urged FDA to allow health claims based on preliminary evidence if the preliminary status of the claim is truthfully disclosed on the label (e.g., "preliminary data suggest"). Many of these comments contended that such claims would not be misleading and asserted that there was no evidence that the public might misunderstand such claims. Some of the comments asserted that such claims would be consistent with the statutory scientific standard because that standard requires only that there be agreement that the claim is supported by some of the available scientific evidence. Other comments argued that any preliminary study that is sufficiently well-designed and well-conducted should be sufficient to engender "significant scientific agreement" that it supports the health claim being made. Another comment stated that there was no evidence to warrant FDA concern that the public might misunderstand such claims, and that past regulatory policies and court cases involving both FDA and FTC clearly allowed such claims.

Some comments maintained that preliminary claims should be permitted because the benefit to a consumer if a preliminary claim is later proven to be true is significantly greater than the loss if it proves to be false. The comments cited various cases in which preliminary evidence has proven to be correct only after a period of several years. For example, one comment asserted that many lives would have been saved had FDA allowed preliminary health claims regarding cholesterol and heart disease. Other comments expressed concern that one effect of limiting health claims on food labels will be that manufacturers, not being able to assert the dietary characteristics of new foods which fail to meet the new standards, will lose a significant incentive to conduct nutrition research of new food formulations.

A few comments maintained that FDA should permit all preliminary claims, including claims about those nutrient-disease relationships that the agency proposed not to authorize, because those claims that FDA proposed to permit are actually preliminary claims. The comments explained that the claims that FDA proposed use qualifying words such as "may," as in the phrase "may help to reduce disease risk," rather than absolute claims.

However, other comments, primarily from the health care and regulatory sectors, favored the scientific standard as proposed and strongly opposed permitting preliminary health claims, stating that preliminary evidence does not meet the scientific standard of the 1990 amendments. The comments pointed out that one of the main purposes of this new standard is to prevent the type of questionable health claims that have grown all too common in recent years. They noted that if a health claim is still the subject of conflicting reports, it is entirely inappropriate for the food label. Many comments suggested that, even with a disclosure statement as to the preliminary nature of the claim, many consumers would be misled, as the word "preliminary" does little to lessen the impact of a claim, and many consumers would not understand that the findings could be disproved later. Other comments stated that allowing preliminary claims could open the floodgates to a large number of partially supported claims, thereby undercutting the credibility of the valid health claims on food labels.

FDA does not have authority to modify the scientific standard for health claims. Section 403(r)(3)(B)(i) of the act directs FDA to promulgate regulations authorizing health claims only if it determines:

> * * * based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

FDA has incorporated this standard into its regulations. Thus, the requirement objected to by several of the comments, that there be significant scientific agreement that the claim is supported by the publicly available evidence, derives directly from the act.

FDA does not agree that a "substantial evidence" standard, as described by one comment, was intended by Congress, or that the agency is under any obligation to adopt such a standard. Congress adopted the scientific standard for health claims in section 403(r)(3)(B)(i) of the act from FDA's February 13, 1990, reproposal (55 FR 5176). Congress had the opportunity to adopt a different standard, to modify FDA's proposed standard, or to equate the standard with the substantial evidence standard, but it did not. The standard adopted permits FDA to make case-by-case determinations on the scientific validity of a claim, giving greater weight to studies that it finds more persuasive (Ref. 1). Congress intended the scientific standard to be "strong" and for the agency to have a high level of confidence that a claim is valid. Id. Of course, in applying this standard, FDA will act in a manner that is fair and neither arbitrary nor capricious.

In determining whether preliminary evidence would provide the basis for a health claim under this standard, FDA looked carefully at the language of the act and its legislative history. The legislative history establishes that Congress' intent was to ensure the scientific validity of authorized health claims. (See statement of Rep. Waxman; Ref. 4, H5844: "What we have sought to do is to permit health claims but only health claims based on *scientifically valid* information * * *" (emphasis added).) If Congress' aim had been solely to prohibit false or misleading claims, it could have left FDA with its authority under sections 403(a) and 201(n) of the act. Instead it added section 403(r) of the act to ensure not only that claims are not false or misleading, but also that they are scientifically valid.

The fact that Congress adopted in section 403(r)(3)(B)(i) of the act the standard that FDA set out in its reproposed rule on health messages is significant in other respects. In the reproposal, the agency stated that it would not accept preliminary support for a label statement (55 FR at 5180). FDA proposed to permit only claims "supported by a sound body of scientific evidence" (55 FR at 5180). Congress adopted FDA's proposed standard without stating that it was expanding the standard to include preliminary claims; instead it stated that it was adopting the same standard (Ref. 1).

Allowing claims based only on preliminary data would thus not be consistent with the terms of the statute and indeed would undercut the statutory scheme. The standard for permitting a health claim requires that the claim be supported by the totality of publicly available scientific evidence, and that there be significant scientific agreement among qualified experts that this support exists. A claim based on

preliminary data would not reach the threshold of scientific validity required by this standard. It is not sufficient that there simply be agreement among scientists that a statement accurately characterizes the preliminary nature of the data, or that preliminary data could be interpreted in the way stated. Authorizing a claim in such circumstances would produce claims that are little more than hypotheses. While such claims might not be false or misleading, they would not be scientifically valid. Under the statutory scheme, a health claim is to describe the scientifically established relationship between a nutrient and a disease or health-related condition, not the state of the evidence that might support such a claim. FDA is to focus on the state of the evidence in determining whether the claim is valid. Thus, preliminary claims are not permissible under the act.

FDA does not agree that its past regulatory practices dictate that it permit preliminary or controversial health claims. The 41 year-old consent decree in *United States* v. *Mytinger & Casselberry*, referenced by one comment, is not relevant to the current situation and has been superseded by subsequent developments. With the 1990 amendments, Congress added the specific requirement to the act that any health claim on a food must not only not be misleading but also must be scientifically valid. The agency does not have the authority to permit preliminary or controversial health claims that are qualified by an explanation that a difference of scientific opinion exists. Moreover, the agency does not consider itself in any way obligated to follow the FTC consent decree referenced by a comment.

While FDA concludes that preliminary claims are not consistent with the act, that does not mean that the agency concludes that any qualification in a health claim would bar its use. Elsewhere in this issue of the **Federal Register**, FDA is authorizing health claims on food labels that are qualified claims. FDA is authorizing these claims because it finds that they meet the standard of scientific validity. For each of the claims that FDA is authorizing, there is significant scientific agreement that there is a high probability that a reduction in risk of disease will occur.

Further, absolute claims about diseases affected by diet are generally not possible because such diseases are almost always multifactorial. Diet is only one factor that influences whether a person will get such a disease. For example, in the case of calcium and osteoporosis, genetic predisposition (e.g., where there is a family history of fragile bones with aging) can play a major role in whether an individual will develop the disease. Because of factors other than diet, some individuals may develop the disease regardless of how they change their dietary patterns to avoid the disease. For those individuals, a claim that changes in dietary patterns will reduce the risk of disease would be false. Thus, health claims must be free to use the term "may" with respect to the potential to reduce the risk of disease. However, use of this term would not be appropriate for health claims on food labeling where significant scientific agreement does not exist that there is a high probability that a reduction in disease risk will occur.

Furthermore, Congress clearly concluded that there is a great deal of consumer confusion over health claims on food labeling (Ref. 1). FDA believes that much of the confusion results from claims based on preliminary data, and the agency believes that comments opposed to permitting preliminary claims are correct in their assessment that many consumers do not understand that preliminary claims are based on science considerably weaker than claims based on science about which there is a significant amount of scientific agreement. Also, FDA agrees with those comments maintaining that allowing preliminary claims would open the floodgates to a large number of partially supported claims, thereby undercutting the credibility of valid health claims on food labels and of the food label itself. FDA believes that health claims must be credible if they are to be useful to consumers.

If FDA were to focus only on the impact of a single preliminary claim, arguments that benefits to consumers from permitting that claim where it might be true would outweigh losses where the claim later proved to be false might have merit. However, FDA must focus on the ultimate impact that permitting a multitude of preliminary claims would have on public health and on public confidence in the food label. That ultimate impact could easily involve a perception among many consumers that health claims and food labels are not reliable. To the extent that consumers do not change their dietary patterns to reduce their risk of disease, they will be less healthy, and there will be needless deaths from disease as well as costs to the national economy. Thus, FDA disagrees with comments asserting that preliminary claims would be in the best interests of consumers.

Further, FDA doubts the accuracy of comments asserting that manufacturers will lose significant incentive to conduct research on new food formulations. The agency believes that the high credibility of FDA sanctioned claims and their impact on consumer purchasing decisions will prove to be sufficient incentive to continue such research. Further, if the agency were to permit almost all health claims of a preliminary nature, the value of such claims as marketing tools would surely be considerably weakened as consumers lose faith in all claims.

Of even more importance, however, is the fact that, even though FDA's approach to permitting health claims may not permit as many claims as some firms desire, FDA's approach will provide for scientifically valid health claims. Over time, FDA's approach is likely to prove to be of far greater value in promoting good public health than permitting almost all preliminary claims. Further, FDA's approach does not require absolute proof of the validity of a claim. Instead, this approach requires that there be sound science to support the claim.

54. A number of comments called for a consensus among scientists prior to the approval of a claim.

The legislative history of the 1990 amendments makes clear that Congress did not intend, in calling for significant scientific agreement about the support for a claim, to require that such agreement represent a full consensus among scientists. The House Report (Ref. 1) states: "* * * the standard does not require that there be a unanimous agreement among experts. Instead there must be a significant agreement among experts, but it does not require that every expert in the field approve or agree with the claim."

The agency believes that a consensus, if defined as unanimous agreement among scientists about the validity of a particular claim, would be difficult to achieve, and that a standard requiring consensus would therefore prove impracticable. The agency is concerned that the stringent requirement of consensus would cause many valid health claims not to be approved and, by restricting such claims, would counter Congress' intent that health claims supported by a significant scientific agreement be made available to consumers. In view of these concerns, and in conformity with the expressed intent of Congress and with the statutory language of the 1990 amendments, the agency will not require that claims be supported by a consensus among scientists.

55. Several comments objected that the scientific standard, particularly the phrase "significant scientific agreement," is vague and subjective. One comment asked for clarification as

to the degree to which this phrase is qualitative or quantitative in nature and noted that a standard of evidence must be specific and consistent. Several comments suggested that the manner in which FDA applied the scientific standard is overbroad.

The agency is sensitive to the comments' perception that the scientific standard, particularly the phrase "significant scientific agreement," is subjective. The agency believes, however, that any standard involving the evaluation of scientific evidence and the opinions derived from that evidence must be somewhat subjective. FDA, in choosing not to define "significant agreement" among experts in the November 27, 1991, proposal (56 FR 60548), noted that each situation may differ with the nature of the claimed substance/disease relationship. The agency believes that in deciding whether significant scientific agreement about the validity of a claim exists, it is necessary to consider both the extent of agreement and the nature of the disagreement on a case-by-case basis. The agency is concerned that if scientific agreement were to be assessed under any quantitative or rigidly defined criterion, the associated inflexibility of such a criterion might cause some valid claims to be disallowed where the disagreement, while present, is not persuasive.

The House Report (Ref. 1) affirms the intended flexibility of the "significant scientific agreement" standard by pointing out that, in reviewing scientific studies, FDA may give greater weight to the studies that it finds more persuasive. The House Report also clarifies that the overriding consideration in assessing whether to authorize a claim should be the Secretary's level of comfort about the validity of the claim. Id. The agency believes that this clarification provides clear guidance for the application of the standard.

56. Several comments suggested that FDA should look to the new drug provisions in section 505 of the act (21 U.S.C. 355) for direction in assessing significant agreement with the proposed validity requirement and suggested that the degree of scientific agreement needed for health claims approval should be significant but less than that necessary for approval of a new drug application.

FDA agrees that the scientific standard for health claims is less stringent than the requirements for approval of a new drug. In the case of a new drug, section 505(d)(5) of the act provides that the Secretary shall refuse to approve an application for approval of such a drug where there is a lack of substantial evidence that the drug will have the effect that it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof. The term "substantial evidence" is not, in and of itself, a particularly stringent standard. Section 505(d) of the act provides, however, that the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations (human studies conducted in a controlled clinical setting), by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. (In identifying the source of substantial evidence, the law limits the kinds of studies that can be used. Even this high standard, however, has a degree of flexibility.) Based on this statutory direction, the agency has identified a number of characteristics that are present in "adequate and well-controlled" studies in 21 CFR 314.126.

However, section 403(r) of the act does not mandate requirements as stringent as those for drugs in section 505(d)(5) of the act. Section 403(r) of the act does not reference substantial evidence, adequate and well-controlled investigations, or clinical investigations. To the contrary, section 403(r) of the act contains more flexibility than the drug provisions of the act by providing FDA with authority to authorize claims based on "scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence" (section 403(r)(3)(B)(i)).

The legislative history of this section of the act evidences a concern by Congress that health claims should not necessarily be restricted to the stringent evidence necessary to support a drug claim. H. Rept. 101–538 states: "Under this standard, the Secretary must review all the scientific evidence available that is pertinent to a claim." (Ref. 1).

In debate preceding passage of the 1990 amendments, the sponsors of the bill raised concerns as to whether food claims should not be subject to a more flexible standard than drug claims. For example, in the July 30, 1990, Congressional Record (H5844) (Ref. 3), Congressman Waxman stated:

> And then there is the issue of health claims. Prior to the mid-1980's, health claims were simply not permitted. A health claim on a food product turned that food product, in a legal sense, from a food to drug because if the health claim were made, then the product had to go through the approval process at FDA to show the efficacy of that claim was valid, the same as would be required by a pharmaceutical.
>
> That was an awfully stringent requirement.

Further, on October 26, 1990 (Ref. 3), Congressman Madigan, the other House sponsor of the 1990 amendments, stated:

> Neither Federal regulation nor industry efforts have kept pace with scientific knowledge about diet and nutrition. This bill is an effort to remedy this situation while allowing FDA sufficient flexibility to modify the rules when valid, new scientific information is presented. Given increased awareness and advances in our scientific knowledge on the relationship between diet and health, this legislation is very timely.

Consistent with this flexibility, FDA is not now prescribing a specific set, type, or number of studies as being necessary to support a health claim. The agency will consider all relevant data on a topic, including clinical studies, epidemiological data, and animal studies. Of course, the type, quality, and relevance of a study from which data are derived have an important bearing on how much weight is placed upon the data. For example, FDA will give the greatest weight in its evaluation to well-designed studies conducted with human subjects. Data from laboratory studies using animals, in vitro tests, and chemical analyses of the food substance may be useful, however, in providing an understanding of the nature of the relationship between the substance and the disease or health-related condition.

In the preamble to the proposal (56 FR 60537 at 60548 through 60549), FDA drew heavily on chapter two of the Diet and Health report (Ref. 6) for a discussion of how it will evaluate the studies that are submitted on the impact of intake of a substance on health. Interested persons are referred to that preamble discussion for further information about how the agency intends to apply the validity standard in new § 101.14(c).

In summary, FDA sees the standard for health claims as different from the standard for establishing the effectiveness of a new drug. The agency is not now establishing any minimum data requirements under this standard, although the agency might find it appropriate to do so in the future as it

gains more experience under the health claims regime. Rather, the agency will review all available scientific evidence that is pertinent to a claim and decide whether, on the basis of that evidence, the characterization of the relationship of a substance to a disease or health-related condition that is presented in the claim is scientifically valid.

B. Assessment of Conformity to Scientific Standard

1. General

57. A few comments expressed concern about specific types of studies that FDA advised that it would consider in evaluating health claims. One comment objected that human studies in general would not be very useful. Another comment objected that human studies based on non-U.S. populations that exhibit consistent results may not be useful. Another comment noted that case-control and cohort studies based on the U.S. population are often not powerful enough to detect diet-disease relationships because the range of nutrient intakes within the population is too narrow. However, most comments agreed with the agency's intention not to prescribe a specific set, type, or number of studies as being sufficient to support a disease-related claim, and with its statement that it will "seek to avoid the pitfalls of inflexible adherence to rigidly defined criteria" (56 FR 60548).

The statutory language of section 403(r)(3)(B)(i) of the act is specific in directing the Secretary to consider the totality of publicly available scientific evidence. FDA cannot, therefore, and would not be inclined to, exclude any scientific evidence from consideration in assessing the validity of a claim. The agency recognizes, however, that the evidence relating to a particular claim may vary in its usefulness, and that some types of studies may be more probative than others in establishing the validity of particular nutrient-disease relationships. The agency will consider, therefore, as it stated in the November 1991 proposal (56 FR 60537 at 60548), the type, quality, appropriateness of design and relevance of each of the studies and of the other information that together constitute the totality of scientific evidence when assessing the validity of a claim. The agency will evaluate the strengths and weaknesses of each individual study and weight it accordingly in reaching a decision about the validity of a particular claim.

58. Other comments urged FDA to consider with fairness any proposed health claim that relies on data derived from non-Western cultures.

The agency advises that it will consider the evidence submitted in support of a claim on its scientific merits and in the context of the totality of available evidence. It will not underrate any study on the basis of its cultural or geographic origin. Evidence in support of a proposed health claim, however, will attain value in direct proportion to the significance in the U.S. population of the effects of the disease or health-related condition addressed by the claim.

2. Dietary supplements

59. Many comments asserted that FDA should establish a more lenient standard for substances in dietary supplements. Some of these comments argued that such a standard is mandated by Congress and cited the statement of Senator Hatch, one of the primary authors of the 1990 amendments, that "a more lenient standard for dietary supplement[s] is envisioned." (Ref. 2). Other comments argued that the standard should be sufficiently lenient to permit marketing of supplements without any labeling restrictions. Some of these comments argued that dietary supplements needed no stringent requirements because supplements could be adequately regulated under the regulatory regime of a label needing to be truthful and not misleading under section 403(a)(1) of the act. A number of comments asserted that the same standard effectively renders section 403(r)(5)(D) of the act superfluous. Some comments asserted that, by not adopting a more lenient standard, FDA would restrict the amount of health information available to consumers and stated that such information is important to consumers in deciding which products to buy. A number of comments asserted that the same standard for supplements is counter to the intent of the 1990 amendments because Congress intended to make more, rather than less, information about the health benefits of foods available to consumers.

However, other comments agreed with FDA's proposal to use the same scientific standard for dietary supplements that the act provides for conventional foods. One comment noted that it is especially important to place dietary supplements under the same standard because they are marketed mainly on the basis of their purported health benefits. Another pointed out that the proposed standard will facilitate purchasing decisions for consumers by reducing fraudulent labeling claims.

A few comments contended that FDA should establish a more stringent standard for substances in dietary supplements. One comment asserted that FDA has adequate authority to do so and asserted that the legislative history of the 1990 amendments supports a more stringent standard. The comment stated that FDA recognized, when it proposed not to authorize a health claim for omega-3 fatty acids in Docket No. 91N-0103 (56 FR 60663, November 27, 1991), that it does make a difference whether one receives nutriment from food or from pills. In that document, the comment maintained, FDA asserted that benefits have been shown for fish but not for omega-3 fatty acids.

Under the DS Act, there is a moratorium on the implementation of the 1990 amendments with respect to dietary supplements. Therefore, FDA is not adopting a standard to implement section 403(r)(5)(D) of the act. The agency will adopt a standard in accordance with the procedures established in the DS Act. However, FDA has carefully considered these comments and, in response, would make the following observations.

Although Congress did convey flexibility in resolving this issue to FDA, and one sponsor did state that this flexibility should be used to establish a more lenient standard, as the agency explained in the preamble of the proposal (56 FR 60537 at 60539 through 60540), the legislative history concerning section 403(r)(5)(D) of the act makes clear that Congress did not intend to require that the agency adopt a different standard for these products (Refs. 2 and 3). Instead, the exemption on its face gives the agency the discretion to adopt a scientific standard respecting the validation of claims for supplements, regardless of whether the standard is more lenient or more stringent (Ref. 3). The exemption gives the agency the same discretion with respect to establishing a procedure under which claims may be made.

The statement of House Floor Managers (Ref. 3), addresses section 403(r)(5)(D) of the act by stating, in part:

> The Senate version of the bill, which we are voting on today, retains this standard for all foods except vitamins, minerals, herbs, and other similar nutritional substances (referred to below as "vitamins"). The bill requires that vitamins that include claims defined under section 403(r)(1)(B) shall be subject to a "procedure and standard" defined by the Secretary in regulations that require an evaluation of the validity of the claim. The FDA is given the discretion to define both the procedure and the standard because the principals in the Senate could not agree on the appropriate procedure or the appropriate standard.

It is obvious from the language that the agency could adopt the same procedure and standard that Congress has adopted for disease claims on food other than vitamins; it is also obvious that it could adopt a stronger standard for vitamins, minerals, herbs, and other similar nutritional substances.

In addition, the Metzenbaum-Hatch managers' statement in the Senate (Ref. 2) addresses section 403(r)(1)(B) of the act by stating, in part: "The purpose for the different handling of conventional food products and dietary supplements is to provide the Secretary flexibility in the development of the procedure and standard for health claims for dietary supplements."

Thus, both the Senate and the House of Representatives agreed that FDA has the flexibility to adopt the standard and procedure for dietary supplements that appears appropriate to the agency. As pointed out by the comments, Senator Hatch left no question about his position that FDA should use this flexibility to adopt a more lenient standard. However, other members of Congress were equally clear about their position that FDA should not adopt a more lenient standard. In the October 24, 1990, Congressional Record, (Ref. 2), Senator Metzenbaum, the other primary author of the Senate amendments, stated:

* * * It is my view that there is no reason to do anything other than utilize the same procedure and standard for dietary supplements.

Whatever approach the Secretary takes, he must establish a system that evaluates the validity of health claims for dietary supplements. The system must be based on the same considerations that guide other agency decisions: public health, sound scientific principles and consumer fraud.

Further, the House of Representatives clearly did not support a more lenient standard for dietary supplements. The statement of House Floor Managers that appears in the October, 26, 1990, Congressional Record (Ref. 3) states:

* * * Whatever approach the agency takes, it must adopt a system that evaluates the validity of any disease claims made with respect to these substances. Its system must be based on considerations of public health and consumer fraud. As in every similar decision made by the agency today, we fully expect that the agency's evaluation of disease claims made with respect to vitamins will be based on sound scientific principles.

There is a great potential for defrauding consumers if food is sold that contains inaccurate or unsupportable health claims. The potential is just as great for vitamins as it is for other products. In our view, vitamins and other substances covered by this provision should be subject to at least as strong a standard as is applicable to other foods that contain claims that the food will treat a disease or health condition.

Thus, some members of Congress opposed a more lenient standard for dietary supplements. However, it also seems that assertions that Congress supported a more stringent standard in the legislative history of the 1990 amendments are not well-founded. The above-mentioned statements on a more stringent standard were included in the legislative history to demonstrate that one could be established, if appropriate.

The agency will consider this legislative history together with the legislative history of the DS Act in proposing rules to implement the 1990 amendments, with respect to the DS Act. The agency notes that if it were to adopt a more lenient standard and procedure for supplements, there might be a significant potential for consumer confusion when confronted with a situation in which there would be health claims for substances when they are present in supplements but not when they are present in conventional foods. If there is reason to conclude that this would not in fact be the case, FDA urges interested persons to come forward with evidence to support such a conclusion during the rulemaking mandated by the DS Act.

The Managers Report on the DS Act (Ref. 34) states that among the policy goals of the DS Act is to assure the public that health or disease-related claims for dietary supplements are properly supported. In the rulemaking under the DS Act, FDA will try and determine what proper support should incude. In particular, the agency is interested in why the standard for the scientific validity of health claims in section 403(r)(3)(B)(i) which applies by law to claims for all substances for which claims are made except for those in dietary supplements, is not also appropriate for substances in dietary supplements.

The agency also points out that it did not tentatively conclude in the omega-3 fatty acids proposal that it makes a difference whether one receives nutriment from food or from pills, as the comment suggested. While FDA did state in the summary of that docket that there is inadequate evidence to support a beneficial relationship between reduced risk of coronary heart disease and increased consumption of omega-3 fatty acids, and that there is some evidence that benefit may be gained through the consumption of fish, the agency noted that benefits attributed to fish could not necessarily be ascribed to the presence of omega-3 fatty acids. The example, therefore, does not show that a substance is any more beneficial when it is in a conventional food than when it is not in a conventional food.

60. A number of comments suggested that the agency should adopt a separate mechanism for evaluating the validity of claims for herbs. Under the suggested mechanism, an oversight committee would appoint an expert panel that would consist of a director and at least four scientists with training and experience related to herbal and botanical products. (FDA would participate as a nonvoting member.) The panel could hire outside consultants. The committee, which would be charged with the responsibility of reviewing all health claims petitions pertaining to herb or botanical components, would relieve FDA of all responsibility for initial review of these petitions. Such petitions would not be permitted to be submitted directly to FDA. The expert panel that was selected by the committee would conduct an evaluation of scientific data pertaining to the requested claim, subject the evaluation to peer review, and prepare a final recommendation about the claim. The recommendation and all supporting documents would then be forwarded to FDA, and the agency would be permitted 120 days to approve, disapprove, or modify the report. Under draft regulations submitted by one of the comments, there would be a codified presumption in favor of the committee recommendation.

The comment asserted that this mechanism for evaluating petitions would not involve a transfer of the agency's authority and obligation to enforce the act because the final authority for decisions rests with FDA. Further, the comment asserted that there is precedent for the requested mechanism in FDA's past use of reviews of food and cosmetic ingredients that have been prepared by the Federation of American Societies for Experimental Biology (FASEB) and the Cosmetic Ingredient Review (CIR).

Although the DS Act establishes a moratorium on the implementation of the 1990 amendments with respect to dietary supplements of herbs, the agency considers it appropriate to respond to this comment. FDA believes that the mechanism suggested by the comment would involve a significant transfer of agency authority for the control of health claims on herbs, and there is no basis under the act for such a transfer. Although the comment asserts that such a transfer would not take place by maintaining that the final authority for decisions rests with FDA, the assertion is not correct. Because of the codified provision providing that there would be a presumption in favor of the committee recommendation, the agency would be obligated to prove that

the committee was wrong or else it would be required to follow the committee's recommendation. Under such circumstances, FDA could be forced to propose to authorize a health claim that the agency believed, but was unable to prove, was not valid. Thus, there would, in fact, be a significant transfer of authority under the requested mechanism.

Further, there is no precedent for the requested mechanism in FDA's use of FASEB and CIR reviews of food and cosmetic ingredients. Neither type of review created a presumption in favor of the review recommendation. Also, FDA has never required that petitions pertaining to food and cosmetic ingredients be submitted for such reviews. With respect to FASEB reviews, FDA contracted for these reviews as part of its GRAS review in the early 1970's and then once to update information on sulfiting agents. FASEB only submitted a recommendation as to whether, and what, uses of a substance were GRAS. FDA conducted its own review of the evidence and was free to elect to use the FASEB review as it saw fit.

With respect to CIR reviews, such reviews are used primarily by industry to make self-determinations of cosmetic ingredient safety. The agency may, or may not, comment on any CIR review. Even where FDA comments on a CIR review, there would be little likelihood that agency rulemaking would result. In situations where such a review does serve as a stimulus for a rulemaking proceeding, the review would not be the sole reason for the proceeding. The agency fully retains its enforcement authority in both situations.

Moreover, the committee suggested by the comment would be subject to the Federal Advisory Committee Act (5 U.S.C. App. 2). The burdens imposed on an agency by this statute are heavy. FDA has limited resources for advisory committees. While the agency may, on occassion, use advisory committees as part of the health claims process, it believes that it would be an inappropriate expenditure of those limited resources to commit them to the committee suggested by the comment.

Of course, both the conventional food and dietary supplement industries may, if desired, work through committees in preparing well-supported petitions for submission to FDA, and FDA will cooperate with such committees at a scientific level by explaining the agency's requirements to them and sharing publicly available information. However, the agency would not require firms to use such committees, and FDA would still have the ultimate obligation of determining whether the petitioned-for claim is scientifically valid. To clarify that the agency will consider all recommendations by such committees, FDA has revised provisions of new § 101.70(b) to provide that information that is submitted with petitions may include any findings, along with the basis of the findings, of an outside panel with expertise in the subject area at issue. While the agency will consider any findings of a panel included in a petition, the agency will not use that panel to make its decision.

61. Some comments asserted that in addition to the proposed regulatory framework for evaluating health claims, which involves permitting supplement claims on the same terms as for conventional foods, FDA should also subject dietary supplements to an alternative involving a different level of validity substantiation and a different procedure. Under the alternative procedure, claims for which there is substantial scientific evidence but not yet significant scientific agreement would have to undergo a certification and notification procedure rather than rulemaking proceedings. Under the alternative, claims could be made for supplements so long as: (1) The claim expressly discloses the absence of scientific agreement as to the relationship, (2) the manufacturer provides FDA with a fully documented certification by a panel of at least three qualified experts that there is substantial scientific evidence supporting the claim, and (3) FDA does not disapprove the claim within 90 days of receipt of the certification. [When additional information is needed, the 90 day period could be extended an additional 45 days.) Under the alternative, FDA would have an opportunity to participate in the selection of the expert panel.

Given the moratorium on the implementation of the 1990 amendments established by the DS Act, the agency is reserving making a detailed response to these comments at this time. The Managers Report on the DS Act (Ref. 34) states that FDA may wish to propose new rules or to repropose rules under section 403(r)(5)(D) of the act. FDA will consider these comments in deciding what action to take with respect to section 403(r)(5)(D) of the act in responding to the DS Act.

V. General Labeling Requirements

Proposed § 101.14(d)(1) provides that when FDA determines that a health claim is valid, the agency will propose a regulation in part 101, subpart E to authorize the use of the claim. Further, the provision states that if the claim pertains to a substance not provided for in § 101.9 or § 101.36, FDA will propose amending those regulations to include declaration of the substance. FDA points out that § 101.9(a) requires that where a claim about a nutrient is made, the nutrition labeling information shall include appropriate information about that nutrient. Proposed § 101.36(a) also would require nutrition information on dietary supplements. However, given the moratorium established by the DS Act, FDA is not adopting § 101.36 at this time. FDA has deleted the reference to that section from § 101.14(d)(1).

62. Several comments argued that FDA should not permit firms to place any health claims on the labels of conventional foods or of dietary supplements.

Through enactment of section 403(r) of the act, Congress has mandated that firms be permitted to place health claims on food labels when FDA finds that the claims are valid and establishes regulations authorizing their use. Although the comments cited a wide variety of reasons to support their objections, FDA is not addressing these reasons because the 1990 amendments settled this issue. The agency has, therefore, not made any changes in response to these comments.

A. Consistency with Summary of Scientific Information and Model Health Claim

Proposed § 101.14(d)(2)(i) stated that all label or labeling statements about the health benefit that is the subject of the health claim shall be based on, and consistent with, the conclusions set forth in the summary of scientific information and model health claims provided in regulations in part 101, subpart E.

63. Some comments urged FDA not to allow manufacturers to paraphrase an established model health claim. These comments stated that claims should be repeated in the same way on each qualifying food product to ensure that only one clear message is being given to consumers. One of these comments cautioned that consumers faced with health claims stated in a wide variety of ways will be confused about the possibility of differences among the claims. Another suggested that in light of the practical inability of FDA to police varying wordings for accuracy, the only way to ensure that claims are an accurate representation of the facts is to require that agency-drafted claims be used. The comment noted that although the 1990 amendments did not specifically contemplate mandatory FDA-created wording for the health

claims, section 403(r)(3)(B)(iii) of the act could be interpreted to allow such an approach on the basis that the agency wording is the only one that "enables the public to comprehend the information provided in the claim."

However, other comments maintained that manufacturers should not be held to the specific language in the model health claims and asked that the regulations be amended to specifically state that label claims need not be identical to the model claim language. The comments explained that the model claims are too complex to be meaningful to consumers and expressed concern that the proposed requirement for consistency might be interpreted in such a rigid manner that effectively only the model claim would be permitted.

FDA does not believe that the 1990 amendments allow the agency to prohibit manufacturers who wish to place a health claim on a product from paraphrasing language in the model claim. Section 3(b)(1)(A)(vii) of the 1990 amendments prohibits FDA from requiring persons to secure agency approval before placing a health claim on a product, provided that the claim is in compliance with the applicable regulation. The House Report (Ref. 1), states that this section "makes it clear that the regulations will not require premarket review of each claim; they will only require that the claim be consistent with the terms and requirements of the regulations." The agency believes that it is possible to paraphrase a model health claim while remaining consistent with the terms and requirements of the regulations permitting that claim. This position is similar to agency policy that permits the use of terminology other than that established in a final OTC drug monograph in labeling of an OTC drug product to describe indications for use (51 FR 16258, May 1, 1986). Consistent with that policy for OTC drug labeling, the agency believes that the goal of ensuring scientifically valid, truthful, and nonmisleading labeling without inhibiting effective consumer communication does not require exclusive use of language in a model health claim. The model language along with other requirements for that claim will, nevertheless, provide the standard for measuring the accuracy of alternative language developed by food manufacturers for their products because FDA has included all mandatory labeling elements of a health claim in the model claim. Of course, manufacturers should recognize that a paraphrased health claim that fails to convey all the mandatory elements of the claim will subject a product to regulatory action.

Section 403(r)(3)(B)(iii) of the act does not require the verbatim use of the agency's model health claims. The provision states that the agency must require in a regulation authorizing a health claim that the claim be stated in such a way as to allow the public to comprehend the presented information and to understand the relationship of the substance to the disease or health-related condition, the significance of the substance in affecting the disease or health- related condition, and the significance of the information in the context of the total daily diet. The agency's model wording of a health claim is likely not to be the only way in which one can convey all the required information.

Although FDA agrees that manufacturers should not be held to the specific language in the model health claims, the agency does not believe that it is necessary to state this fact in the regulations. Just as some could misinterpret the proposed codified requirement that claims be "consistent with" model claims, others could misinterpret a provision stating that claims "need not be identical to the model claim language." Thus, FDA has revised new § 101.14(d)(2)(i) to require that labeling statements conform to the conclusions set forth in the regulations in part 101, subpart E without any specific reference to provisions contained therein.

64. Some comments contended that FDA's proposed regulations would require too much information in health claims, and that the appearance of so much information in a health claim would confuse consumers. Some of these comments suggested that this confusion could thwart FDA's goal of educating the public. Others asserted that, rather than trying to clear up their confusion, many consumers would simply assume that the product is unhealthy for them and choose products that did not bear the lengthy claims. One of these comments stated that the calcium/osteoporosis claim was, according to computer analysis, so complex that a "fourteenth-grade" reading level was required to properly understand it.

Another comment objected that the proposed policy of codifying "all" effects of a nutrient on a condition or disease would lead to the inclusion of effects that were of tangential importance or that were not the subject of significant scientific agreement. Instead, the comment stated, FDA should limit its description to significant effects on which there was such scientific agreement.

However, other comments agreed with FDA's proposal that health claims should include information on factors that affect the nutrient-disease relationship (e.g., exercise). One consumer advocacy organization strongly asserted that it is important that nutrient intake not appear to be the sole factor in matters affecting the risk of disease when other factors are considered to be of similar importance. The comment stated that use of such language as "one of several factors" and "can help" in health claims will help the public to understand that the nutritional characteristics of the foods bearing claims are not "cure-alls" for the disease/health condition mentioned.

FDA agrees that consumers should be presented with health claim information in a clear, nonconfusing manner, and the agency realizes that there is a limit to the amount and complexity of information that can be presented in a health claim. However, the agency believes that it must require enough information in a health claim to ensure that consumers understand that factors other than dietary intake of the nutrient may bear on the substance-disease relationship. Given these imperatives, the agency is faced with the difficult task of determining what information is necessary in a claim, and what information is not.

FDA has reviewed the requirements for the health claims that it is authorizing elsewhere in this issue of the **Federal Register** to determine whether they call for the inclusion of information in the claim that is not absolutely necessary to allow the consumer to understand the claims in the context of a total daily diet. FDA has deleted information that is not necessary from the list of mandatory information and instead has listed this information as information that a manufacturer may opt to include in a health claim. FDA will take a similar approach in the future. FDA believes that its regulations in part 101, subpart E now represent an acceptable balance between the consumer's right to understand the full context of the claim and the manufacturer's concern over claim length. By delineating the information that is mandatory and optional in a claim, FDA is relieving manufacturers from having to include information that is of tangential importance but allowing those who wish to use the information to do so without violating the authorizing regulation.

As for the comments that asserted that the sentence structure and phrasing of

the model claims are too complex, the agency has sought to minimize complexity but has found that some unavoidably results from trying to provide the information necessary to ensure that consumers understand the claim in its proper context. FDA believes that the versions of the claims that it is adopting mandate less information, and are significantly less complex, than those proposed. However, manufacturers who are not satisfied with the model claims are free to develop their own versions of the claim, provided that those versions include all of the information required by the authorizing regulation.

65. One comment asserted that product-specific health claims, which emphasize the role of a specific product or brand of product in a diet-disease relationship already the subject of an agency regulation, should be allowed and even encouraged.

FDA disagrees with this comment. Section 403(r)(3)(B)(iii) of the act directs the agency to require that health claims enable the public to understand the information in the context of the total daily diet. FDA believes that a claim that refers specifically to the health benefits conferred by the consumption of a certain brand name of product would unduly emphasize the importance of that brand in the context of the daily diet. Also, such claims could imply that other brands of the same food, as well as other foods containing the substance, might not have the same effect on the disease or health-related condition and thus be misleading under section 403(a) of the act. Accordingly, the agency rejects this comment's recommendation.

66. A number of comments suggested that FDA should develop health claims about general food choices, rather than substances, and a disease or health-related condition. Other comments, however, cautioned that such an approach might create more consumer confusion than benefit.

As FDA pointed out in its response to comment 1 of this document, claims about the benefits of general classes of food such as fruits and vegetables that do not make an express or implied connection to any specific substances do not constitute health claims because the multiplicity of substances found in those foods renders the claim too general to satisfy the first basic element of a health claim (i.e., substance). However, where a claim about a general food choice is an implied claim for a substance or specific substances contained in the food and a disease or health-related condition, it would be subject to the health claims regime.

Development of information about general food choices and diseases or health-related conditions, to the extent it is not subject to section 403(r) of the act, is an activity authorized by the National Nutrition Monitoring and Related Research Act of 1990 (Ref. 32) which was enacted at about the same time as the 1990 amendments. In brief, the Nutrition Monitoring and Related Research Act authorizes the Secretary of the Department of Health and Human Services and the Secretary of the Department of Agriculture to establish dietary guidance by jointly publishing at least every 5 years a report entitled "Dietary Guidelines for Americans." Each such report is to contain nutritional and dietary information and guidelines for the general public which are based on the preponderance of the scientific and medical knowledge that is current at the time the report is prepared. The Secretaries are also authorized to review and approve any dietary guidance for the general population or identified population subgroup proposed to be issued by any Federal agency to assure that the guidance either is consistent with the "Dietary Guidelines for Americans," or that the guidance is based on medical or new scientific knowledge that is determined to be valid by the Secretaries.

The goals to be achieved by both the 1990 amendments and the Nutrition Monitoring and Related Research Act (7 U.S.C. 5341) are complementary in every respect. Where the 1990 amendments ensure the validity of health claims, the Nutrition Monitoring and Related Research Act ensures the validity of dietary guidance. In considering whether to authorize health claims, the agency will exercise great care to see that the claims that it authorizes are fully compatible with national dietary guidance.

B. Complete, Truthful, and Not Misleading

Proposed § 101.14(d)(2)(iii) stated that a health claim shall be complete, truthful, and not misleading. In keeping with these requirements, FDA asserted that where factors other than consumption of the substance bear on the claimed effect on a disease or health-related condition, such factors must be addressed in the claim.

67. One comment proposed that the word "complete" as used in proposed § 101.14(d)(2)(iii) is vague and would lead to confusion. It noted that each company in the food industry will be free to paraphrase FDA's model health claims and, since such paraphrasing necessarily implies different words and sentences, to the extent that a company's claim does not track the model exactly, such claims will not be "complete." The comment suggested that the word "complete" be deleted from the final regulation.

FDA disagrees that the word "complete" should be deleted from the regulation. The agency believes that it is imperative that consumers be informed of factors other than the consumption or nonconsumption of the substance that significantly bear on the claimed effect on a disease or a health-related condition. To this end, FDA will codify all such information in part 101, subpart E. FDA believes that the word "complete" is necessary in § 101.14(d)(2)(iii) to ensure that manufacturers understand that their health claims must include all such mandated information. This policy is consistent with section 201(n) of the act, which provides that an article's labeling may be misleading if it omits material facts.

68. One comment stated that dietary supplements should be required to balance their health claims by including warnings against any negative health effects that might result from their use. The comment also suggested that the labels of such products should declare the maximum amount of the dietary supplement that can be consumed without incurring risk of toxicity.

FDA disagrees. To be eligible for a health claim, a substance, if it is to be consumed at other than decreased dietary levels, is required to be a food or a food ingredient whose use at the levels necessary to justify the claim is safe and lawful under the applicable food safety provisions of the act. Thus, there is no reason to treat dietary supplements any differently than other food by requiring that they bear special warnings.

To avoid any misunderstanding as to the appropriate level of consumption in relation to the daily diet, the agency may require, in its authorizing regulation for a claim, that the claim state the level of consumption beyond which no additional benefit is likely to be gained. The agency notes as an example that the calcium/osteoporosis health claim includes the statement that "adequate calcium intake is important, but daily intakes above about 2,400 mg are not likely to provide any additional benefit."

If at some point in the future, the agency approves a health claim that has some safety concern to any subpopulation of consumers, the agency will, of course require that the claim include sufficient information to alert that subpopulation. For example, if FDA

ever approves a health claim for vitamin D, the claim would be required to inform consumers of the potential for an adverse effect from excess consumption.

C. Layout

Proposed § 101.14(d)(2)(iv) stated that all claims must appear in one place, in the same type size, without intervening material. FDA included in this provision an exception to allow a short reference statement to appear on the label, "See ———— for information about the relationship between ———— and ————," with the blanks filled in with references to the location of the labeling (other than the label) on which the full claim appears, the name of the substance, and the disease or health-related condition.

69. A number of comments suggested that proposed § 101.14(d)(2)(iv) be amended to allow the use of a front-panel reference to a full health claim appearing on the side or back panels. Many of these comments contended that a referral statement on the principal display panel would help make consumers aware of the full claim, which itself might be too long to appear on the principal panel. Some comments suggested that abbreviated forms of a health claim be allowed to serve as reference statements. One of these comments suggested that this approach would avoid overcrowding of the principal display panel, would place the health claims where they would be of greatest use to consumers, and would still provide conveniently located, detailed information to consumers.

FDA takes note of those comments on reference statements and abbreviated health claims. Some of the issues raised by these comments have been resolved with revisions made in all of the model health claims. For example, among the sample claims for sodium and hypertension in new § 101.74(e) is one that reads: "Diets low in sodium may reduce the risk of high blood pressure, a disease that is dependent upon many factors." Similarly short claims have been developed for other health claims. Since these abbreviated claims are not much different in length than a reference statement that would have been used on the principal display panel or elsewhere in labeling of a product, it is now possible to present the health claim in place of a reference statement. However, since the agency cannot provide assurance that future health claims will be crafted to be as short at the example given above, FDA has retained proposed § 101.14(d)(iv). The agency's responses to comments on reference statements and abbreviated claims follow.

FDA does not believe that it is appropriate to use abbreviated health claims as referral statements. Shortened health claims used as referral statements, even those as simple as "See side panel for information on how calcium may reduce the risk of osteoporosis," still constitute a health claim because they clearly characterize the relationship between a substance and a disease or health-related condition. Further, such a health claim is misleading because it does not include facts that are material in light of the representation that is made, and that are necessary to understand the claim in the context of the daily diet. For example, in the case of calcium and osteoporosis, the shortened claim does not reveal that regular exercise and a balanced diet are important to the maintenance of good bone health, and that a daily intake of calcium in excess of 2,400 mg is not likely to provide additional benefit for reducing the risk of osteoporosis.

Such situations are possible whenever the full health claim information appears in a location different from that of the reference statement and are especially likely to occur when a multiplicity of labeling is associated with a product. For example, a cereal manufacturer could place an abbreviated claim as a reference statement on the principal display panel of the cereal box and then bury the full claim on one of several paper inserts. In such a case, a consumer is unlikely to search through the inserts to find the full claim. A similar situation might arise were a grocer to display an abbreviated calcium-osteoporosis claim as a referral statement on a dairy case and then place the full claim on a billboard in a far corner of the store. A consumer is not likely to search through the store for the detailed health information.

In each of these examples, the consumer would be misled because he/she has received an incomplete health claim that does not disclose information on nondietary factors that may affect the nutrient-disease relationship and that does not allow the consumer to understand the claim in the context of the total daily diet. Case law clearly supports the agency's position that the mere presence of the full health claim elsewhere in the product labeling does not counteract the misleading nature of the abbreviated reference statements in such instances. See, e.g., *U.S.* v. *An Article of Food * * * "Manischewitz * * * Diet Thins,"* 377 F. Supp. 746, 749 (E.D.N.Y. 1974).

The referral statement provided in § 101.14(d)(2)(iv) does not constitute a health claim, as it does not characterize the relationship between a substance and a disease or health-related condition. The statement simply refers the consumer to a location where the complete health claim appears. A consumer who reads the referral statement without reading the full health claim may realize that there is some relationship between the nutrient and the disease. The nature of that relationship, however, is only presented in a context that is complete, truthful, and not misleading and that thus allows the consumer to fully understand and evaluate the claim. Thus, the consumer will not be misled by reading the provided referral statement. Accordingly, the referral statement provided in proposed § 101.14(d)(2)(iv) is the only one that should be used. As explained previously in this preamble (section I.D.5. of this document), the statement must appear in immediate proximity to any graphic material such as a symbol that constitutes an explicit or implied health claim.

70. A number of comments suggested that the complete health claim should be allowed only on the principal display panel unless the panel is too small to accommodate it.

FDA does not agree that health claims should be required to appear only on the principal display panel. The adoption of such a policy, for those labels that are physically large enough to contain the full health claim, could easily lead to overcrowding of some principal display panels and would eliminate their use on those that are not. Such a requirement would significantly undercut the congressional intent in providing for health claims in section 403(r) of the act. Therefore, FDA rejects this comment.

71. A number of comments asserted that the type size requirement proposed for health claims is not mandated by law. It was also argued that the requirement may make it impossible for manufacturers to include other truthful and nonmisleading information on the principal display panel.

FDA recognizes that the proposed type sizes are not mandated by law. The agency proposed this requirement because it was concerned that many consumers, when faced with a health claim printed in differing type sizes, might read only those portions of the claim that appear in larger type and thus would overlook the information printed in smaller type. However, FDA has reconsidered this issue and now believes that, as proposed, the provision is unnecessarily restrictive. Certainly consumers would not likely ignore portions of a health claim that are

printed in a reasonably related type size to the largest printed matter in the claim. FDA believes that any abusive use of type size could adequately be prevented under § 101.14(d)(2)(iii), which requires, in part, that a claim not be misleading. Accordingly, FDA has removed the requirement that a claim appear in the same type size. While the agency encourages manufacturers to observe the minimum type size required by § 101.2 for mandatory labeling information to ensure that the claims are easily legible, manufacturers who want to include a complete health claim on the principal display panel of a product may utilize whatever type size they feel is necessary to achieve this end.

72. One comment recommended that, in order to avoid the label space problems that would result from the appearance of lengthy bilingual claims, health claims on imported products should be allowed to appear in English without translations into the foreign languages that appear on the label. The comment asserted that competitive pressure will force U.S. importers to make label claims comparable to domestically produced products and cited the model health claim for calcium and osteoporosis in exemplifying the difficulty that would result from providing lengthy bilingual claims. Another comment from a foreign industry organization objected to permitting any health claims on food labels because multi-language labeling will be so burdensome that it will serve as a nontariff trade barrier.

FDA advises that the provisions of § 101.15(c)(2) require only that all mandatory labeling information be translated into any foreign languages that appear on any part of a product's labeling. Because the presence of a health claim on a food label is voluntary, manufacturers who place an English-language health claim on a multi-language label may choose whether to translate that claim into one, all, or none of the foreign languages appearing on the label.

D. Enables Public to Understand Significance of Claim in Context of Total Daily Diet

Proposed § 101.14(d)(2)(v) stated that a health claim must enable the public to comprehend the information provided and to understand the relative significance of such information in the context of a total daily diet.

73. Some comments asserted that the multiplicity of labeling requirements exceeds the statutory language of the 1990 amendments and stated there is no evidence in the legislative history to suggest that Congress intended label claims about nutrient/disease relationships to include the kinds of detailed information mentioned in the preamble. One of these comments stated that FDA is authorized under the amendments to require only that information that is necessary to prevent the health claim from being misleading.

Another comment disagreed with FDA's conclusion that section 403(r)(3)(B)(iii) of the act allowed "only those effects found to be substantiated" to be included in the health claim. The comment instead asserted that the requirements of the provision would be fulfilled if a health claim merely characterized the level of a nutrient vis-a-vis a disease, provided that there was significant scientific agreement that the intake of the nutrient at the level present in the food was beneficial in reducing the risk of the disease.

FDA disagrees with these comments. Section 403(r)(3)(B)(iii) of the act requires that a regulation that authorizes a claim require that the claim be stated in a manner that enables the public to comprehend the information in the claim and to understand the relationship of the substance to the disease, the significance of the substance in affecting the disease, and the significance of the information in the context of the total daily diet. Thus, a wide variety of factors may need to be addressed in the claim in order to fulfill these requirements, and the agency is not limited to requiring only that information that is necessary to prevent a claim from being misleading.

For example, the regulation authorizing a claim on the relationship between calcium and osteoporosis requires that the claim explain that adequate calcium intake during adolescence and early adulthood appears to have a positive effect on bone health, and that optimizing peak bone mass during that period may reduce the risk of osteoporotic fracture in old age (see new § 101.72(d)(3)). Additionally, the regulation requires that claims point out that adequate calcium intake be accompanied with exercise and the maintenance of a balanced diet. The claim must also identify factors such as the age range within which women can expect to achieve the greatest effect for decreasing the risk of developing osteoporosis in later life (see new § 101.72(d)(2)). These are considered to be facts essential for consumers to understand the conditions and circumstances under which the claimed effect of calcium on the risk of osteoporosis is more likely to be obtained.

Accordingly, if FDA were to permit a health claim that simply characterized the level of a nutrient vis-a-vis a disease or health-related condition, the agency would not meet the statutory requirements of section 403(r)(3)(B)(iii) of the act. Therefore, FDA rejects the comments.

74. Some comments stated that the model health claims were themselves misleading in that the identification of certain high-risk groups in a claim might easily lead consumers in other groups to believe that the information presented in the claim does not apply to them, when in fact it may (for example, osteoporosis affects some men as well as women).

The model claims that are targeted to specific subpopulations have been carefully worded to encompass all of the affected subpopulations. The agency, therefore, sees no potential for a consumer who is in a group that is at increased risk of a disease that is discussed in a health claim to be misled by the claim into believing that he/she is not at an increased risk of the disease. The agency addresses concerns about specific model health claims in the preambles to the specific regulations authorizing those claims.

75. Other comments asserted that model health claims should emphasize the importance of good nutrition habits to all consumers. One also recommended that FDA require a statement about the need to seek medical advice for treating the related disease as part of the health claim.

FDA does not agree that it is appropriate to require that all health claims emphasize the importance of good nutrition to all consumers. In many cases, a health claim may be targeted toward a specific subpopulation. The inclusion of a statement directed at the general U.S. population could lead some consumers who are not targets of the claim to mistakenly believe that the entire health claim has relevance to them. For example, a calcium-osteoporosis claim targeted toward teenage women that bears a statement concerning the importance of good nutrition to the general population could mislead some middle-age men with no family history of osteoporosis to believe that the claim was also targeted toward them.

Also, FDA does not believe that it is appropriate for health claims to bear statements concerning the need to seek medical advice for treating the disease or health-related condition mentioned in a claim. The agency is concerned that the appearance of a statement concerning the treatment of a disease on the label of a food could mislead some consumers to believe that the food possesses therapeutic value for an

existing disease or health-related condition. Further, such an interpretation could encourage some consumers who suffer from the disease or condition to attempt "home remedies" by consuming more of the product and, ironically, temporarily or even permanently foregoing the medical attention that they need.

E. Presence of "Low" Level of Nutrient to be Consumed at Decreased Dietary Levels; Presence of "High" Level of Nutrient to be Consumed at Other Than Decreased Dietary Levels

Proposed § 101.14(d)(2)(vi) stated that to bear a claim about the benefits of consuming a substance at reduced dietary levels, a food must be sufficiently low in that substance to meet the definition of the term "low" if the term has been defined for that substance, or if the term has not been defined, to meet the level set in the regulation authorizing the claim. Proposed § 101.14(d)(2)(vii) stated that to bear a claim about consuming a substance at other than decreased dietary levels, a food must be sufficiently high in that substance to meet the definition of "high" if the term has been defined for that substance, or if the term has not been defined, to meet the level set in the regulation authorizing the claim.

With the decision in section II.B of this document to revise the definition of "substance" in proposed § 101.14(a)(2) to include a specific food as well as a component of food, the requirements of proposed § 101.14(d)(2)(vii) (i.e., the requirements for "high") must be revised as they apply to a health claim for a specific food. Where a health claim for a specific food (e.g., garlic, rice bran) is established by the agency, it is presumed that the claim will deal with either inclusion of the food in the diet or increased dietary intake to effect the benefit that is the object of the claim. The agency does not envision authorizing a health claim for a specific food based on decreased intake of that food because, where moderation in or a decrease in daily intake is at issue, that action is directed toward food components rather than whole foods (e.g., "choose a diet low in fat, saturated fat, and cholesterol;" "use sodium only in moderation").

Accordingly, FDA has revised proposed § 101.14(d)(2)(vii) to state that, where no definition for "high" has been established, that is where the claim pertains to a whole food or to the food's use as an ingredient in other foods, the claim must specify the daily dietary intake necessary to achieve the claimed effect as established in the regulation authorizing the claim.

76. Most comments concurred with the proposal to allow a health claim only when a food contains the claimed substance in an amount that meets the criterion for either a "high" or "low" level of that substance. However, some comments qualified their concurrence by saying that they did not agree with the definitions for "high" and "low." One comment stated that, absent a definitive showing that health claims would be misleading on foods that do not meet the "high" or "low" definitions, FDA's approach cannot be considered narrowly tailored to directly advance the government's interest in providing important diet and health information to consumers. Unless deception could be proved, the comment urged FDA to eliminate the requirements linking health claims to "high" and "low" definitions for nutrient content of foods.

The agency has considered these comments and concludes that it is appropriate to retain the requirements in proposed§§ 101.14(d)(2)(vi) and (d)(2)(vii) linking health claims to "high" and "low" definitions for nutrient content of foods. The definitions for "low" and "high" levels of a substance (nutrient) have been developed specifically to assist consumers in maintaining healthy dietary practices (see section 403(r)(2) of the act). The same basis underlies the purpose for health claims. This is evident from the House of Representatives report on the 1990 amendments (Ref. 1):

> The Surgeon General has advised Americans that diets low in fats, low in salt and high in fiber can reduce the risk of chronic diseases such as cancer and heart disease. Health claims supported by a significant scientific agreement can reinforce the Surgeon General'[s] recommendations and help Americans to maintain a balanced and healthful diet. Similarly, statements regarding the level of these nutrients in foods will assist Americans in following the Surgeon General's guidelines.

Accordingly, a requirement with respect to the level in a food of a substance that is the subject of a health claim is consistent with the intent of the 1990 amendments. The definitions of "high" and "low" are addressed by FDA in the rule on nutrient content claims published elsewhere in this issue of the **Federal Register**.

77. One comment urged FDA to modify the proposed requirement that would permit a health claim on a product for which a nutrient (specifically sodium) is assessed only on the basis of the reference amount customarily consumed (as defined in the final rule on serving size published elsewhere in this issue of the **Federal Register**). The comment suggested that the product should additionally comply on the basis of the total amount of the nutrient in the actual package if the package contains less than 200 percent of the reference amount customarily consumed.

This comment misinterpreted FDA's proposal. In the proposal on serving sizes (56 FR 60394), FDA proposed that both the reference amount customarily consumed (hereinafter referred to as the reference amount) and the label serving size be used to determine whether a product met the criteria for both nutrient content and health claims. The agency solicited comment on another approach that is based solely on the reference amount and that would require a disclaimer where, for example, a reference amount of a product would qualify for a sodium claim, but a single-serving container with 150 percent of the reference amount would not.

As discussed in detail in the preamble to the final rule on serving sizes published elsewhere in this issue of the **Federal Register**, the agency has considered the comments on this issue, along with the advantages and disadvantages of both options, and acknowledges that nutrient content claims should reflect, and health claims should be based on, the reference amount customarily consumed. The agency has concluded that problems created when the amount of the substance in the labeled serving size would not qualify for a claim are resolved by requiring a disclaimer that makes clear the basis for the claim. This disclosure is necessary to ensure that the consumer is not misled. On this basis, the agency is rejecting the recommendation made by this comment.

The agency has reflected this determination with respect to claims in new § 101.12(g) of the final rule on serving sizes, published elsewhere in this issue of the **Federal Register**, which has been revised in response to comments to that proposal to state, in part:

> The reference amount [i.e., the reference amount customarily consumed] set forth in paragraphs (b) through (f) of this section shall be used in determining whether a product meets the criteria for nutrient content claims, such as "low calorie," and for health claims. If the serving size declared on the product label differs from the reference amount, and the product meets the criteria for the claim only on the basis of the reference amount, the claim shall be followed by a statement that sets forth the basis on which the claim is made. That statement shall include the reference amount as it appears in § 101.12(b)

followed, in parenthesis, by the amount in common household measure if the reference amount is expressed in measures other than common household measures (e.g., for a beverage, "Very low sodium, 35 mg or less per 240 mL (8 fl. oz)").

That declaration is necessary because in containers of this type, consumers customarily consume more than the reference amount. The declaration is necessary to ensure that the claim is not misleading. The criteria for health claims referenced in proposed § 101.12(g) are the qualifying criteria contained in proposed §§ 101.14(d)(2)(vi) and (d)(2)(vii). Therefore, to reflect the modification that has been made in § 101.12(g) that a health claim can be made on a product when the product meets the criteria of proposed §§ 101.14(d)(2)(vi) or (d)(2)(vii) only on the basis of the reference amount customarily consumed, new § 101.14(d)(2)(vii)(A) has been added to state:

Where the food that bears the claim meets the requirements of paragraphs (d)(2)(vi) or (d)(2)(vii) of this section based on its reference amount customarily consumed, and the labeled serving size differs from that amount, the claim shall be followed by a statement explaining that the claim is based on the reference amount rather than the labeled serving size (e.g., "Diets low in salt and sodium may help lower blood pressure in many people. A serving of ——— ounces of this product conforms to such diets.").

F. Requirements for Restaurants

1. Health claims on restaurant foods

FDA received many comments regarding the proposed health claims criteria as they would apply to restaurant foods and to foods sold in other establishements in which food that is ready for human consumption is sold (e.g., institutional food service, delicatessens, catering). In this discussion, such foods will be referred to as "restaurant foods," firms selling such foods will be referred to as "restaurants," and responsible individuals in these firms will be referred to as "restaurateurs." However, the concepts and policies discussed are intended to apply broadly to the foods covered by section 403(q)(5)(A)(i) and (q)(5)(A)(ii) of the act. Issues with respect to menus are dicussed separately below.

78. Many comments objected that the proposed health claim provisions should not apply to restaurant foods and foods sold in other establishments in which food that is ready for human consumption is sold. These comments asserted that Congress did not mandate the application of the proposed health claim regulations to restaurant foods. A number of comments observed that section 403(q)(5)(A)(i) of the act exempts restaurant foods from mandatory nutrition labeling requirements, and that sections 403(r)(2)(A)(iii) and (r)(2)(A)(iv) exempt them from the restrictions placed on claims related to cholesterol, fat, and fiber content. The comments further noted that the 1990 amendments are silent with respect to the regulation of health claims made in connection with restaurant foods, and that, at a minimum, FDA is not required to regulate restaurant foods. Other comments maintained that even if the agency does believe that restaurants must be subject to health claims regulations, FDA is not obligated to regulate these foods in an identical manner to that proposed for packaged foods.

However, many other comments disagreed. Some of these comments maintained that because the 1990 amendments contain no specific exemptions for health claims in restaurants, Congress intended for restaurants to be fully subject to the health claim regulations. Other comments argued that restaurant food plays too great a role in the American diet not to have been covered by the 1990 amendments. One comment pointed out that a large percentage of the money spent for food by Americans is spent away from home in restaurants. Several comments stated that requiring restaurants to comply with all of the health claims regulations where they choose to make health claims would best support the philosophy of an "even playing field" between restaurateurs and other food vendors. Others expressed concern that the preemption clause of the 1990 amendments could prohibit state and local authorities from enacting regulations concerning health claims made on restaurant foods if FDA fails to do so. One consumer comment proposed that FDA ban restaurants from making any health claims for any of their products, rather than exempting them from the health claim regulations.

FDA believes that the provisions of the 1990 amendments pertaining to health claims clearly encompass restaurant food wherever a health claim is made (except, for the reasons discussed below, when the claim is made on a menu). FDA disagrees with comments that asserted that the absence of specific exemptions for restaurant food from the health claims provisions in these amendments conveys flexibility to the agency to exempt such food from § 101.14. The House Report (Ref. 1) states that "under sections 403(r)(1)(B) and 403(r)(3) of the act, restaurants and similar food service establishments would have to comply with the bill in order to make a disease claim concerning a food sold in such establishment." In view of this explicit statement of congressional intent on this matter and the presence of specific exemptions for restaurant food pertaining to other provisions of the 1990 amendments where Congress wanted different regulatory treatment for restaurant food, the absence of a restaurant food exemption pertaining to health claims can only mean that Congress intended for restaurants to be subject to health claim regulations. Because of the congressional intent that restaurants be subject to the health claim regulations, FDA disagrees with assertions that the agency should not permit health claims on restaurant food.

However, FDA agrees that it is not legally required to regulate claims on restaurant foods in a manner identical to that for packaged foods. Nevertheless, it is only logical that if claims on food are to be useful for consumers, the criteria for those claims must be consistent. Therefore, the agency has determined that additional flexibility is needed to facilitate the helpful provision of health claims on restaurant foods, but that there must be assurance that the claims being made are indeed valid. The agency's responses to the following comments discuss how FDA intends to achieve this degree of flexibility with appropriate assurance of validity.

79. Many comments argued that all health claims provisions affecting packaged food should also apply to restaurant food. Several comments stated that the regulation of restaurant foods would be practical because many of the menu items are centrally manufactured and are required to conform to system-wide composition and quality standards. One comment asserted that many restaurant chains, especially the larger ones, already have access to nutrition information about their products. Another comment stated that private services that determine the level of various nutrients in foods are readily accessible to restaurants. A comment from an organization representing the nation's state, local, and Federal food regulatory officials asserted that the proposed regulations would not place an additional burden on restaurants seeking compliance with the health claim requirements, as most state laws already require that foods be labeled in compliance with all applicable laws and regulations and do not differentiate between labeling at the wholesale or manufacturing level and the retail level. The comment cited the model regulations developed jointly

between FDA and the Association of Food and Drug Officials (Rules of Food Service Sanitation and the Retail Food Store Sanitation Code) as an example. Other comments argued that health claims are misleading without nutrition labeling information. Some comments suggested that restaurants be required to at least provide an abbreviated nutrition statement, consisting of a disclosure of the amount of calories, fat, and sodium as well as of all nutrients relevant to the health claim.

However, many comments confirmed that restaurant food differs in a number of significant respects from other types of food that is mass-produced and packaged and maintained that the differences make it impracticable for restaurants to conform to some of the health claims provisions that were proposed. The comments advised that the provisions at issue are those pertaining to qualifying levels (e.g., the "low" or "high" levels of the substance, as appropriate) and the "disqualifying nutrient levels," as well as nutrition labeling. The comments asserted that the cost of providing nutrient content information would be unreasonable for each of these provisions. Some of these comments explained that restaurants experience significant variations in the foods they serve because of variations in the manner of preparation, varying ingredients, consumer preferences, varying serving sizes, and the lack of central control over food preparation in many restaurants. Because of this wide variation, frequent nutrient analyses would have to be performed to determine nutrient content, so that restaurants may conform to these provisions. The comments advised that these analyses could become very burdensome, and that the cumulative costs of these analyses could prevent establishments from making health claims, prevent them from making frequent changes in the dishes they offer, or force them to limit the options that consumers have in ordering a food. Further, the comments advised that small businesses would be especially burdened by such cumulative costs.

Even in "standard" items in multi-unit operations, the comments asserted, there is inherent variation. The comments advised that such variation is present in items such as daily specials, test products, local optional items, promotional items, and all items in restaurants offered for limited periods of time. A number of comments objected to the application of the proposed health claim regulations to traditional ethnic restaurants and similar small businesses on the grounds that it is extremely difficult to modify many of their foods to the degree necessary to meet the various provisions of the health claim proposals.

In addition, some comments pointed out that the proposal requires that qualifying and disqualifying levels be met per reference amount, per serving, and per 100 g. This aspect of the proposed definition, the comments maintained, wreaks havoc when applied to restaurant foods. Comments advised that restaurant foods that conform to the proposed qualifying and disqualifying levels in terms of reference amounts and 100 g are nonetheless ineligible to use health claims because their larger serving size results in the food failing to conform to the disqualifying nutrient levels. A number of comments suggested that restaurant food claims be judged on a per 100 g basis consistent with FDA's meal proposal, since most consumers view restaurant foods as a "meal."

Given that almost half of the American food dollar is spent on food consumed away from home, and that perhaps as much as 30 percent of the American diet is composed of foods prepared in food service operations, FDA believes that, from an overall public health perspective, this important segment of the diet can not be ignored. Further, FDA believes that dietary information, including health claims, provided to consumers at point of purchase in restaurants may be useful in helping Americans in maintaining healthy dietary practices. FDA wants to encourage the provision of such information. However, FDA firmly believes that consumers expect health claims made at point of purchase to be truthful and not misleading.

FDA advises that not all claims made for restaurant foods are necessarily the type of claims that are covered by the 1990 amendments. For the sake of clarification, the agency offers the following observations. Because of the importance of context, a restaurant may be able to use symbols next to the listing of an item where the symbols are clearly explained in terms that would not subject the claim to the 1990 amendments. Thus, restaurant labeling may use symbols or make reference to the criteria of a health professional organization and explain that the entree or meal is consistent with the general dietary guidelines of that group and not be subject to the 1990 amendments. For example, use of a heart symbol with reference to a note that explains that this entree is consistent with the dietary guidelines of the American Heart Association will be considered dietary guidance, and not a health claim subject to section 403(r) of the act. If the restaurateur went on to link the claim with levels of substances in the food, however, it would subject the food and the claims to the health claims regime (see discussion above about implied health claims).

When a restaurant makes explicit or implied reference to a substance and directly or indirectly links levels of that substance in the food to an effect on the risk of a disease or health-related condition (i.e., when both basic elements of a health claim are present) on a sign or placard, it must comply with the health claims regime.

How the restaurant demonstrates compliance with that regime is a difficult matter. FDA recognizes that, as detailed in the comments, there are variations in the nutrient values for restaurant foods. Some of these variations are not unique to restaurants. Manufacturers of packaged foods also have to deal with differences in nutrient levels that result from seasonal, regional, and supplier variations. FDA has been able to develop workable criteria that take into account these variations. However, the agency acknowledges that there are variations unique to restaurant foods (e.g., methods of preparation). Moreover, FDA recognizes that there are difficult questions, as demonstrated by the comments, as to how exactly to analyze restaurant foods in a reasonable and cost effective manner.

While there are difficulties associated with restaurant foods, FDA concludes that the difficulties are not so great as to preclude restaurants from making health claims or to prevent the agency from being able to assure consumers that the health claims that are made for restaurant foods are valid. Because of the nature of the difficulties, however, FDA is providing in § 101.14(d)(2)(vii)(B) that a restaurant food may bear a health claim if the restaurateur has a reasonable basis on which to believe that the food that bears the claim meets the regulations for the claim that FDA has established under section 403(r) of the act, and that basis is provided upon request. The difficulties and costs outlined in the comments would make it unfair to require that restaurateur determine whether their food qualifies for a claim in the same manner that a manufacturer of a packaged food makes this determination. By requiring that the restaurateur have a reasonable basis to believe that the food qualifies, the restaurateur, is provided with a readily achievable way to make claims for his or her food, and the consumer is provided with a reasonable assurance that the claim is valid. Thus, if a

restaurateur labels a vegetarian main dish or meal as "heart healthy," he must have a reasonable basis for believing that the product contains less than the disqualifying level for sodium and meets the "low" definitions for fat, saturated fat, and cholesterol.

The reasonable basis can be provided in a number of ways. The restaurateur can show, for example, that FDA's guidelines on nutrition labeling of fruits and vegetables show that meal or main dish is "low fat," "low saturated fat," "low cholesterol," and does not contain a disqualifying level of sodium, and that the method of cooking the meal or main dish would not add fat or any disqualifying nutrient. In addition, the restaurateur could show that he or she used a reliable cookbook that gave values for fat, saturated fat, sodium, and cholesterol in the finished food that met FDA's requirements for making the health claim. Certainly other methods are possible. If a restaurateur uses recognized data bases for raw and processed foods to compute nutrient levels in the foods or meals and then does not use methods of preparation that violate the appropriate use of data bases (e.g., uncontrolled addition of ingredients, inappropriate substitutions of ingredients), FDA will consider this use to be a reasonable basis for believing that the food meets the qualifying and disqualifying levels. Upon demand, the restaurateur will be expected to present to appropriate regulatory officials information on the pertinent nutrient levels in the foods and the basis on which these levels were determined. A determination will then be made as to whether the basis of calculation reasonably supports the restaurateur's use of a permitted health claim. FDA believes that the reasonable basis approach will make it practicable for all restaurants, including those that are very small businesses, to provide consumers with better information on more healthful dietary choices for the foods that they offer for sale.

Further, this reasonable basis approach for making a health claim will provide regulatory officials, especially State and local authorities, with an effective standard for verifying that claims made for restaurant-type foods are truthful and not misleading and in accordance with FDA regulations. While health claims used in restaurants are under FDA's jurisdiction, the agency does not have resources to adequately enforce its regulations in restaurants. State and local authorities have traditionally carried out this responsibility. In addition, section 4 of the 1990 amendments provides that State and local authorities may enforce section 403(r) of the act in Federal court.

While restaurants, and particularly small restaurants, have nominally been subject to FDA's existing nutrition labeling regulation (see § 101.10), they have, as a practical matter, not been required to comply with these regulations or with State or local regulations that focused on the nutrient content of the food. Thus, the efforts that will be necessary on the part of restaurants to show that they have a reasonable basis to believe that their food complies with the health claims requirements will be significant. These efforts will place particularly great demands on the resources of the small business segment of the industry, that is, restaurant firms that have ten or less individual restaurant establishments (Ref. 37). FDA will refer to this segment of the industry as "small restaurants."

Small restaurants generally do not have the established nutrition support component that larger restaurant chains have. Thus, it will be more difficult for small restaurants to determine how to adapt health claims information to their food preparation methods. In addition, it is likely that they will not be as aware of available information sources, like nutrient content data bases, as large chains. Moreover, because of resource limitations, a small restaurant is not as likely as a large restaurant chain to be familiar with Federal requirements. Thus, small restaurants will have to become familiar with not only FDA's requirements, but with available FDA information, like the nutrient content information that FDA published in conjunction with its regulation on the voluntary labeling of raw fruits and vegetables (56 FR 60880, November 27, 1991).

Because of the great initial demands that small restaurants will find if they wish to make claims, FDA has decided that they should be given additional time to come into compliance with these regulations. Without additional time for the reasons discussed above, small restaurants will be place at a disadvantage with respect to their ability to make claims. As a result, they may decide not to even attempt to provide useful nutrition information to consumers about the foods they serve. To provide for equitable implementation of these requirements for small restaurants, FDA has decided to not make part 101 effective with respect to such establishments until May 1994.

While the statute will be in effect during that period, FDA will not enforce the statute's health claim requirements in small restaurants until the regulations are effective. Although state action is not preempted under section 403A(a)(5) of the act until Federal regulations are effective, the agency expects that states will refrain from enforcing any health claim requirements in small restaurants until the Federal regulations are effective for those restaurants.

FDA believes that this action is fully consistent with the 1990 amendments and with the act. The 1990 amendments impose no date by which the agency's regulations must be effective, only when they must be promulgated (see sections 3 and 10 of the 1990 amendments). Moreover, FDA believes that this action will facilitate effective enforcement of the act. FDA believes that the agency's and State resources can best be used during this initial period in educating small restaurants about the requirements of the law and by developing a better understanding of the unique practical circumstances of small restaurants in complying with health claims labeling requirements. Moreover, during this period, there will be an opportunity for interested persons to develop new data bases that will help facilitate the provision of nutrition information on foods sold in restaurants and particularly in small restaurants.

As an additional measure of flexibility, which will especially benefit small restaurants, it was decided not to include claims on menus within the coverage of these regulations. FDA has considerable discretion in regulating health claims in restaurants. As the comment's have indicated, there are unique problems and concerns associated with regulating such claims. The 1990 amendments do not specify precisely how such claims are to be regulated. These regulations will apply to health claims made in restaurants except on menus. The agency's efforts will focus on signs, placards, and posters, which are increasingly used in fast food and other restaurants to bring nutrition information and claims about food to consumer's particular attention The comments pointed out that menus are subject to frequent, even daily, change. This additional measure of flexibility for menus will help assure that restaurants, especially small restaurants, will not be deterred by the 1990 amendments from providing useful nutrition-related information to their customers. State's remain free, however, to ensure under their own consumer protection laws that menus do not provide false or misleading information.

Although it has arrived at an approach that will provide for health claims on restaurant foods, FDA does not consider the problem of restaurant

food to be solved. It is possible that there are other health claim criteria that are more appropriate for restaurant foods than those that FDA has developed based largely on packaged foods. Also, it may be that consumers have completely different expectations for, and understanding of, restaurant foods as compared to packaged foods. If so, different criteria for use of health claims in restaurants may be appropriate. However, at this time, the agency simply does not have the data or knowledge on which to base such determinations. FDA is working, and will continue to work, with the restaurant industry to determine how health claims are used on restaurant foods, and whether such claims are appropriate. For example, with FDA's cooperation, the National Restaurant Association has undertaken a survey of industry use of nutrition information and of consumer knowledge, practices, expectations, and understanding of various terms and symbols in restaurants. FDA is open to petitions for different criteria for health claims for restaurant foods, and if data warrant, the agency will consider establishing regulations specifically for restaurant foods.

FDA also recognizes that there are a number of significant issues concerning the adequacy of currently existing data bases for use to compute nutrient levels in restaurant meals. However, the agency is working, and will continue to work, with the restaurant industry to assess the adequacy of these data bases and to encourage the development of additional or newer data where those data bases are found to be lacking.

In developing more specific policies, FDA will also consider whether restaurant foods should be afforded greater latitude in the compliance criteria than the criteria that are currently applied to nutrient variations in processed foods. FDA regulations state that, for naturally occurring vitamins, minerals, and protein, the nutrient content must be at least 80 percent of the value declared and for calories, carbohydrate, fat, and sodium, the level must not exceed the declared value by more than 20 percent. The agency recognizes that all data bases have inherent variabilities, and that a computed nutrient level for a food with several ingredients may have an accumulated variability that exceeds the agency's criteria for packaged foods. FDA is concerned about the accuracy of nutrient level estimations, but pending the development of better data, the agency will accept, as a reasonable basis, claims verification based on nutrient levels from recognized nutrient data bases, without regard to the computed variability or to differences between the computed nutrient levels and levels determined by laboratory analyses. The agency is open to comments and suggestions on how nutrient variability issues should be addressed for restaurant foods and will continue to work with the industry on this issue.

80. Some comments cautioned that any adopted health claims provisions applied to restaurants must be flexible in format and content. These comments asserted that the distinct differences between the delivery systems of restaurant foods and packaged retail products must be factored into the regulations if they are to apply to restaurant foods, as most consumers select and purchase their food before ever seeing it or its container. Other comments asserted that the impracticality of compliance with the current inflexible health claims regulations would tempt restaurant operators to simply choose not to promote healthful menu alternatives.

FDA does not agree that firms should be given special flexibility concerning the content of health claims that appear on restaurant food. FDA believes that section 403(r)(1)(B) and (r)(3)(b)(iii) of the act require that a health claim be complete and consistent with the authorizing regulation. Specific health claims regulations in part 101, subpart E set forth certain mandatory aspects of permitted health claims. Where any mandatory aspect of a health claim is absent, the claim will be misleading, and the agency cannot sanction such a situation.

With respect to format, FDA believes that there is already ample flexibility in the rules that it is adopting. For example, new § 101.14(d)(2)(iv) permits full health claims to appear on any part of a food's labeling, including a sign or a placard. Accordingly, labeling listing 20 items, 3 of which qualify for the fat-cardiovascular disease claim, could carry the full health claim next to each of the 3 qualifying items. Alternately, it could list the names of the three items in a distinct area, such as a box or section, and print the full health claim once within that area.

New § 101.14(d)(2)(iv) also provides for the use of a short referral statement that directs the consumers' attention to another part of the food's label or labeling where the full health claim appears. Therefore, in the example above, the message "See ———— for details concerning the relationship between fat and cancer" could appear next to each of the items or in the box, with the full health claim printed only once in the label or in the labeling location identified in the blank. For example, the labeling could be in the form of placards placed in full view of the consumer, flyers made available to the public, and other such items. The agency cautions, however, that the referral statement must clearly be associated only with the item or items that qualify for the health claim, and that the location of the full health claim must not be such that it is likely to be associated with a product that does not qualify for the claim.

2. Nutrition labeling on restaurant foods making health claims

81. Many comments asserted that the cost of providing nutrient content information for restaurant foods making health claims would be unreasonable. Some comments that opposed any form of mandatory labeling requirements offered ways in which FDA could minimize the financial burden on restaurants, if any such regulations were in fact adopted. Many of these comments proposed that only fixed items should be required to bear nutrition labeling, thus exempting items such as daily specials, test products, local optional items, promotional items, and all items in restaurants for limited periods of time. Some comments asserted that FDA should permit the use of various data bases, including computer reference bases, for the determination of a food's nutrient content. Other comments suggested that only chains should be required to furnish nutrition labeling for their foods. Other comments suggested that any restaurant with profits of below $50,000 be exempted from any nutrition labeling requirements. However, comments from larger restaurant chains argued that any nutrition labeling requirements should be applied equitably to the restaurant industry as a whole, because a selective application of the regulations could place major chains at an economic disadvantage.

FDA finds nothing in the comments to persuade the agency to adopt a position different from that stated in the general requirements proposal (56 FR 60553). The agency continues to believe that it has the authority to issue regulations requiring restaurants that make health claims to adhere to the requirements for such claims including nutrition labeling. Full nutrition labeling provides the consumer with a way of evaluating a claim within the nutrient context of the food or meal and, therefore, is advantageous in allowing more informed comparisons. However, in the general principles proposal for nutrient content claims (56 FR 60427),

the agency recognized the difficulty of providing nutrition labeling for restaurant foods and asked for comment. The comments have persuaded the agency that, at this time, a requirement for full nutrition labeling could be a significant barrier to the transfer of information about favorable health-related characteristics of restaurant foods. Therefore, FDA is not requiring that full nutrition labeling be provided when a health claim is made for restaurant foods. The agency is adopting a somewhat different approach to the provision of nutrient information to the consumer, as explained below.

FDA believes that consumers should have information about the nutrient content of restaurant foods on which health claims are based. The agency has therefore established alternative nutrition labeling provisions for restaurant food in new § 101.14(d)(3) providing for such information in lieu of full nutrition labeling. For example, if a meal is characterized as being "heart healthy," the restaurateur should be able to provide consumers with information about the level of the nutrients that provide the basis for the claim. Therefore, the agency will require that if a restaurateur makes a health claim for a meal, he or she must be prepared to advise the consumer about the information that provides the reasonable basis for believing that the food complies with FDA's requirements for the claim (e.g., nutrient levels from data bases, cookbooks, or analyses). For the interim, the agency will consider that the provision of this limited amount of information to consumers will serve as the functional equivalent of nutrition labeling.

82. Many comments asserted that if restaurants are required to provide nutrition labeling, they should be afforded significant flexibility in determining where to present the required nutrient information. Some comments pointed out that restaurant food frequently is not packaged, and that, when it is packaged, the packaging is frequently too small to physically accommodate nutrition information. Other comments stated that much of the labeling used in restaurants is too small to physically accommodate nutrition information for all of the products which could potentially bear health claims. Some suggested that flyers, leaflets, and other printed handouts are acceptable places for such information to appear. Others suggested that all such information should be allowed to appear in a fixed location, such as in a wall display. Others suggested that tray liners be allowed to provide the nutrition information in fast food restaurants.

FDA agrees that restaurants do need significant flexibility in determining where to present the required nutrient information. Accordingly, the agency has revised the nutrition labeling provision in new § 101.14(d)(3) to provide that restaurants may provide nutrition labeling information through conformance with the provisions of § 101.9 or § 101.10, as appropriate. (In response to the DS Act, FDA has removed the reference to § 101.36 in this regulation.) As explained in the next comment, § 101.10 has been revised to convey considerable flexibility for nutrition labeling for restaurants.

83. Many comments contended that in view of the above mentioned problems outlined in the foregoing comments, any regulations regarding health claims on restaurant foods should be promulgated under a separate rulemaking more tailored to the unique nature of the restaurant industry's needs. A number of comments asserted that existing nutrition labeling provisions pertaining to restaurants in § 101.10 are outdated by the application of the proposed health claim regulations to restaurant foods and suggested that those provisions be revoked or modified accordingly.

FDA has determined that § 101.10 should not be deleted. Rather this section is being revised to reflect the agency's determinations with respect to the need for a reasonable basis for believing that the food complies with the qualifying and disqualifying levels and with respect to the provision of information to the consumer. The revision of new § 101.10 has been addressed in the document concerning nutrient content claims that appears elsewhere in this issue of the **Federal Register**.

3. Other restaurant issues

84. One comment suggested that FDA develop educational materials that explain the obligations of restaurateurs relevant to health claims, and that FDA offer alternative, nonmisleading ways in which restaurants might communicate health-related information. The comment noted that the 1990 amendments called for FDA to educate the public about the regulations adopted under them.

Section 2(c) of the 1990 amendments directs the Secretary to carry out activities to educate consumers about the availability of nutrition information in the label or labeling of food and the importance of that information in maintaining healthy dietary practices. While the language of the act does not specifically direct FDA to develop educational materials for industry segments, the agency intends to work with industry, particularly trade associations and small restaurants, so that all parties (e.g., consumers, industry, and State/local regulators) understand the regulations and their obligations and rights under them. Further, FDA believes that the preamble to this document clearly defines those obligations and rights and thus should give the restaurant industry much of the guidance it needs. Where an issue is not resolved in the preamble to the full understanding of a restaurateur, the agency invites correspondence on the specific matters that are unclear.

VI. Prohibited Health Claims

A. Claims not Authorized by FDA

The provisions of new § 101.14(e)(1) and (e)(2) prohibit on a food label or in labeling any claim that expressly or by implication characterizes the relationship of any substance to a disease or health-related condition unless: (1) The claim is a health claim specifically provided for in part 101, subpart E; and (2) the claim conforms to all general provisions of new § 101.14 as well as to all specific provisions in the appropriate section of part 101, subpart E. These provisions embody the statutory restriction in section 403(r)(1)(B) of the act that directs that a food shall be deemed misbranded if a health claim is made in its label or labeling unless the claim is made in accordance with section 403(r)(3), which make such claims subject to the requirements adopted by the Secretary (and FDA, by delegation) by regulation. (Section 403(r)(1)(B) of the act also references section 403(r)(5)(D). However, action on that section is deferred based on the moratorium established by the DS Act).

85. Numerous comments voiced support for or opposition to the proposal to prohibit unauthorized health claims.

FDA has adopted new § 101.14(e)(1) and (e)(2) as proposed because they are explicitly required under section 403(r)(1)(B) and (r)(3) of the act. Because these regulations respond directly to the language of the act, FDA is constrained to adopt them.

B. Disqualifying Levels Exceeded

New § 101.14(e)(3) requires that none of the disqualifying levels identified in new § 101.14(a)(5) be exceeded in a food that bears a health claim, unless specific alternative levels have been established for the substance in part 101, subpart E, or unless FDA has by regulation

permitted such a claim based on a finding that such a claim will assist consumers in maintaining healthy dietary practices. If FDA makes such an exception, the label of the food will have to bear a statement in immediate proximity to the claim that refers the consumer to the nutrition label for information about the nutrient that exceeds the disqualifying level. This statement must be made in a manner that complies with proposed § 101.13(h).

FDA received numerous comments on its proposed disqualifying levels. Some comments voiced unsubstantiated support or disapproval for the proposals, while others offered substantive arguments for their positions. These comments are discussed in section II.G. of this document (see comments 23 through 42 of this document).

C. Inappropriate Levels of Other Substances

New § 101.14(e)(4) will prohibit claims for any food where a substance, other than one for which a disqualifying nutrient level is established, is present at an inappropriate level as determined in the specific provision authorizing the claim in part 101, subpart E. In the preamble to the proposed regulations, the agency explained that this provision will prevent health claims from appearing on foods that contain substances other than the substance that is the subject of the claim if any of those other substances, although not harmful in their own right, could interfere with the claimed effect on the risk of disease. For example, foods containing phosphorus in equal or greater proportion to calcium would not be eligible to bear the calcium-osteoporosis health claim, because diets high in phosphorus and relatively low in calcium result in osteoporosis in experimental animals.

FDA did not receive any comments on this proposed regulation. However, the agency did receive several comments that suggested that disqualifying levels be set for minimum nutrient content, sugars, saccharin, food colors, and various other food additives. These comments are discussed in section II.G.3. of this document (see comments 25 and 26 of this document) and further in this section in response to comment 87 of this document.

D. Infant Foods

Proposed § 101.14(e)(5) provided that no food may bear a health claim if it is represented or purports to be for infants and toddlers less than 2 years of age.

86. One comment questioned the prohibition of health claims on foods promoted for use by infants and toddlers. The comment asserted that claims for all infant formulas, including those formulas that are not subject to the requirements of section 412(h) of the act (i.e., "nonexempt" infant formulas), were meant by Congress to be regulated solely under section 412. More specifically, the comment contended that the agency has already successfully used the premarket notification process of section 412(d) of the act to obtain substantiation of claims from manufacturers of both exempt and nonexempt infant formulas. Further, the comment asserted that the notification process provides the agency adequate oversight of claims for all infant formulas, in keeping with the intent of the requirements for health claims in the 1990 amendments, without impeding product innovation or denying access to product information. Accordingly, the comment recommended deleting proposed § 101.14(e)(5) and revising proposed § 101.14(f)(1) to exclude nonexempt infant formulas, in addition to exempt formulas, from the requirements in that section for health claims.

Another comment viewed a total ban on infant food health claims as an abridgement of commercial free speech protected by the First Amendment. The comment suggested that a more acceptable approach would be to require explanatory information to accompany such claims in order to eliminate any consumer misconceptions.

Although section 403(r)(5)(A) of the act excludes exempt infant formulas from the requirements in section 403(r) for health claims, the 1990 amendments are silent on the applicability of section 403(r) to health claims for nonexempt infant formulas. Thus, health claims on such products are subject to the requirements of section 403(r) of the act. However, in the proposal on general requirements for health claims, FDA pointed out that it had received a letter from the American Academy of Pediatrics that expressed concern that a health claim directed to adults may be inappropriate or harmful to infants and young children (56 FR 60537 at 60556). The letter pointed out that where health claims primarily embody dietary recommendations for the adult U.S. population to reduce the risk of chronic, degenerative diseases, such recommendations are not meant to apply to infants and young children. "Nutrition and Your Health—Dietary Guidelines for Americans" (Ref. 7) states, for example, that the guidelines are "advice for healthy Americans ages 2 years and over—not for younger children and infants, whose dietary needs differ." Accordingly, the agency proposed in § 101.14(e)(5) to prohibit a health claim in labeling of a food represented or purported to be for infants or children less than 2 years of age. The proposed prohibition would have applied to nonexempt infant formulas.

In view of the concerns expressed by the comments, FDA has reconsidered the propriety of health claims on infant food. The agency now believes that the proposed prohibition on infant and toddler foods may have been overbroad. Although health claims based on current dietary recommendations for Americans do not include infants and toddlers, FDA believes that Congress did not intend to limit health claims to only the adult population or to diseases affecting only that population. Thus, the agency cannot discount the possibility that, in the future, information may be developed to support a claim appropriate for infants and young children on the relationship between a substance and a disease or health-related condition. A claim that characterizes this substance-disease relationship would meet the definition for a health claim and thus be subject to the requirements of section 403(r) of the act. The agency has therefore revised new § 101.14(e)(5) to provide for exceptions from the prohibition of infant and toddler health claims when a regulation has been established in part 101, subpart E.

However, the agency has the option, and believes that it may be more prudent, to regulate claims for infant and toddler foods under sections 403(j) and 411(c) of the act, which deal with foods for special dietary use. Thus, should the agency receive a petition that appears to justify a health claim directed to infants and toddlers under section 403(r) of the act, it will decide how best to proceed to authorize the inclusion of the information in the food label.

The agency disagrees with the contention that health claims for nonexempt, as well as exempt, infant formulas should be exempt from section 403(r) of the act and be subject only to the requirements of section 412 of the act. Congress specifically chose to exclude only exempt infant formulas from section 403(r) of the act. Section 412 of the act, although specific to infant formulas, does not exclude such formulas from requirements that are based on other parts of the act. Hence, a labeling claim for an exempt or nonexempt infant formula may be found to misbrand the product under section

403(a) or (j) of the act. In addition, a claim for a nonexempt formula, but not an exempt formula, may also be subject to section 403(r) of the act.

Although the agency has reviewed manufacturers' claims to ensure their validity for both exempt and nonexempt infant formulas in premarket notifications submitted in compliance with section 412 of the act, the agency's conclusions were based on compliance with all applicable sections of the act, not just section 412. The agency is obliged to administer the act as a whole. Because section 412 of the act is not the only section governing labeling for infant formulas (see section 412(e)(1)(B)), the agency must reject the comment's recommendation that health claims requirements in proposed § 101.14 not apply to nonexempt infant formulas.

In light of the agency's conclusion that it will consider health claims for infant and toddler foods, where appropriate, and will establish specific regulations providing for their use, the constitutional issue of a ban on health claims for such foods is now moot. New § 101.14(e)(5) has been revised to prohibit only those claims on infant and toddler foods that are not specifically provided for in part 101, subpart E. Comments that have raised constitutional questions will be dealt with at length later in this document.

E. Additional Limits on Health Claims

87. Some comments urged the agency to allow health claims only on foods that are consistent with dietary guidelines. A number of these comments suggested that this could be done by prohibiting health claims on foods with insignificant amounts of all nutrients required on the label (e.g., coffee), as well as on candies, soft drinks, and other snack foods characterized as not being recognized as part of a sound dietary pattern. However, comments from the snack food industry protested such limitations on health claims and maintained that any food that provides a "high" (or "low") level of a nutrient without exceeding the disqualifying levels for fat, saturated fat, cholesterol, and sodium can be consumed within the framework of a healthy diet and should be allowed to bear health claims.

FDA is not persuaded that a prohibition from bearing a health claim based on a food's categorization or characteristic use—such as a snack food—is in keeping with the intent of the statute. The House Report (Ref. 1) contains an example intended to illustrate the Secretary option to decide whether to grant an exception from a disqualifying nutrient level in the context of the total daily diet. The example compares a frozen dinner with a snack food, both with a particular level of fat, and suggests that the frozen dinner may be considered sufficiently more significant in the total daily diet than the snack food. Implicit in this example, however, is a recognition by Congress that snack foods would be able to bear health claims if they did not contain a level of a nutrient that exceeds the disqualifying level. Thus, the agency concludes that Congress did not intend that snack foods or other foods that could be in general use in the diet should be subject to a per se prohibition on bearing a health claim.

However, as FDA explained earlier in this preamble in its response to comment 23 of this document, Congress intended that FDA establish provisions of health claims regulations by considering the role of the nutrients in food in a way that will enhance the chances of consumers constructing total daily diets that meet dietary guidelines. Thus, FDA finds merit in the suggestion that foods bearing health claims should be those consistent with dietary guidelines, and that the value of health claims should not be trivialized or compromised by their use on foods of little or no nutritional value. The agency, therefore, agrees that the final rule should be modified in some way to more fully assure consistency with dietary guidelines.

Dietary guidelines do stress the importance of selecting foods so that dietary sources of calories are coupled with sources of nutrients. FDA specifically notes that "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 7) states that foods that supply calories but are limited in nutrients should be used in moderation. Furthermore, the recommendations provided in "USDA's Food Guide Pyramid" (Ref. 29) expand on this approach to food selection. Given the requirement in section 403(r)(3)(B)(iii) of the act that states that a claim should enable the public to comprehend the information in a claim and understand the relative significance of that information in the context of a total daily diet, FDA concludes that it is appropriate to provide a basis for health claims that takes into account the nutritional contribution of the food beyond its role as a source of calories. Without such a criterion, foods that are not compatible with dietary guidelines could bear health claims. The claim would promote the consumption of the food but would fail to set the food in its proper dietary context. In addition to being inconsistent with section 403(r) of the act, claims intended to promote the consumption of a food that is incompatible with dietary guidelines would be misleading to consumers and, thereby, be in violation of section 403(a). Such claims would be misleading because consumers would be purchasing the food, in part, to achieve a more healthful diet. However, foods inconsistent with dietary guidelines should not be associated with the more healthful diets recommended by Federal agencies that are mentioned above.

Therefore, in addition to the requirements in new § 101.14(d)(vi) and (d)(vii) for content in a food of a substance that is the subject of a health claim, the agency has developed an approach that would limit health claims to foods that contribute certain nutrients to the diet and, thus, are sources of more than calories. This approach incorporates established levels of significance for nutrients in food and is based on the amounts in foods of certain nutrients required to be listed on the label as part of mandatory nutrition labeling. As such, this approach applies to all foods in conventional food form.

Dietary supplements not in conventional food form are not subject to this requirement. Such supplements are not intended to provide more than nutritive value to the daily diet and make no pretense that they should serve as substitutes for conventional food. As a result it would not be logical to hold such products to criteria designed to assure consistency with dietary guidelines for conventional food. A dietary supplement that meets the qualifying criterion in proposed § 101.14(d)(2)(vii) and does not contain a nutrient at a disqualifying level specified in proposed § 101.14(a)(5) possesses nutritive value for a health claim irrespective of whether or not it may also provide calories. (FDA is including the exception for dietary supplements in § 101.14(e) because under section 202(b) of the DS Act, the agency can approve claims for such products).

The final rule for mandatory nutrition labeling published elsewhere in this issue of the **Federal Register** requires the listing of 12 nutrients apart from calories as follows: Total fat, saturated fat, cholesterol, total carbohydrates, sugars, fiber, protein, sodium, vitamin A, vitamin C, calcium, and iron. As described in that document, FDA concluded that these nutrients are of sufficient public health importance to warrant their inclusion in the nutrition label. Therefore, these same nutrients provide an appropriate basis for a criterion intended to preclude health

claims on foods that do not make a nutritional contribution to the diet and thus are inconsistent with dietary guidelines. This conclusion is supported by comments that suggested that FDA should establish such a criterion based on the nutrients required in the mandatory listing on the food label.

Of the 12 mandatory nutrients, vitamin A, vitamin C, iron, calcium, protein, and fiber constitute nutrients for which the levels in foods can serve as a basis for determining a food's nutritional contribution to the overall diet. Total fat, saturated fat, sodium, and sugars are nutrients for which the current recommendations are to limit intake. Therefore, the presence of the latter nutrients in a food would not provide an appropriate basis for measuring the positive contribution of a food to the diet. While total carbohydrates reflects the contribution to the diet of complex carbohydrates, a nutrient for which current recommendations are to increase intake, it also reflects the contribution of sugars for which current recommendations are to limit intake. Therefore, total carbohydrates is not an appropriate component of a nutritional contribution criterion.

The final rule on nutrient content claims published elsewhere in this issue of the **Federal Register** states that a food is a good source of a nutrient when the nutrient is present in the food at a level of 10 percent or more of the label reference value. The agency concludes, therefore, that this defined level is an appropriate basis for a criterion to measure the nutritional contribution of a food. Therefore, assuming that a food meets the definitions prescribed in this final rule for bearing a health claim, the food must also contain one or more of the six nutrients listed above (vitamin A, vitamin C, iron, calcium, protein, or fiber) in an amount at or above 10 percent of the Reference Daily Intake (RDI) or DRV per reference amount customarily consumed for that nutrient. Based on a review of the regulatory food composition data base (Ref. 33), the agency notes that most foods consistent with dietary guidelines meet this criterion.

Furthermore, in order to preclude the fortification of foods solely for the purpose of making a claim, the nutrient or nutrients must not be derived from fortification or other additions to the food. Fortification of a food of little or no nutritional value for the sole purpose of qualifying that food for a health claim is misleading for several reasons. There is great potential to confuse consumers if foods like sugars, soft drinks, and sweet desserts are fortified to qualify for a health claim when, at the same time, dietary guidance as contained in USDA's Food Guide Pyramid (Ref. 29), for example, states that "[T]hese foods provide calories and little else nutritionally. Most people should use them sparingly." Indiscriminate fortification of such foods with one nutrient would not make such foods consistent with dietary guidelines. Further, fortifying such foods is not consistent with FDA's fortification policy in § 104.20 that has been in effect for many years. The fundamental objective of FDA's policy on appropriate fortification of foods is to establish a uniform set of principles that serve as a model for the rational addition of nutrients to foods. In that policy, FDA clearly states its concern that random fortification of foods could result in deceptive or misleading claims for foods. In the document concerning nutrient content claims that appears elsewhere in this issue of the **Federal Register**, FDA is including a provision requiring that added nutrients must be in compliance with § 104.20 for a food to be eligible to bear the term "more" on its label.

FDA stresses that the exclusion of fortification pertains only to fortification to specifically meet the requirements of this provision and not to fortification of the food itself. Thus, a fortified food, including a dietary supplement in conventional food form, may still qualify for a health claim, provided the qualification is not on the basis of that fortification. Accordingly, FDA has added a new § 101.14(e)(6) to require that, except for dietary supplements not in conventional food form, the food shall contain 10 percent or more of the RDI or DRV for vitamin A, vitamin C, iron, calcium, protein, or fiber prior to any nutrient addition.

VII. Exemption of Medical Foods and Exempt Infant Formulas

FDA proposed in § 101.14(f) that medical foods, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee(b)), and infant formulas subject to section 412(h) of the act are specifically exempted from requirements for health claims and nutrient content claims. This exemption reflects the exemption in section 403(r)(5)(A) of the act.

FDA received no comments on this aspect of the proposal. Therefore, the agency is adopting this section as proposed.

VIII. Applicability of Health Claims

FDA proposed in § 101.14(g) that the requirements for health claims in proposed § 101.14 only apply to foods intended for human consumption that are offered for sale.

FDA received no comments on this aspect of the proposal. Therefore, this section is being adopted by the agency as proposed.

IX. Petitions

A. Agency Review Period

88. One comment asserted that FDA should not establish any health claim petition provisions because citizen petition regulations in § 10.30 (21 CFR 10.30) are adequate to provide for petitions to FDA that request that the agency authorize a health claim.

FDA disagrees with this comment. Section 403(r)(4)(A)(i) of the act establishes unique statutory procedures for the handling of health claim petitions that are not applicable to the existing citizen petition regulation. The statute has specific timeframes for FDA to evaluate health claim petitions and, unlike the provisions of § 10.30, provides for not releasing the content of a petition if it is denied prior to acceptance for filing. If FDA were to accept health claims petitions in accordance with § 10.30, petitions that the agency denies after its initial 100-day review might be released. Further, FDA believes that a procedural regulation for health claims petitions is necessary so that petitioners will clearly understand what is required, that the agency's review will be conducted on a consistent and equitable basis, and that the grounds for agency action on the petition will be clearly understood.

89. Some comments objected that the timeframes in the petition provisions for FDA assessing the validity of the proposed claim and for issuing a proposed regulation are too rigid. One of these comments suggested that in cases where there is minimal or nonexistent controversy, FDA should streamline the petition approval process. The comment noted that while the statutory filing period gives the agency time to determine whether a proposed claim is valid, that filing period also serves to deprive the public of truthful claims until final approval is granted. The comment suggested that FDA adopt a mechanism to quickly determine whether there is a large consensus among scientists on the validity of a proposed claim and, if so, to shorten the timeframes. However, other comments suggested that longer timeframes are needed so that the agency can review the data and request additional information if needed, after which FDA should allow, modify, or reject the health claim application and notify the applicant.

FDA advises that the agency may not consider longer timeframes for the evaluation of petitions about health claims because the timeframes are specifically established in section 403(r)(4) of the act. These short timeframes do not provide an opportunity for continuing correspondence between the petitioner and FDA. With respect to suggestions for shorter timeframes, FDA advises that the agency's ability to meet timeframes is influenced by many factors such as work priorities and availability of personnel. FDA considers the statutory timeframes for assessing the validity of health claims and for issuing a proposed regulation to be extremely short, given the need to evaluate the totality of available scientific evidence on a substance and a disease. Given the agency's limited resources, it would not be practicable to shorten these timeframes further. However, FDA points out that although action on petitions for most claims will require virtually all of the time provided by the statutory timeframes, nothing would prohibit the agency from acting in less time than the timeframes provide if it is possible to do so. Thus, it is likely that a petition for a claim on a well-accepted substance/disease relationship would be reviewed more expeditiously than one for which scientific agreement is not as clear.

90. Some comments recommended that FDA allow new health claims to be used as soon as the proposal issues, instead of waiting until the final regulation becomes effective. One comment asserted that this approach would greatly benefit the public by quickly disseminating truthful health claim information, and that there would be little risk to consumers from consuming additional amounts of a food if the health claim is eventually denied.

The agency advises that there is no basis under the act to provide for the use of proposed health claims. Section 403(r)(1)(B) of the act deems a food misbranded when its label or labeling bears a health claim unless the claim is made in accordance with section 403(r)(3) or (r)(5)(D). Section 403(r)(3) and (r)(5)(D) of the act requires that the health claim be made in accordance with regulations. Proposed rules are not "regulations."

Further, even if FDA had a basis under the act to permit the use of proposed health claims, the agency does not believe that it would be prudent to provide for such use. The comment period following the publication of proposed rules is a critical step in determining whether a proposed regulation is appropriate for adoption. In the instance of health claim regulations, significant information concerning validity of the substance-disease relationship underlying the proposed health claim may be submitted by interested parties during the comment period. In addition, the comment period may bring to light a previously unforeseen potential for the health claim to be misleading to consumers if adopted without modification.

B. Public Disclosure

91. Some comments expressed concern regarding public release of private or proprietary data submitted as part of a health claim petition. Other comments agreed with the proposal as written in § 101.70(j)(2) on the grounds that allowing the public to scrutinize information submitted in a petition will help ensure that the evidence is scientifically sound and unbiased.

Section 403(r)(3)(B)(i) of the act mandates that the Secretary (and FDA, by delegation) determination as to whether to authorize a health claim be based on the totality of "publicly available evidence." Moreover, section 403(r)(4)(A)(i) of the act provides for not making a petition available to the public only when FDA decides to deny it without filing it. Consequently, FDA does not have authority to withhold this information from public scrutiny and will make all information submitted in support of a health claim publicly available when the petition is filed.

C. Preparation of Model Health Claim

92. One comment objected to the petitioner having to propose model health claims, asserting that the format and wording of model health claims should be the responsibility of FDA. The comment stated that the 1990 amendments did not require the petitioner to prepare model health claims. Another comment, however, endorsed the proposal that a petitioner include a model health claim, because it will promote efficiency by giving FDA a starting point and ensure that the petitioner is planning to use the claim to promote the public's health.

FDA agrees with the latter comment. Because the petitioner should be one of the parties most knowledgeable about the relevant substance-disease relationship, the agency does not believe that requiring the inclusion of a model health claim will constitute a significant burden on the petitioner. Such a requirement will, however, provide significant benefit by ensuring that the agency can easily and correctly identify what the petitioner believes to be the full substance-disease relationship within the short review timeframes.

D. Summary of Scientific Data

93. Some comments argued that unpublished research findings, including proprietary data, should be considered in support of proposed health claims. However, a number of comments disagreed asserting that only data suitable for publication and data already accepted for presentation in a scientific community would be suitable for the substantiation of health claims.

FDA will consider all unpublished findings that are submitted in support of proposed health claims. Although the agency will consider such findings, FDA points out that, as suggested in the legislative history (Ref. 1), the agency may give greater weight to a research report published in a peer-reviewed journal because such reports have been subjected to scientific evaluation before publication. The agency is likely to give greatest weight, however, to research reports of well-conducted, relevant studies regardless of publication status.

E. Denial of Petitions

94. A number of comments stated that if the agency is to deny a petition without filing it, FDA should do so based on a review of the petition as a whole. One comment said that even if the "Preliminary Requirements" section of the petition is inadequate FDA should still examine the "Summary of Scientific Data." The comment stated that if the agency did so, and discussed that review in the denial notice, it would provide the petitioner with some indication as to whether a redrafted petition would be justified. The comment contended that such a procedure would be more efficient in the longrun and presumably would save FDA from having to review repeatedly submitted petitions.

FDA does not believe that it would be prudent to adopt a general policy of conducting exhaustive reviews of petitions that are to be denied because they fail to meet preliminary requirements. The denial of a petition on the grounds that the preliminary requirements are not met would reflect a fundamental problem with the petition. Such problems may take a fair amount of time to remedy. Therefore, to ensure that it uses its resources most effectively and efficiently, FDA will not undertake an evaluation of the scientific validity of a claim unless the preliminary requirements are satisfied.

95. Several comments dealt with the language of the regulation disapproving the health claim. They particularly disapproved of the language "FDA has

concluded that there is no basis for claims about the following * * *." The comments suggested alternate wordings for proposed § 101.71 that would recognize that "although there is considerable interest in these areas, and although new evidence is continually emerging, the data are not yet strong enough to permit approval of health claims for the reasons summarized below." The comments stated that this language should be followed by an enumeration of the disapproved claims together with a short paragraph describing both the strength and the perceived shortcomings of the evidence in each case. This approach would, according to comments, establish an appropriate record of FDA's determination, without unnecessarily damaging any of these active areas of scientific research.

FDA agrees with the comments that there should be some codified record of its consideration of the health claims on which it proposed action, either in response to the 1990 amendments or a petition, but ultimately decided not to authorize. That record is provided by the citation to the final rule denying the health claim that is included in the listing in new § 101.71. The discussion in the preamble to the final rule summarizes the agency's consideration of the claim. Thus, the agency does not believe that paragraphs describing the strengths and shortcomings of the evidence regarding specific health claims are needed in the codified language to "establish an appropriate record of FDA's determinations."

The agency disagrees that a negative decision regarding a particular health claim will be damaging to active areas of scientific research. It is obvious that the extensive literature regarding the complex relationships between substances and diseases and health-related conditions developed without consideration of whether specific health claims on particular foods might be allowed at some time in the future. FDA's denial is just as likely to highlight the matters on which further research is needed as it is to damage the prospects for further research. However, for greater clarity, the agency has revised the statement in new § 101.71 that there is "no basis for claims" to state that there is "not a sufficient basis for claims * * *."

F. Other Petition Issues

96. Another comment urged that FDA not redelegate to the Director and Deputy Director of CFSAN all the functions of the Commissioner concerning petitions for label claims under section 403(r) of the act that do not involve controversial issues. The comment stated that all petitions that will be submitted to the agency concerning health claims will involve controversial issues that will require a response from the Commissioner.

FDA does not agree. Based on the agency's experience with petitions that have been submitted to FDA for consideration, it is not uncommon for a petition to contain major deficiencies that necessitate denial of the petition. The agency believes that redelegating such functions to the Director and Deputy Director of CFSAN will permit the agency to take the required actions (e.g., denial of a petition) in the most resource efficient manner.

Further, the agency does not agree that it should assume that all petitions submitted under section 403(r) of the act will involve controversial issues. The agency should have the prerogative to take action on a petition in the most resource efficient manner. For example, in the future, it is certainly possible that some substance-disease relationships will become established, and that there will be no controversy about the scientific basis for a claim. If such a situation occurs, the agency should have the flexibility to authorize information about such relationships in food labeling in an efficient manner. Therefore, the agency is retaining the redelegation provision in the final rule.

X. Constitutional Issues

A. The First Amendment

97. Several comments from industry and nonprofit organizations asserted that truthful information about health and diet consists of speech protected under the First Amendment, and at the very least is protected commercial speech. According to the comments, such truthful information encompassed a wide variety of labeling information ranging from information that FDA classifies as a "health claim" to general information about what food categories should be included in a diet to affect disease that FDA classifies as "dietary guidance." (As explained previously in this preamble, for the sake of clarity in this preamble, references by FDA to "dietary guidance" will refer to claims that do not contain both basic elements of a health claim and are therefore not "health claims.") Comments stated that the commercial speech doctrine recognizes that such speech not only serves the economic interests of the speaker but assists consumers and furthers society's interest in "the fullest possible dissemination of information." Therefore, while such speech is entitled to less protection than other forms of expression, that protection is nonetheless substantial. Several comments cited case law that stated that if the commercial expression at issue is neither false nor misleading, then any regulation restricting it must directly advance the governmental interest asserted and must be no more extensive than necessary to serve that interest. Comments contended that any suggestion that consumers should be screened from truthful information "in their own best interest" is the type of paternalism rejected by the Supreme Court in *Virginia State Bd. of Pharmacy* v. *Virginia Citizens Consumer Council Inc.*, 425 U.S. 748 (1976), and the concept that the public cannot be trusted to make valid judgments based on truthful information contravenes the basic principles of the First Amendment. Comments asserted that the public interest and, indeed, the public right is in obtaining useful information, and the government's interest is best served by placing no barriers to its free circulation. Another comment specifically requested that FDA clarify how the health claims regulations comply with Supreme Court standards for constitutionally protected civil or commercial speech.

However, other comments stated that the health claim regulations do not violate manufacturers' First Amendment rights, because food labels that are not in compliance with the act are inherently misleading and therefore not entitled to constitutional protection. The comments argued further that, even if a court found that a nonconforming health claim was not misleading, it would uphold these regulations because they are tailored specifically to meet the substantial Government interest of protecting the public.

FDA advises that neither these regulations, nor the act as amended by the 1990 amendments, violate the First Amendment. The act has withstood numerous First Amendment challenges. (See, for example, *United States* v. *General Nutrition, Inc.*, 638 F. Supp. 556, 562 (W.D.N.Y. 1986); *American Frozen Food Institute* v. *Mathews*, 413 F. Supp. 548 (D.D.C. 1976), aff'd, 555 F.2d 1059 (D.C. Cir. 1977); *United States* v. *Articles of Food * * * Clover Club Potato Chips*, 67 F.R.D. 419 (D. Idaho 1975); *United States* v. *8 Cartons, Containing Plantation The Original etc. Molasses*, 103 F. Supp. 626 (W.D.N.Y. 1951).) The 1990 amendments amended the act to permit certain information about the relationship of nutrients in food and disease to appear on a food label without misbranding the food under section 403 of the act or transforming it into a drug under section

201(g)(1)(B) of the act. The regulations implementing these amendments thus permit more information on food labels than has previously been allowed under the act.

Nonetheless, parts of the act and these regulations may have an incidental effect on speech in a narrowly defined area, food labeling. (See *NAACP* v. *Claiborne Hardware Co.*, 458 U.S. 886, 912 (1982).) The Supreme Court, however, "has recognized the strong governmental interest in certain forms of economic regulation, even though such regulation may have an incidental effect on rights of speech and association." Id. The Government may regulate in areas of economic activity such as securities, antitrust, and labor in ways that affect speech. *SEC* v. *Wall Street Publishing Institute*, 851 F.2d 365, 372–73 (D.C. Cir. 1988), cert. denied, 489 U.S. 1066 (1989); see also *SEC* v. *Suter*, 732 F.2d 1294, 1299 (7th Cir. 1984) (the First Amendment does not remove a business engaged in the communication of information from general laws regulating business practices). The Government "does not lose its power to regulate commercial activity deemed harmful to the public whenever speech is a component of the activity." *Ohralik* v. *Ohio State Bar Association*, 436 U.S. 447, 456 (1978); see also *Home Box Office, Inc.* v. *FCC*, 567 F.2d 9, 46 (D.C. Cir. 1977), cert. denied, 434 U.S. 829 (1977) ("[R]ules restricting speech do not necessarily abridge freedom of speech.")

As with securities, labor, and antitrust regulation, the Government exerts extensive regulatory authority over the economic activity surrounding food and its labeling. Yet the regulation of food and food labeling clearly encompasses more than mere economic activity: It protects consumer health and safety in an area where harm to the public can be direct and immediate. (See *Ohralik*, 436 U.S. at 456.) FDA's crucial role in ensuring that food labels are informative, are not misleading, and do not otherwise misbrand products under the act has long been recognized. (See 79 Congressional Record 4734 (1935), reprinted in "Dunn, Federal Food, Drug, and Cosmetic Act," 280 (1938) (statement of Sen. Copeland) ("No one disputes that the [FDA] should determine the quality of the product; no one disputes that it should determine what is on the label.")) In such an area of extensive Federal regulation, the Government may place restrictions on speech that bears directly on the Government's objectives. *SEC* v. *Wall Street Publishing Institute*, 851 F.2d at 373. Indeed, regulation of food labeling would be impossible if the Government could not restrict speech. Id.

Thus, when FDA seeks to ensure that food is not misbranded, it may place restrictions on label contents. "Freedom of Speech does not include the freedom to violate the labeling provisions of the Federal Food, Drug, and Cosmetic Act." *United States* v. *Articles of Food * * * Clover Club Potato Chips*, 67 F.R.D. 419, 424 (D. Idaho 1975). "[C]ertain speech in a certain limited context" becomes part of the labeling of a product and may serve as evidence of a violation of the act. *United States* v. *General Nutrition, Inc.*, 638 F. Supp. 556, 562 (W.D.N.Y. 1986). Thus, the seizure and condemnation of a book that misbrands a product is not a violation of the First Amendment, even though in another context the book might be protected. (See *United States* v. *8 Cartons, Containing Plantation The Original etc. Molasses*, 103 F. Supp. 626, 628 (W.D.N.Y. 1951); *United States* v. *Article of Drug*, 32 F.R.D. 32 (S.D. Ill. 1963).) "It is the product and the manner in which the product is marketed which is said to be illegal," rather than the speech itself. *General Nutrition*, 638 F. Supp. at 562. A prohibition on selling a misbranded product restrains the violative act of selling, not speech itself. *Kellogg Co.* v. *Mattox*, 763 F. Supp. 1369, 1381 (N.D. Tex. 1991) (construing Texas food and drug law). "The substantial government interest in the goals of the Act justif[ies] this extremely narrow encroachment" on speech. *General Nutrition*, 638 F. Supp. at 562. Indeed, where certain claims misbrand a product, "[a] requirement that the claims be removed, in order to sell the product, is certainly less restrictive than a flat prohibition of the sale of the product." *Kellogg*, 763 F. Supp. at 1381.

With the provisions of the 1990 amendments that govern health claims, Congress sought to "permit health claims but only health claims based on scientifically valid information." (statement of Rep. Waxman; Ref. 4). In order to assist consumers improving their eating habits, Congress devised a scheme to permit certain claims not previously allowed under the act. Under this scheme, only those claims that FDA finds to be "supported by science" are permitted, (statement of Rep. Waxman; Ref. 3), and a food that bears an unapproved health claim is misbranded. Because FDA case law makes clear that a label statement that misbrands a food product is not subject to First Amendment protection, an unapproved health claim on a food label would not be protected speech. (See *United States* v. *General Nutrition, Inc.*, 638 F. Supp. 556 (W.D.N.Y. 1986); *United States* v. *Articles of Food * * * Clover Club Potato Chips*, 67 F.R.D. 419 (D. Idaho 1975); *United States* v. *8 Cartons, Containing Plantation The Original etc. Molasses*, 103 F. Supp. 626 (W.D.N.Y. 1951); *United States* v. *Article of Drug*, 32 F.R.D. 32 (S.D. Ill. 1963).)

Congress considered the use of "unfounded" health claims on the food label to be harmful to the public (statement of Rep. Waxman; Ref. 3); cf. *Ohralik*, 436 U.S. at 456 ("[T]he State does not lose its power to regulate commercial activity deemed harmful to the public whenever speech is a component of that activity.") Congress dealt with this problem by crafting a system to permit certain useful information to appear on the food label, while ensuring that the information is scientifically valid and not misleading (statement of Rep. Waxman; Ref. 4). Congress considered these restrictions on speech necessary to further the Government's interest in ensuring the scientific validity of health claims on the food label. The Government's action in regulating the food label does not offend the First Amendment simply because speech is involved. *Ohralik*, 436 U.S. at 456. The case law establishes that FDA's power to regulate the food label derives from its broad regulatory powers over food, and these regulations are valid under the limited scrutiny that has been afforded restrictions on speech under extensive regulatory schemes involving areas of economic activity. (See *SEC* v. *Wall Street Publishing Institute*, 851 F.2d at 372–73; see also *Dun & Bradstreet, Inc.* v. *Greenmoss Builders*, 472 U.S. 749, 785 n.5 (1985); *Ohralik* v. *Ohio State Bar Association*, 436 U.S. 447, 456 (1978).)

Many comments argued that labeling is commercial speech, and that restrictions placed on it must pass the tests enunciated by the Supreme Court in cases involving commercial speech. Unlike "advertising pure and simple," labeling does not fall clearly within the bounds of commercial speech. *Zauderer* v. *Office of Disciplinary Counsel*, 471 U.S. 626, 637 (1985). The agency does not consider it necessary for its First Amendment analysis to determine whether or not food labeling fits the definition of commercial speech. (See *SEC* v. *Wall Street Publishing Institute*, 851 F.2d at 372.) Rather, the agency considers labeling on foods to form "a distinct category of communications in which the government's power to regulate is at least as broad as with respect to the general rubric of commercial speech." *SEC* v. *Wall Street Publishing Institute*, 851 F.2d at 373.

Recognizing, however, that at least one court has categorized labeling as commercial speech, *General Nutrition*, 638 F. Supp. at 562, FDA agrees that labeling should certainly be considered closer to commercial speech than to "pure" speech.

Even if labeling is analyzed as commercial speech, however, these regulations do not violate the First Amendment. First, speech that is inherently misleading is not protected and may be prohibited. *Central Hudson Gas & Electric Corp.* v. *Public Service Commission*, 447 U.S. 557, 563–64 (1980). Secondly, speech that is only potentially misleading may be restricted, so long as the restrictions directly advance a substantial governmental interest and are no more extensive than necessary to serve that interest. Id. at 566. These regulations govern speech that is inherently misleading, health claims on the food label. However, even if such claims are considered to be only potentially misleading, the regulations pass the test enunciated in *Central Hudson*.

Commercial speech receives only limited protection under the First Amendment. (See, for example, *Bolger* v. *Youngs Drug Products Corp.*, 463 U.S. 60, 64–65 (1983).) For commercial speech to be protected, it must concern lawful activity and not be misleading. *Central Hudson*, 447 U.S. at 563 through 564. The Supreme Court has recognized that restrictions on commercial speech may be appropriate to prevent deception. *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council*, 425 U.S. at 771 n.24. These regulations will have the effect of ensuring that the health claims that appear in food labeling are scientifically valid and not misleading. (See *American Frozen Food Institute* v. *Mathews*, 413 F. Supp. 548, 555 (D.D.C. 1976), aff'd, 555 F.2d 1059 (D.C. Cir. 1977)) (FDA regulation constituted the agency's conclusion "that labeling which fails to meet the requirements of the regulation is misleading or otherwise not in compliance with the act," and as such it did not violate the First Amendment).

The Supreme Court has labeled as misleading—and thus not protected—both speech that is inherently likely to deceive and that "experience has proved * * * is subject to abuse." In re *R.M.J.*, 455 U.S. 191, 203 (1982). For example, in *Friedman* v. *Rogers*, 440 U.S. 1, 14–15 (1979), the Court held that Texas could prohibit the use of trade names by optometrists where there was a history of deception and abuse of the public. See also *Ohralik* v. *Ohio State Bar Association*, 436 U.S. 447, 468 (1978) (upholding state bar's rules against in-person solicitation where there was an inherent potential for abuse and prophylactic regulation was needed).

By enacting the 1990 amendments, Congress sought to ensure that health claims would be scientifically valid and not misleading. (See, for example, statement of Rep. Madigan, and statement of Rep. Waxman, Ref. 4). Experience had shown that many "unfounded" health claims were being used on foods (statement of Rep. Waxman; Ref. 3). Congress recognized the "great potential for defrauding consumers if food is sold that contains inaccurate or unsupportable health claims." Id. (statement of House floor managers).

In response to the high potential for health claims to be misleading, Congress legislated that any claim that is not consistent with FDA regulations will misbrand a food. Section 403(r)(1)(B) of the act states that a food is misbranded if its label or labeling contains a claim that "expressly or by implication * * * characterizes the relationship of any nutrient * * * of the food to a disease or a health-related condition *unless* the claim complies with regulations promulgated by FDA. § 403(r)(1)(B)" (emphasis added). By taking this approach, Congress chose to permit only those health claims on food that FDA determines to be scientifically valid, effectively recognizing that health claims are so potentially misleading as to be inherently misleading.

Indeed, particular attributes of health claims on the food label make them inherently misleading. Because health claims are of great importance to the public, they have a great potential to be deceptive: Representations relating a product to an issue of public concern as a means to induce consumer purchases may take on increased importance in the mind of the public and thus be more likely to mislead. *FTC* v. *Pharmtech Research, Inc.*, 576 F. Supp. 294, 301 (D.D.C. 1983) (advertisements for food supplement were misleading where they "played on the average consumer's well-founded fear of cancer"). A health claim on a food label is the type of information that a consumer would have difficulty verifying independently. *American Home Products* v. *FTC*, 695 F.2d 681, 698 (3d Cir. 1982); cf. *Peel* v. *Attorney Reg. & Disciplinary Commission*, 496 U.S. 91, 110 S. Ct. 2281, 2288 (1990) (a lawyer's certification is a "verifiable fact"). Consumers place great reliance on the portions of the food label that they believe to be regulated by the Government (Ref. 36). Unapproved health claims that consumers assume to be consistent with government regulations are therefore more likely to be misleading. "Pervasive government regulation * * * and consumer expectations about such regulation, create a climate in which questionable claims * * * have all the more power to mislead." *American Home Products* v. *FTC*, 695 F.2d at 697.

Even if health claims are considered only potentially misleading, rather than actually or inherently misleading, these regulations are constitutional. The government may place restrictions on commercial speech that is merely potentially misleading. Such restrictions must directly advance a substantial governmental interest and be no more extensive than necessary to serve that interest. *Central Hudson Gas & Electric Corp.* v. *Public Service Commission*, 447 U.S. 557, 566 (1980). These regulations pass that test.

First, the government's interest is clearly substantial. The 1990 amendments and these regulations seek to ensure that consumers have access to information about food that is scientifically valid, truthful, reliable, understandable, and not misleading. This information will enable consumers to make more healthful food choices. The Supreme Court has recognized "the health, safety, and welfare of * * * citizens" as a substantial government interest. *Posadas de Puerto Rico Associates* v. *Tourism Co.*, 478 U.S. 328, 341 (1986). Moreover, consumers have a First Amendment interest in obtaining information on which to base a decision whether to buy a product, and this interest is "served by insuring that the information is not false or deceptive." *National Commission on Egg Nutrition* v. *FTC*, 570 F.2d 157, 162 (7th Cir. 1977), cert. denied, 439 U.S. 821 (1978). "The fact that health is involved enhances the interests of both consumers and the public in being assured 'that the stream of commercial information flow clearly as well as freely.'" Id. (citing *Virginia State Board of Pharmacy*, 425 U.S. at 772); *American Home Products*, 695 F.2d 681, 714. Moreover, FDA is implementing legislation whose purpose is "essential if the consumer is to obtain reasonable information regarding * * * the foods he buys." *American Frozen Food Institute* v. *Mathews*, 413 F. Supp. 548 (D.D.C. 1976), aff'd, 555 F.2d 1059 (D.C. Cir. 1977).

Secondly, the regulations directly advance the government interest. Under the 1990 amendments and these regulations, FDA will assess the relevant scientific evidence on a proposed health claim before permitting that claim to

appear on the food label. In this way, the regulations ensure that health claims are scientifically valid, reliable, understandable, and do not mislead consumers. At the same time, the regulatory scheme encourages the provision of information to consumers that will enable them to improve their diets. There is an "immediate connection" between health claims on food labels and consumers' food choices. *Central Hudson*, 447 U.S. at 569.

Finally, these regulations are no more extensive than necessary to serve the government interest. Under *Board of Trustees* v. *Fox*, regulations that are narrowly tailored to serve the government interest will meet this prong of the *Central Hudson* test. 109 S. Ct. 3028, 3032–35 (1989). Narrow tailoring requires a reasonable fit between regulatory ends and means: "not necessarily the single best disposition but one whose scope is 'in proportion to the interest served.'" Id. at 3035. These regulations reasonably and effectively ensure that health claims on food labels will be scientifically valid, informative, and not misleading. (See *Ward* v. *Rock Against Racism*, 109 S. Ct. 2746, 2757–58 (1989).) Thus they meet the third prong of the *Central Hudson* test, and they do not violate the First Amendment.

98. Some comments maintained that dietary guidance may, in appropriate circumstances, be classified as pure speech entitled to constitutional protection, and that merely because speech is presented in a commercial context does not necessarily categorize it as "commercial speech." Thus, for example, "speech is not rendered commercial by the mere fact that it relates to an advertisement." *Pittsburgh Press Co.* v. *Pittsburgh Comm'n on Human Relations*, 413 U.S. 376, 384 (1973). Speech is also "not commercial merely because it proposes a transaction or because there is an economic motivation." *Asian American Business Group* v. *City of Pomona*, 716 F. Supp. 1328, 1330 (C.D.Cal. 1989) (citing *Bolger* v. *Youngs Drug Prods. Corp.*, 463 U.S. 60 (1983)). The consensus of the comments was to conclude that where a manufacturer, either on a label or in package inserts or accompanying brochures, accurately summarizes dietary guidance promulgated by some public health body or medical institution, that message should be treated as noncommercial speech deserving full protection under the First Amendment, and that the such messages are not solely the product of economic motivation.

FDA believes that its approach to dietary guidance, as discussed above, does not raise First Amendment concerns. Dietary guidance on labeling will be considered to fall outside the coverage of section 403(r)(1)(B) of the act, although it would remain subject to other provisions of the act (e.g., sections 403(a) and 201(n) of the act).

FDA disagrees with the comments that argue that certain dietary guidance—e.g., label summaries of information promulgated by a public health body—should be considered pure, noncommercial speech. To the extent that it may be necessary to categorize these statements, FDA believes they should be considered commercial speech. Labeling statements on food products intended for sale would clearly appear in the context of a commercial transaction and would "propose" such a transaction. (See *Bolger* v. *Youngs Drug Products*, 463 U.S. 60, 66, 103 S. Ct. 2875, 2880 (1983); *Central Hudson Gas* v. *Public Service Commission*, 447 U.S. 557, 562 n.5, 100 S. Ct. 2343, 2349 n.5 (1980).) A label is not entitled to the protection due noncommercial speech simply because it contains a discussion of an issue of broad public interest. *Board of Trustees* v. *Fox*, 109 S. Ct. 3028, 3032 (1989); *Bolger*, 463 U.S. at 68, 103 S. Ct. at 2881; *Central Hudson*, 447 U.S. at 562 n.5, 100 S. Ct. at 2349 n.5. Nor is dietary guidance that discusses a product generically, rather than by specific name, exempt from categorization as commercial speech. *Bolger*, 463 U.S. at 66 n.13, 103 S. Ct. at 2880 n.13. And in determining whether the statements on a label are pure speech, it is irrelevant that they might be considered protected in other contexts. (See *Zauderer* v. *Office of Disciplinary Counsel*, 471 U.S. 626, 637 n.7, 105 S. Ct. 2265, 2274 n.7 (1985).) Just as informational pamphlets were considered commercial speech in *Bolger*, so too dietary guidance on food labels should be considered commercial speech. (See *Bolger*, 463 U.S. at 66–68, 103 S. Ct. at 2880–81.)

99. Some comments suggested that the proposed regulations were in conflict with the First Amendment because it protects manufacturers from burdensome and unnecessary labeling requirements.

FDA disagrees with the comments' assertion that the agency is imposing unduly burdensome and unnecessary labeling requirements. Nothing in the regulations goes beyond the statutory requirements imposed by the 1990 amendments. In formulating these regulations, the agency has attempted to reach a reasonable balance between the interest in making information available about the relationship between diet and disease and the interest in ensuring that this information is scientifically valid. The regulations are narrowly tailored to serve a significant governmental interest and do not violate the First Amendment.

100. A number of comments recommended that foods exceeding a disqualifying nutrient level be allowed to bear an approved health claim if they also bear a statement disclosing the level of the disqualifying nutrient. Comments contended that the legislative history of the 1990 amendments clearly establishes Congress' intent to require increased information and disclosure on food labels, and that section 403(r)(3)(A)(ii) of the act is consistent with this approach. Some comments argued that this procedure is consistent with the public's "right to know" and the manufacturers' First Amendment rights to present consumers with information that is truthful and not misleading. Most maintained that the First Amendment principles discussed under the Preliminary Health Claims and Dietary Guidance sections also prohibit FDA from using disqualifying levels to ban health claims on products.

FDA agrees that section 403(r)(3)(A)(ii) of the act gives it the ability to permit approved health claims on foods exceeding a disqualifying nutrient level if they bear a statement disclosing the level of the disqualifying nutrient. The agency "may by regulation permit * * * a claim based on a finding that such a claim would assist consumers in maintaining healthy dietary practices" (section 403(r)(3)(A)(ii) of the act).

FDA disagrees, however, with the implication expressed by the comments that it should permit approved health claims for all foods exceeding a disqualifying nutrient level if their labels disclose the level of the disqualifying nutrient. The agency will permit such claims on a case-by-case basis, when it finds that a claim would assist consumers in maintaining healthy dietary practices. Reading the statute to mandate disclosure rather than disqualification would ignore the terms of the statute and would be inconsistent with Congress's intent. When the bill that became the 1990 amendments was reported out of committee in the House, the prohibition in section 403(r)(3)(A)(ii) of the act on health claims was on food containing "any nutrient in an amount which increases to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food

in the total daily diet." H. Rept. 538, 101st Cong., 2d sess. 5 (1990). Subsequently, while the bill was awaiting passage in the House, language was added to section 403(r)(3)(A)(ii) of the act permitting the agency to exempt certain foods from the prohibition (statement of Rep. Waxman; Ref. 4). Had Congress chosen to require disclosure rather than disqualification in all cases, it could have done so explicitly rather than providing for exceptions to the general rule.

In its proposal, the agency noted that "a health claim on a food label is a promise to consumers that including the food in a diet, along with other dietary modifications, will be helpful in attaining the claimed benefit and will not introduce a risk of another disease or health-related condition" (56 FR 60537 at 60544). Including a health claim on the label of a food that contains unhealthful levels of nutrients would be misleading, and the First Amendment permits the government to ban misleading speech. *Central Hudson Gas & Electric Corp.* v. *Public Service Commission*, 447 U.S. 557, 566 (1980). FDA recognizes that the Supreme Court has expressed a preference for disclaimers or explanations over prohibitions in the context of commercial speech that is merely potentially misleading. In re *R.M.J.*, 455 U.S. 191, 203 (1982). Nothing in these regulations is inconsistent with that approach. Section 403(r)(3)(A)(ii) of the act specifically permits the agency to allow disclosure instead of disqualification where a claim "would assist consumers in maintaining healthy dietary practices." In situations where the government's substantial interest in improving dietary practices would be promoted by permitting disclosure rather than disqualification, and where disclosure would ensure that the health claim was not misleading, FDA will permit disclosure instead of disqualification.

101. Several comments asserted that the First Amendment allows manufacturers to place preliminary health-related statements on labeling as long as those statements are properly qualified. In support of this position, comments cited a series of opinions in *FTC* v. *National Comm'n on Egg Nutrition*, 517 F.2d 485 (7th Cir. 1975), appeal after remand, 570 F.2d 157 (7th Cir. 1977), cert. denied, 483 U.S. 921 (1978). The comments noted that in affirming the grant of a preliminary injunction, the Seventh Circuit held that the Commission could not "prohibit NCEN from stating that there is scientific evidence supporting the theory that dietary cholesterol intake is not unhealthy, provided that it also states that there is substantial contrary evidence." 517 F.2d at 489–490. The comments also noted that the Seventh Circuit struck down an anti-egg warning statement that FTC had asked be mandated in all future advertising, saying that "the First Amendment does not permit a remedy broader than that which is necessary to prevent deception * * * or correct the effects of past deception * * *." The desired preventative effect can be achieved by requiring the disclosure that there is a controversy among the experts and NCEN is presenting its side of that controversy. The additional statement in the form now ordered by FTC should be required only when NCEN chooses to make a representation as to the state of the available evidence or information concerning the controversy." (570 F.2d at 164)

The comments also cited Court of Appeal decisions that followed the Seventh Circuit in requiring a manufacturer to qualify controversial or preliminary claims with statements that a substantial question exists regarding their scientific validity. Bristol-Myers Co., 102 F.T.C. 21, 294–295 (1983), enforced, 783 F.2d 554 (2d. Cir. 1894), cert. denied, 469 U.S. 1189 (1985); American Home Prods. Corp., 98 F.T.C. 136, 333 (1981), enforced as modified, 695 F.2d 681 (3d. Cir. 1982). The comments asserted that FDA policy must therefore allow the inclusion of properly disclosed health claims that are based on preliminary or controversial findings, as long as the studies that led to those findings are sufficiently well-designed and well-conducted to garner "significant scientific agreement" about how the findings should be interpreted.

FDA does not agree that there is a First Amendment right to make preliminary claims on the food label, regardless of the statutory constraints imposed by the 1990 amendments. As discussed in greater detail above, FDA does not have the authority to permit preliminary health claims under section 403(r)(1)(B) of the act. The statutory scheme and these regulations that produce this result do not violate the First Amendment.

As explained above, misleading commercial speech is not protected under the First Amendment. *Central Hudson Gas & Electric Corp.* v. *Public Service Commission*, 447 U.S. 557, 566 (1980). Health claims have such a high potential to be misleading as to be inherently misleading, as Congress recognized when it chose to permit only those health claims on food that FDA determines to be scientifically valid (section 403(r)(1)(B) of the act). In the context of inherently misleading claims, there is no requirement that explanatory information be permitted to eliminate consumers' misconceptions. (See In re *R.M.J.*, 455 U.S. 191, 203 (1982).)

FDA does not agree that it is bound to follow cases involving FTC's regulation of advertising and to permit labeling that presents one side of a scientific controversy, so long as there is a statement that a controversy exists. Although cases involving FTC may sometimes be relevant, it is important to note that fundamental differences exist between the regulatory schemes administered by the two agencies. (See *Bristol-Myers Co.* v. *FTC*, 738 F.2d 554, 559 (2d Cir. 1984), cert. denied, 469 U.S. 1189 (1985).) Congress has long recognized the division of roles between the two agencies. (See 79 Congressional Record 4734 (1935), reprinted in "Dunn, Federal Food, Drug, and Cosmetic Act," 280–281 (1938) (statements of Senators Copeland and Austin) (FTC concentrates on the interests of commerce and economic needs, whereas the objective of FDA is "the health of the people.")) FTC regulates unfair competition and trade practices, including food advertising. (See, for example, 15 U.S.C. sections 45 and 52.) In contrast, FDA is a scientific agency empowered to regulate the food label, among other things. Under section 403(r)(3)(B)(i) of the act, FDA may permit health claims on foods only if it has determined that those claims meet the statutory test for scientific validity. The laws under which FTC operates do not include a comparable statutory standard. Thus, it would not be appropriate for FDA to follow the case law involving FTC.

B. Other Amendments

102. Some comments alleged that outlawing brand names that include an unapproved health claim could violate the Fifth Amendment, as brand names reasonably constitute cognizable private party interests, and banning their use could amount to "taking" those interests without just compensation. Comments warned that the courts have frowned upon banning the use of trade names when less drastic measures would eliminate the possibility of deception. (See In re *R.M.J.*, supra.) (Also, see *Jacob Seigel Co.* v. *FTC*, 327 U.S. 608, 612 (1946) (the policy of the law to protect [brand names] indicates that their destruction should not be ordered if less drastic means will accomplish the same result'").) The comments further suggested that, in keeping with Executive Order 12630 (March 15, 1988), "Governmental Actions and

Interference with Constitutionally Protected Property Rights," FDA should complete a Takings Impact Analysis (TIA) in order to assess whether compensation to the brand name owners would be appropriate, and whether there were viable alternatives to banning the use of the brand names.

In the November 1991 Regulatory Impact Analysis (RIA) (56 FR 60856 at 60865), FDA considered the takings issue and concluded that a TIA was not necessary because the proposed regulations "serve to reemphasize existing regulations as to how products may be named." In view of the comments and concerns raised involving the takings issue, the agency has concluded that it was necessary to conduct the more formalized TIA as set forth in Executive Order 12630. The agency has completed the TIA and concludes that the regulations as set forth below do not present a potential takings. Under the provisions of the Executive Order, the TIA is an internal government decision making document to assist the responsible agency in reducing the likelihood that a "takings" will occur and to provide the decision maker for the agency with information as to any likely cost due to compensable takings. As such, the TIA is not released for public review.

In its November 1991 RIA statement (56 FR 60856 at 60865), FDA stated that the required alteration of trade names did not constitute a taking, and that, as a result, no takings analysis was necessary. FDA still believes that there is no regulatory taking under the Fifth Amendment if a manufacturer is required to alter its brand name when that brand name asserts by implication a relationship between the presence or level of a substance in the food and a disease or health-related condition, and that relationship is not the subject of an approved health claim. These final regulations on health claims constitute a reasonable exercise of the agency's authority to promote policies in the interest of public health. (See *Keystone Bituminous Coal Association* v. *DeBenedictis*, 480 U.S. 470, 488 (1987).) The 1990 amendments made explicit FDA's authority to permit certain health claims if it determines, based on the totality of publicly available scientific evidence, that the claims are scientifically valid. H. Rept. 538, 101st Cong., 2d sess. 9 (1990). The food industry "has long been the focus of great public concern and significant government regulation," and "the possibility was substantial" that the government would, "upon focusing on the issue," decide that the actions now being undertaken are in the public interest. *Ruckelshaus* v. *Monsanto Co.*, 467 U.S. 986, 1009 (1984); see also *Connolly* v. *Pension Benefit Guarantee Corp.*, 475 U.S. 211, 227 (1986) ("Those who do business in the regulated field cannot object if the legislative scheme is buttressed by subsequent amendments to achieve the legislative end.")

Companies that use brand names that contain implied health claims lack a reasonable investment-backed expectation that they will be able to continue to use those names. *Monsanto*, 467 U.S. at 1005. Under the act before the 1990 amendments, and under prior FDA policy, products whose labeling included implied health claims were subject to regulation as drugs without regard to the content of the claim. In 1987, FDA proposed to permit certain health claims on food, but this proposal was never made final and thus cannot be considered to provide the basis for reasonable expectations that specific claims would be allowed. The 1990 amendments for the first time provided companies with the basis for an expectation that certain implied claims, if approved, could be made. Only with the publication of these final rules does the possibility arise that a company might have a reasonable investment-backed expectation in continuing to use an approved claim.

103. One comment noted the possibility that the scientific standard for health claims has the potential to be unconstitutional, either facially or as applied, under the First (manner of application is overbroad and limits constitutionally protected free speech), the Fifth (the vagueness of the standard is such that due process will be violated when organizations are not given fair notice of what conduct is prohibited), the Ninth (without a clearer definition of the standard, oversight of agency actions that exceed its authority would be hindered), and the Fourteenth Amendments.

FDA disagrees with the comment's assertion that these regulations are unconstitutional. As discussed in greater detail at the beginning of this section of this preamble, these regulations do not violate the First Amendment.

FDA further disagrees that the scientific standard is unconstitutionally vague or overbroad, and it questions the applicability of the vagueness and overbreadth doctrines in the current context. The vagueness doctrine is generally applied to strike down prohibitions on speech that leave individuals without clear guidance on the type of speech that is prohibited. (See, for example, *Village of Hoffman Estates* v. *Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498–99 (1982); *Grayned* v. *City of Rockford*, 408 U.S. 104, 108 (1972).) This is not the case here. Only approved health claims will be permitted on the food label, and all other health claims will misbrand a food. It will thus be clear which type of speech is prohibited and which permitted. Further, these regulations are narrowly tailored to meet a substantial government interest and are not overbroad. They do not "sweep[] within [their] prohibition what may not be punished under the First * * * Amendment[]." *Grayned*, 408 U.S. at 115. In any event, it is doubtful that the overbreadth doctrine would apply to these regulations, particularly if they were considered to regulate commercial speech, because the overbreadth doctrine does not apply to commercial speech. *Village of Hoffman Estates*, 455 U.S. at 497.

The comment does not explain its reasons for arguing that the regulations violate the Ninth and Fourteenth Amendments, and the agency does not agree that they do so. These regulations do not deny any fundamental rights not enumerated in the Constitution and so do not violate the Ninth Amendment. Because these regulations involve Federal and not State action, the Fourteenth Amendment does not apply.

The agency also disagrees that the regulations violate the due process clause of the Fifth Amendment because organizations will not be on notice of what constitutes prohibited conduct. Under the statutory scheme, as implemented by these regulations, certain health claims will be permitted to appear on food labels without misbranding the food or making the food a drug. No other health claims will be permitted. Organizations will be on notice that the use of an unapproved health claim is prohibited conduct.

The agency also disagrees that Congress has unconstitutionally delegated legislative power to FDA. "Congress does not violate the Constitution merely because it legislates in broad terms, leaving a certain degree of discretion to executive or judicial actors. As long as Congress 'lay[s] down by legislative act an intelligible principle to which the person or body authorized to [act] is directed to conform, such legislative action is not a forbidden delegation of legislative power.'" *Touby* v. *United States*, 111 S. Ct. 1752, 1756 (1991) (citing *J.W. Hampton, Jr., & Co.* v. *United States*, 276 U.S. 394, 409 (1928)).

XI. Consumer Summaries

FDA's 1990 proposal (55 FR 5176), issued prior to the enactment of the

1990 amendments, would have required that a health claim reference a consumer summary that provided full information about the relationship between the food and the disease about which the claim pertained. The summary was intended to facilitate the consumer's assessment of whether the health claim applied to him or her, and, in certain instances, to what extent it applied. The summary was also intended to help alleviate the potential problem of information overload on the label.

In the 1991 proposal for health claims (56 FR 60537), issued in response to the 1990 amendments, FDA suggested that consumer summaries may no longer be necessary. Section 403(r)(3)(B)(iii) of the act provides that the regulation authorizing a claim shall require that the claim be stated in a manner that: (1) Accurately reflects the relationship between a substance and a disease or health-related condition, and the significance of the substance in affecting the disease or health-related condition; and (2) enables the public to comprehend the information provided in the claim and understand the relative significance of such information in the context of a total daily diet. This statutory provision requires that the claim present the most significant aspects of the information that the agency was intending to require in the consumer summaries.

104. Some comments contended that FDA should require or strongly encourage the use of consumer summaries. Several of these comments asserted that their use is necessary to put health claims into the perspective of the total daily diet and alluded to their use as being similar to the package inserts employed for certain drug products. Others stated that their use would be an excellent vehicle for consumer education, and they should be provided and widely disseminated.

However, other comments argued that consumer summaries will have limited benefit in the light of the provisions of the 1990 amendments. Some of these comments stated that any of the proposed health claims will succinctly express the same message originally intended by FDA to be contained in the corresponding summary.

FDA is not persuaded that the use of consumer summaries is necessary in light of the provisions of this final rule. The comments did not contain a basis for the agency to require the summaries. New § 101.14(d)(2) requires, in part, that a health claim that appears in labeling be based on, and consistent with, the authorizing regulation in part 101, subpart E, and that the claim allow the public to understand the information provided in the claim and to understand the significance of that information in the context of a total daily diet. The agency agrees that these requirements fulfill the objectives of the consumer summaries, and that requiring the use of consumer summaries would therefore not be of additional benefit to the consumer. Furthermore, FDA knows of no basis under the act nor any other reason to require more information in the health claim than that that is already required under these rules.

105. Other comments suggested that FDA prepare and distribute a consumer guide containing information on how to use the new nutrition labels and health claim messages to improve eating habits.

Section 2(c) of the 1990 amendments directs the Secretary to carry out activities to educate consumers about the availability of nutrition information in the label or labeling of food and about the importance of that information in maintaining healthy dietary practices. Although FDA has not yet determined all of the measures that it will undertake to fulfill this directive, the agency believes that the guide suggested by these comments would be extremely useful in assisting consumers to achieve healthier dietary habits. Thus, the agency advises that it will prepare such a guide in partial fulfillment of this provision of the law. These comments, as well as those received in response to the 1990 proposal (55 FR 5176), will be considered in developing this guide.

XII. Other Issues

106. One comment objected to allowing a health claim for a nutrient that has been added to a food, arguing not only that the food containing the added nutrient would be subject to undue emphasis in the diet, but that the added nutrient would have a "dilution effect" on the food's naturally-occurring nutrients. The comment made specific reference to added fiber.

FDA disagrees. FDA believes that it is almost always the nutrient content of the diet that is significant, not the source. The comment provided no data to justify a change in the agency's belief. However, wherever the agency becomes aware of a situation in which the relationship of a particular nutrient to a disease or health-related condition is dependent upon the source of the nutrient, FDA will make appropriate provisions in the specific regulation in part 101, subpart E to ensure that the health claim is valid with respect to the source of the nutrient.

107. One comment objected that foods should not be permitted to bear multiple health claims because they might be viewed as "wonder foods." The comment submitted no data to support this position.

The agency has no basis to conclude that multiple valid health claims will be misleading to consumers. To the contrary, FDA believes that if it were to limit the number of different health claims that could appear on the label of a single product, it would place the manufacturer in the position of having to choose which of several valid health claims should appear on the label. Such choices would inevitably lead to a situation where the same food would bear different health claims depending on the particular manufacturer's marketing preferences. Under such circumstances consumers may question which claim was valid, or whether there were differences in the beneficial nutrients in the same food packaged by different manufacturers. Further, if the agency were to restrict the number of health claims on food, such a restriction would be contrary to the Congressional intent of the 1990 amendments that consumers be helped by health claims to maintain a healthful diet (Ref. 1).

108. A comment stated that a manufacturer may occasionally run an offer inviting consumers to submit requests for brochures containing dietary guidance or specific recommendations of a private organization, such as NCI. The comment requested that FDA clarify whether such brochures should conform to the health claims regulations.

For many years, the agency has taken the position that brochures containing nutrition information about a food constitute labeling. For example, § 101.9(f) provides that a statement may be included on the label or in labeling offering additional nutrition information upon written request to a specified address. The provision states further that any additional labeling furnished to consumers or professionals shall comply with all applicable requirements of chapter 1. (The preamble discussion about this provision appears in the response to comment 37 in the **Federal Register** of March 14, 1973 (38 FR 6950 at 6957).) Accordingly, FDA advises that where a food label contains an offer inviting consumers to submit requests for a brochure, and the brochure explicitly or implicitly characterizes the relationship of a substance to a disease or a health-related condition, the brochure is labeling that contains a health claim and thus must conform to the health claims regulations.

109. Some comments contended that in-store educational programs should not be subject to the health claim regulations. One comment noted that

such programs provide beneficial health and dietary information to consumers and can assist the agency in educating the public about the new labeling initiative. Another comment advised that the guidance in these programs may, or may not, conform to health claims regulations.

FDA recognizes that a wide variety of in-store nutrition education programs incorporating written, printed, or graphic materials, videotapes, or other media, may serve a useful role in assisting consumers maintain a balanced and healthful diet and thereby make a positive contribution toward one of the major goals of the 1990 amendments. Accordingly, the agency wishes to encourage, rather than discourage, their use, provided that such programs conform to health claims regulations if they characterize the relationship of a substance to a disease or health-related condition.

However, the agency points out that such programs, by virtue of their association with the articles of food in the retail store, generally constitute food labeling under section 201(m)(2) of the act and, as such, would be subject to regulation under section 403(r) of the act if a health claim is made. FDA does not agree that such programs should be exempt from these regulations. Consumers could be confused by differing claims on food labels and in these programs. For example, if under an in-store program, informational placards with a calcium/osteoporosis health claim were placed on a dairy case containing a wide variety of dairy products, some of the products contained in the case would likely be misbranded, as a number of dairy products exceed the disqualifying nutrient levels for fat and saturated fat or fail to meet other provisions of new § 101.14. Even those products that would otherwise qualify for a health claim would likely be misbranded if the placard claim itself did not conform to the provisions of new § 101.14 and part 101, subpart E.

The agency's regulations are designed to enable consumers to understand the significance of the consumption of the substance on the risk of disease within the context of the daily diet. Relevant in-store programs should be carefully crafted to convey such an understanding.

110. A number of comments took a position that one or more of the proposed provisions should not be established because they are subjects for regulatory review under the January 28, 1992, Presidential memo, "Reducing the Burden of Government Regulation." The comments asserted that these requirements are exercises in discretion by the agency rather than requirements mandated by Congress.

FDA advises that after considering these comments, it has concluded that none of the preliminary requirements reaches beyond the act to impose an unnecessary burden on manufacturers. As explained in the preamble of the proposal (56 FR 60537 at 60545 through 60547), each of these requirements is directly derived from existing provisions of the act. Even though these provisions are derived from the act, FDA has carefully reviewed each provision in accordance with the direction provided by the January 28, 1992, Presidential memo. FDA has carefully considered the benefits to society of these rules and concluded that the benefits clearly outweigh the expected costs (see the final RIA, published elsewhere in this issue of the **Federal Register**). Each provision of the rules has been fashioned to maximize net benefits to society. Further, the provisions have been crafted to clearly convey to the regulated community what is required of firms choosing to make health claims.

XIII. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), along with the food labeling proposals, and the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

XIV. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (November 27, 1991 (56 FR 60537 at 60562)). At that time, FDA determined under 21 CFR 25.24(a)(8) and (a)(11) that this action was of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

Several comments on the proposed rules on health claims suggested that there would be significant adverse environmental effects from these rulemakings because it would cause large stocks of labels and labeled packaging materials to be discarded and require a great number of trees to be harvested to provide new labeling material. One comment estimated the number of label units from the dairy industry that would need to be discarded following publication of FDA's final rules on several food labeling actions, including this action. However, this comment did not: (1) Show how these estimates were derived, (2) identify what portion of the estimated amounts are attributable solely to this action, or (3) describe what impact the discarded labeling and packaging would have on the disposal of solid waste. Another comment questioned the appropriateness of requiring lengthy explanations on the labels of foods for which health claims are made because those requirements might result in extra packaging so that sufficient label space would be available for the required elements of the health claims. The comment said that this extra packaging might increase the burden on the environment but did not estimate the amount of extra packaging that might be needed or describe what impact this extra packaging would have on the environment.

According to section 10(a)(2) of the 1990 amendments, section 403(r) of the act does not apply to food labeled before May 8, 1993. Thus, all labels that are

applied to food prior to that date will not have to be destroyed. The comments contained no data with respect to labels that might remain that would fail to comply with the requirements of section 403(r)(1)(B) of the act. In the absence of such data, FDA has no basis on which to assess the validity of assertions that considerable label stocks will be destroyed and thereby determine the extent of any potential adverse environmental impact. Given the fact that section 10(a)(2) of the 1990 amendments provides an exemption for labeled products, and that FDA is authorizing various health claims elsewhere in this issue of the **Federal Register**, FDA believes that very little, if any, labeling will have to be discarded because of this final rule. Also, in its final rules, FDA has limited the required elements of many of the health claims compared to the elements that were proposed. Thus, FDA believes that the information required on a label when a health claim is made can be incorporated into the label without significantly increasing the amount of packaging required. Consequently, FDA concludes that the comments on the potential for adverse environmental effects do not affect the agency's previous determination that no significant impact on the human environment is expected and that an environmental impact statement is not required.

XV. Paperwork Reduction Act

In the **Federal Register** of February 14, 1992 (57 FR 5396), FDA announced that the agency had submitted to the Office of Management and Budget (OMB) for its review the collection of information requirements contained in the proposed rule (November 27, 1991, 56 FR 60537) that provided, in proposed § 100.70, for petitions regarding the use of health claims in conjunction with food labeling. Also in the February 1992 document, FDA published its estimated annual collection of information burden.

FDA considered over 6,000 written comments received in response to the aforementioned **Federal Register** documents and the oral presentations made at the public hearing on food labeling in developing this final rule. FDA has not been persuaded by the comments or any other relevant information to modify, in this final rule, the health claim petition requirements that it proposed last year. Thus, the agency's estimated annual reporting and recordkeeping burden from the health claim petition requirements contained in this final rule remains unchanged from that announced in February.

FDA has submitted copies of the final rule to OMB for its review of these reporting requirements.

XVI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. House of Representatives, House Report 101–538, "Nutrition Labeling and Education Act of 1990," June 13, 1990.
2. 136 Congressional Record—Senate, S16607–16612, October 24, 1990.
3. 136 Congressional Record—House, H12951–12955, October 26, 1990.
4. 136 Congressional Record—House, H5836–5845, July 30, 1990.
5. DHHS, Public Health Service, "The Surgeon General's Report on Nutrition and Health," DHHS (PHS) Publication No. 88–50210 (GPO Stock No. 017–001–00465–1), U.S. Government Printing Office, Washington, DC, 1988.
6. Committee on Diet and Health, Food and Nutrition Board, Commission on Life Sciences, NRC, "Diet and Health: Implications for Reducing Chronic Disease Risk," National Academy Press, Washington, DC, 1989.
7. USDA and DHHS, "Nutrition and Your Health: Dietary Guidelines for Americans," 3d ed., Home and Garden Bulletin No. 232, U.S. Government Printing Office, Washington, DC, 1990.
8. Dresser, C. M., National Center for Health Statistics, Interagency memorandum to Marilyn Stephenson, FDA, December 3, 1981.
9. USDA, Human Nutrition Information Service, "Nationwide Food Consumption Survey—1986," NFCS, Continuing Survey of Food Intakes by Individuals, Report No. 86–3, Hyattsville, MD, p. 168, September 1988.
10. Buzzard, I. M., Letter to Virginia Wilkening, FDA, February 12, 1991.
11. Clinical Nutrition Branch, memo to file: Data Analysis HM1, Percent Daily Reference Value Per Serving, October 16, 1991.
12. Clinical Nutrition Branch, memo to file: Data Analysis HM2, Presence of Nutrients in Food Categories, October 16, 1991.
13. Clinical Nutrition Branch, memo to file: Data Analysis HM3, Assessment of Disqualifying Levels of 10, 15, and 20 Percent of the DRV Per Serving, October 16, 1991.
14. Clinical Nutrition Branch, memo to file: Data Analysis HM4, Assessment of Need for Disqualifying Levels Based on 100 Grams, October 16, 1991.
15. Senate Report No. 493, 73d Cong., 2d sess., March 15, 1934. Cited in: Food and Drug Administration, "A Legislative History of the Federal Food, Drug, and Cosmetic Act," vol. 2, pp. 721–3, FDA, Rockville, MD, 1979.
16. Fosmire, G. J., "Zinc Toxicity," *The American Journal of Clinical Nutrition*, 51:225–227, 1990.
17. Fischer, P. W. F., A. Giroux, and M. R. L'Abbe, "Effect of Zinc Supplementation on Copper Status in Adult Man," *The American Journal of Clinical Nutrition*, 40:743–746, 1984.
18. FDA, "Compliance Program Guidance Manual," Chapter 21, Program No. 7321.002 (1988–1991), FDA, 1990.
19. Schoeller, D. E., "How Accurate is Self-Reported Dietary Energy Intake?", *Nutrition Reviews*, 48:373–379, 1990.
20. Food and Nutrition Board, NRC, "Recommended Dietary Allowances," 10th ed., Chapter 1, National Academy Press, Washington, DC, 1989.
21. Yetley, E. A. and Y. K. Park, "Obtaining Data on Intake of Supplements," in *Nutritional Status of the Individual*, G. E. Livingston, Ed., pp. 113–123, Food and Nutrition Press, Inc., Trumbull, CT, 1989.
22. Burke Marketing Research, "Analysis: Restaurant Users Focus Group Session," Study BMR No. 39–545 conducted for the American Heart Association, Dallas, TX, March 1989.
23. Burke Marketing Research, "Logo/Name Study for American Heart Association," Study BMR No. 39–651 conducted for the American Heart Association, Dallas, TX, June 1989.
24. U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Health and the Environment, Hearing on the Nutrition Labeling and Education Act of 1989, H.R. 3028, August 3, 1989, Serial No. 101–65, U.S. Government Printing Office, Washington, DC, 1989.
25. U.S. Senate, Committee on Labor and Human Resources, Hearing on the Nutrition Labeling and Education Act of 1989, S. 1425, November 13, 1989, U.S. Government Printing Office, Washington, DC, 1990.
26. Congressional Record—Senate, S8894–8895, July 27, 1989.
27. NCI, "Eat More Fruits and Vegetables—Five-a-Day For Better Health," NIH Publication No. 92–3248, October, 1991.
28. Glinsmann, W. H., H. Irausquin, and Y. K. Park, "Evaluation of Health Aspects of Sugars Contained in Carbohydrate Sweeteners," *The Journal of Nutrition*, 116:S1–S216, 1986.
29. USDA, Human Nutrition Information Services, "USDA's Food Guide Pyramid," Home and Garden Bulletin No. 249, April, 1992.
30. FDA, Clinical Nutrition Branch, memo to file: Data Analysis HC1, Disqualifying Levels at 20 Percent versus 15 Percent of the Daily Reference Value, October 15, 1992.
31. FDA, Clinical Nutrition Branch, memo to file: Data Analysis HC2, Disqualifying Levels per 50 Grams versus per 100 Grams, October 15, 1992.
32. The National Nutrition Monitoring and Related Research Act of 1990, Pub. L. 101–445, October 22, 1990.
33. FDA, Clinical Nutrition Branch, memo to file: Data Analysis HC3, Health Claim Requirement for Minimum Levels of Nutrients, October 15, 1992.
34. Managers Statement on the DS Act of 1992.
35. FDA, Clinical Nutrition Branch, memo to file: Data Analysis HC4, Disclosure/Disqualifying Levels for Meals and Main Dishes, October 15, 1992.
36. FDA's 1990 Health and Dietary Survey, Division of Consumer Studies, Center for Food Safety and Applied Nutrition, FDA.

37. Food Retailing Review—1992 Edition, The Food Institute Information and Research Center, Fairlawn, NJ, p. 245, February 1992.

List of Subjects

21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 20 and 101 are amended as follows:

PART 20—PUBLIC INFORMATION

1. The authority citation for 21 CFR part 20 continues to read as follows:

Authority: Secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–393); secs. 301, 302, 303, 307, 310, 311, 351, 352, 354–360F, 361, 362, 1701–1706, 2101 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1); 5 U.S.C. 552; 18 U.S.C. 1905.

2. Section 20.100 is amended by revising the section heading and by adding new paragraph (c)(34) to read as follows:

§ 20.100 Applicability; cross-reference to other regulations.

* * * * *

(c) * * *

(34) Health claims petitions, in § 101.70 of this chapter.

PART 101—FOOD LABELING

3. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

4. Section 101.9 is amended by adding new paragraph (k)(1) to read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(k) * * *

(1) That the food, because of the presence or absence of certain dietary properties, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom. Information about the relationship of a dietary property to a disease or health-related condition may only be provided in conformance with the requirements of § 101.14 and part 101, subpart E.

* * * * *

5. New § 101.14 is added to read as follows:

§ 101.14 Health claims: general requirements.

(a) *Definitions.* For purposes of this section, the following definitions apply:

(1) *Health claim* means any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including "third party" references, written statements (e.g., a brand name including a term such as "heart"), symbols (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition. Implied health claims include those statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition.

(2) *Substance* means a specific food or component of food.

(3) *Nutritive value* means a value in sustaining human existence by such processes as promoting growth, replacing loss of essential nutrients, or providing energy.

(4) [Reserved]

(5) *Disqualifying nutrient levels* means the levels of total fat, saturated fat, cholesterol, or sodium in a food above which the food will be disqualified from making a health claim. These levels are 13.0 grams (g) of fat, 4.0 g of saturated fat, 60 milligrams (mg) of cholesterol, or 480 mg of sodium, per reference amount customarily consumed, per label serving size, and, only for foods with reference amounts customarily consumed of 30 g or less or 2 tablespoons or less, per 50 g. For dehydrated foods that must have water added to them prior to typical consumption, the per 50-g criterion refers to the as prepared form. Any one of the levels, on a per reference amount customarily consumed, a per label serving size or, when applicable, a per 50 g basis, will disqualify a food from making a health claim unless an exception is provided in subpart E of this part, except that:

(i) The levels for a meal product as defined in § 101.13(l) are 26.0 g of fat, 8.0 g of saturated fat, 120 mg of cholesterol, or 960 mg of sodium per label serving size, and

(ii) The levels for a main dish product as defined in § 101.13(m) are 19.5 g of fat, 6.0 g of saturated fat, 90 mg of cholesterol, or 720 mg of sodium per label serving size.

(6) *Disease or health-related condition* means damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition (claims pertaining to such diseases are thereby not subject to § 101.14 or § 101.70).

(b) *Eligibility.* For a substance to be eligible for a health claim:

(1) The substance must be associated with a disease or health-related condition for which the general U.S. population, or an identified U.S. population subgroup (e.g., the elderly) is at risk, or, alternatively, the petition submitted by the proponent of the claim otherwise explains the prevalence of the disease or health-related condition in the U.S. population and the relevance of the claim in the context of the total daily diet and satisfies the other requirements of this section.

(2) If the substance is to be consumed as a component of a conventional food at decreased dietary levels, the substance must be a nutrient listed in 21 U.S.C. 343(q)(1)(C) or (q)(1)(D), or one that the Food and Drug Administration (FDA) has required to be included in the label or labeling under 21 U.S.C. 343(q)(2)(A); or

(3) If the substance is to be consumed at other than decreased dietary levels:

(i) The substance must contribute taste, aroma, or nutritive value, or any technical effect listed in § 170.3(o) of this chapter, to the food and must retain that attribute when consumed at levels that are necessary to justify a claim; and

(ii) The substance must be a food or a food ingredient or a component of a food ingredient whose use at the levels necessary to justify a claim has been demonstrated by the proponent of the claim, to FDA's satisfaction, to be safe and lawful under the applicable food safety provisions of the Federal Food, Drug, and Cosmetic Act.

(c) *Validity requirement.* FDA will promulgate regulations authorizing a health claim only when it determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

(d) *General health claim labeling requirements.* (1) When FDA determines that a health claim meets the validity requirements of paragraph (c) of this

section, FDA will propose a regulation in subpart E of this part to authorize the use of that claim. If the claim pertains to a substance not provided for in § 101.9, FDA will propose amending that regulation to include declaration of the substance.

(2) When FDA has adopted a regulation in subpart E of this part providing for a health claim, firms may make claims based on the regulation in subpart E of this part, provided that:

(i) All label or labeling statements about the substance-disease relationship that is the subject of the claim are based on, and consistent with, the conclusions set forth in the regulations in subpart E of this part;

(ii) The claim is limited to describing the value that ingestion (or reduced ingestion) of the substance, as part of a total dietary pattern, may have on a particular disease or health-related condition;

(iii) The claim is complete, truthful, and not misleading. Where factors other than dietary intake of the substance affect the relationship between the substance and the disease or health-related condition, such factors may be required to be addressed in the claim by a specific regulation in subpart E of this part;

(iv) All information required to be included in the claim appears in one place without other intervening material, except that the principal display panel of the label or labeling may bear the reference statement, "See ———— for information about the relationship between ———— and ————," with the blanks filled in with the location of the labeling containing the health claim, the name of the substance, and the disease or health-related condition (e.g., "See attached pamphlet for information about calcium and osteoporosis"), with the entire claim appearing elsewhere on the other labeling, Provided that, where any graphic material (e.g., a heart symbol) constituting an explicit or implied health claim appears on the label or labeling, the reference statement or the complete claim shall appear in immediate proximity to such graphic material;

(v) The claim enables the public to comprehend the information provided and to understand the relative significance of such information in the context of a total daily diet; and

(vi) If the claim is about the effects of consuming the substance at decreased dietary levels, the level of the substance in the food is sufficiently low to justify the claim. To meet this requirement, if a definition for use of the term "low" has been established for that substance under this part, the substance must be present at a level that meets the requirements for use of that term, unless a specific alternative level has been established for the substance in subpart E of this part. If no definition for "low" has been established, the level of the substance must meet the level established in the regulation authorizing the claim; or

(vii) If the claim is about the effects of consuming the substance at other than decreased dietary levels, the level of the substance is sufficiently high and in an appropriate form to justify the claim. To meet this requirement, if a definition for use of the term "high" for that substance has been established under this part, the substance must be present at a level that meets the requirements for use of that term, unless a specific alternative level has been established for the substance in subpart E of this part. If no definition for "high" has been established (e.g., where the claim pertains to a food either as a whole food or as an ingredient in another food), the claim must specify the daily dietary intake necessary to achieve the claimed effect, as established in the regulation authorizing the claim; *Provided* that:

(A) Where the food that bears the claim meets the requirements of paragraphs (d)(2)(vi) or (d)(2)(vii) of this section based on its reference amount customarily consumed, and the labeled serving size differs from that amount, the claim shall be followed by a statement explaining that the claim is based on the reference amount rather than the labeled serving size (e.g., "Diets low in salt and sodium may help lower blood pressure in many people. A serving of ———— ounces of this product conforms to such a diet.").

(B) Where the food that bears the claim is sold in a restaurant (except if the claim is made on a menu) or in other establishments in which food that is ready for human consumption is sold, the food can meet the requirements of paragraphs (d)(2)(vi) or (d)(2)(vii) of this section if the firm that sells the food has a reasonable basis on which to believe that the food that bears the claim meets the requirements of paragraphs (d)(2)(vi) and (d)(2)(vii) of this section and providing that basis upon request.

(3) Nutrition labeling shall be provided in the label or labeling of any food for which a health claim is made in accordance with § 101.9 or, for restaurant foods, in accordance with § 101.10.

(e) *Prohibited health claims.* No expressed or implied health claim may be made on the label or in labeling for a food unless:

(1) The claim is specifically provided for in subpart E of this part; and

(2) The claim conforms to all general provisions of this section as well as to all specific provisions in the appropriate section of subpart E of this part;

(3) None of the disqualifying levels identified in paragraph (a)(5) of this section is exceeded in the food, unless specific alternative levels have been established for the substance in subpart E of this part; or unless FDA has permitted a claim despite the fact that a disqualifying level of a nutrient is present in the food based on a finding that such a claim will assist consumers in maintaining healthy dietary practices, and, in accordance with the regulation in subpart E of this part that makes such a finding, the label bears a referral statement that complies with § 101.13(h), highlighting the nutrient that exceeds the disqualifying level;

(4) Except as provided in paragraph (e)(3) of this section, no substance is present at an inappropriate level as determined in the specific provision authorizing the claim in subpart E of this part;

(5) The label does not represent or purport that the food is for infants and toddlers less than 2 years of age except if the claim is specifically provided for in subpart E of this part; and

(6) Except for dietary supplements not in conventional food form, the food contains 10 percent or more of the Reference Daily Intake or the Daily Reference Value for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed prior to any nutrient addition.

(f) The requirements of this section do not apply to:

(1) Infant formulas subject to section 412(h) of the Federal Food, Drug, and Cosmetic Act, and

(2) Medical foods defined by section 5(b) of the Orphan Drug Act.

(g) *Applicability.* The requirements of this section apply to foods intended for human consumption that are offered for sale.

6. Subpart E, consisting of §§ 101.70 and 101.71, is added to read as follows:

Subpart E—Specific Requirements for Health Claims

Sec.
101.70 Petitions for health claims.
101.71 Health claims: claims not authorized.

Subpart E—Specific Requirements for Health Claims

§ 101.70 Petitions for health claims.

(a) Any interested person may petition the Food and Drug

Administration (FDA) to issue a regulation regarding a health claim. An original and one copy of the petition shall be submitted, or the petitioner may submit an original and a computer readable disk containing the petition. Contents of the disk should be in a standard format, such as ASCII format. (Petitioners interested in submitting a disk should contact the Center for Food Safety and Applied Nutrition for details.) If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall state the petitioner's post office address to which any correspondence required by section 403 of the Federal Food, Drug, and Cosmetic Act may be sent.

(b) Pertinent information may be incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of FDA. Such information may include any findings, along with the basis of the findings, of an outside panel with expertise in the subject area. Any reference to published information shall be accompanied by reprints, or easily readable copies of such information.

(c) If nonclinical laboratory studies are included in a petition, the petition shall include, with respect to each nonclinical study contained in the petition, either a statement that the study has been conducted in compliance with the good laboratory practice regulations as set forth in part 58 of this chapter, or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(d) If clinical or other human investigations are included in a petition, the petition shall include a statement that they were either conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter, or were not subject to such requirements in accordance with § 56.104 or § 56.105, and a statement that they were conducted in compliance with the requirements for informed consent set forth in part 50 of this chapter.

(e) All data and information in a health claim petition are available for public disclosure after the notice of filing of petition is issued to the petitioner, except that clinical investigation reports, adverse reaction reports, product experience reports, consumer complaints, and other similar data and information shall only be available after deletion of:

(1) Names and any information that would identify the person using the product.

(2) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(f) Petitions for a health claim shall include the following data and be submitted in the following form:

_____

(Date)
Name of petitioner _____
Post office address _____
Subject of the petition _____
Food and Drug Administration,
Regulatory Affairs Staff (HFF–204),
Office of Nutrition and Food Sciences,
200 C St. SW.,
Washington, DC 20204,

The undersigned,

_____ submits this petition pursuant to section 403(r)(4) or (r)(5)(D) of the Federal Food, Drug, and Cosmetic Act with respect to (statement of the substance and its health claim).

Attached hereto, in quadruplicate, and constituting a part of this petition, are the following:

A. Preliminary requirements. A complete explanation of how the substance conforms to the requirements of § 101.14(b) (21 CFR 101.14(b)). For petitions where the subject substance is a food ingredient or a component of a food ingredient, the petitioner should compile a comprehensive list of the specific ingredients that will be added to the food to supply the substance in the food bearing the health claim. For each such ingredient listed, the petitioner should state how the ingredient complies with the requirements of § 101.14(b)(3)(ii), e.g., that its use is generally recognized as safe (GRAS), listed as a food additive, or authorized by a prior sanction issued by the agency, and what the basis is for the GRAS claim, the food additive status, or prior sanctioned status.

B. Summary of scientific data. The summary of scientific data provides the basis upon which authorizing a health claim can be justified as providing the health benefit. The summary must establish that, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

The summary shall state what public health benefit will derive from use of the claim as proposed. If the claim is intended for a specific group within the population, the summary shall specifically address nutritional needs of such group and shall include scientific data showing how the claim is likely to assist in meeting such needs.

The summary shall concentrate on the findings of appropriate review articles, National Institutes of Health consensus development conferences, and other appropriate resource materials. Issues addressed in the summary shall include answers to such questions as:

1. Is there an optimum level of the particular substance to be consumed beyond which no benefit would be expected?

2. Is there any level at which an adverse effect from the substance or from foods containing the substance occurs for any segment of the population?

3. Are there certain populations that must receive special consideration?

4. What other nutritional or health factors (both positive and negative) are important to consider when consuming the substance?

In addition, the summary of scientific data shall include a detailed analysis of the potential effect of the use of the proposed claim on food consumption, specifically any change due to significant alterations in eating habits and corresponding changes in nutrient intake resulting from such changes in food consumption. The latter item shall specifically address the effect on the intake of nutrients that have beneficial and negative consequences in the total diet.

If the claim is intended for a significant subpopulation within the general U.S. population, the analysis shall specifically address the dietary practices of such group, and shall include data sufficient to demonstrate that the dietary analysis is representative of such group (e.g., adolescents or the elderly).

If appropriate, the petition shall explain the prevalence of the disease or health-related condition in the U.S. population and the relevance of the claim in the context of the total daily diet.

Also, the summary shall demonstrate that the substance that is the subject of the proposed claim conforms to the definition of the term "substance" in § 101.14(a)(2).

C. Analytical data that show the amount of the substance that is present in representative foods that would be candidates to bear the claim should be obtained from representative samples using methods from the Association of Official Analytical Chemists (AOAC), where available. If no AOAC method is

available, the petitioner shall submit the assay method used and data establishing the validity of the method for assaying the substance in food. The validation data should include a statistical analysis of the analytical and product variability.

D. Model health claim. One or more model health claims that represent label statements that may be used on a food label or in labeling for a food to characterize the relationship between the substance in a food to a disease or health-related condition that is justified by the summary of scientific data provided in section C of the petition. The model health claim shall include:

1. A brief capsulized statement of the relevant conclusions of the summary, and

2. A statement of how this substance helps the consumer to attain a total dietary pattern or goal associated with the health benefit that is provided.

E. The petition shall include the following attachments:

1. Copies of any computer literature searches done by the petitioner (e.g., Medline).

2. Copies of articles cited in the literature searches and other information as follows:

a. All information relied upon for the support of the health claim, including copies of publications or other information cited in review articles and used to perform meta-analyses.

b. All information concerning adverse consequences to any segment of the population (e.g., sensitivity to the substance).

c. All information pertaining to the U.S. population.

F. The petitioner is required to submit either a claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter.

Yours very truly,

Petitioner ————

By ————

(Indicate authority)

(g) The data specified under the several lettered headings should be submitted on separate pages or sets of pages, suitably identified. If such data have already been submitted with an earlier application from the petitioner or any other final petition, the present petition may incorporate it by specific reference to the earlier petition.

(h) The petition shall include a statement signed by the person responsible for the petition that, to the best of his/her knowledge, it is a representative and balanced submission that includes unfavorable information as well as favorable information, known to him/her to be pertinent to the evaluation of the proposed health claim.

(i) The petition shall be signed by the petitioner or by his/her attorney or agent, or (if a corporation) by an authorized official.

(j) *Agency action on the petition.* (1) Within 15 days of receipt of the petition, the petitioner will be notified by letter of the date on which the petition was received. Such notice will inform the petitioner that the petition is undergoing agency review and that the petitioner will subsequently be notified of the agency's decision to file for comprehensive review or deny the petition.

(2) Within 100 days of the date of receipt of the petition, FDA will notify the petitioner by letter that the petition has either been filed for comprehensive review or denied. The agency will deny a petition without reviewing the information contained in B. *Summary of Scientific Data* if the information in A. *Preliminary Requirements* is inadequate in explaining how the substance conforms to the requirements of § 101.14(b). If the petition is denied, the notification will state the reasons therefor, including justification of the rejection of any report from an authoritative scientific body of the U.S. Government. If filed, the date of the notification letter becomes the date of filing for the purposes of this regulation. A petition that has been denied without filing will not be made available to the public. A filed petition will be available to the public to the extent provided under paragraph (e) of this section.

(3) Within 90 days of the date of filing, FDA will by letter of notification to the petitioner:

(i) Deny the petition, or

(ii) Inform the petitioner that a proposed regulation to provide for the requested use of the health claim will be published in the **Federal Register**. If the petition is denied, the notification will state the reasons therefor, including justification for the rejection of any report from an authoritative scientific body of the U.S. Government. FDA will publish the proposal to amend the regulations to provide for the requested use of the health claim in the **Federal Register** within 90 days of the date of filing. The proposal will also announce the availability of the petition for public review.

§ 101.71 Health claims: claims not authorized.

In response to the Nutrition Labeling and Education Act of 1990, FDA has reviewed the evidence on the following topics that Congress specifically asked FDA to evaluate and has concluded that there is not a sufficient basis for claims about the following:

Dated: December 17, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 92-31511 Filed 12-28-92; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 91N-0098]

RIN 0905-AD08

Food Labeling: Health Claims and Label Statements; Dietary Fiber and Cancer

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing its decision not to authorize the use on the label or labeling of foods of health claims relating to an association between dietary fiber and cancer. However, FDA is authorizing a health claim relating diets low in fat and high in fiber-containing grain products, fruits, and vegetables to a reduced risk of cancer. This action is in response to provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) that bear on health claims, and was developed in accordance with the final rule on general requirements for health claims, published elsewhere in this issue of the **Federal Register**.

Based on the totality of the publicly available scientific evidence, including recently available evidence, the agency has concluded that there is not significant scientific agreement among qualified experts that a claim relating dietary fiber to reduced risk of cancer is supported. The publicly available evidence does indicate, however, that diets low in fat and rich in fiber-containing grain products, fruits, and vegetables are associated with a decreased risk of several types of cancer, and there is significant scientific agreement that the evidence supports this association. The evidence is not sufficient to fully explain the role of total dietary fiber, fiber components, and the multiple nutrients and other substances contained in these foods in reducing cancer risk.

EFFECTIVE DATE: May 8, 1993.

FOR FURTHER INFORMATION CONTACT: Joyce J. Saltsman, Center for Food Safety and Applied Nutrition (HFS-165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5916.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 27, 1991 (56 FR 60566), FDA proposed to deny the use of health claims relating dietary fiber to the risk of cancer on food labeling. The proposed rule was issued in response to provisions of the 1990 amendments (Pub. L. 101-535) that bear on health claims and in accordance with the proposed general requirements for health claims for food (56 FR 60537). As amended in 1990, the Federal Food, Drug, and Cosmetic Act (the act) provides that a food is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition unless the claim is made in accordance with section 403(r)(3) or 403(r)(5)(D) of the act (21 U.S.C. 343(r)(3) or 343(r)(5)(D)).

Congress enacted the health claims provisions of the 1990 amendments (Pub. L. 101-535) to help U.S. consumers maintain good health through appropriate dietary patterns and to protect consumers from unfounded health claims. Section 3(b)(1)(A) of the 1990 amendments specifically requires the agency to determine whether claims respecting 10 nutrient/disease relationships meet the requirements of section 403(r)(3) or 403(r)(5)(D) of the act. The relationship between dietary fiber and cancer is one of the claims required to be evaluated. In carrying out this inquiry, FDA limited its scientific review to the area for which the strongest scientific evidence and agreement existed: Dietary fiber and cancers of the colon and rectum (colorectal cancers).

FDA published a notice in the **Federal Register** of March 28, 1991 (56 FR 12932), requesting scientific data and information on the 10 specific topic areas identified in the 1990 amendments, including dietary fiber and cancer. Relevant scientific studies and data received in response to this request were considered as part of the agency's review of the scientific literature on dietary fiber and cancer, and they were included in the proposed rule. Comments received in response to the notice and not specifically addressed in the proposed rule are summarized and addressed below.

In the proposed rule (56 FR 60566), FDA requested written comments on its tentative determination not to authorize a health claim for dietary fiber and cancer. FDA also requested comments on the following issues: (1) Should the agency permit the label or labeling of certain foods to state, for example, that diets high in fruit, vegetables, and whole grains are associated with a reduced risk of certain forms of cancer and cardiovascular disease?; (2) If such a statement were permitted, what criteria should be used to identify eligible foods? For example, should such statements be limited to fresh fruit, vegetables, and milled whole grains; or should processed foods derived from these products also be included?; (3) What measures should the agency adopt to assure that consumers are not misled as to the benefit of consuming a specific product?; (4) Does FDA have the authority to allow health claims for foods as well as nutrients?; (5) What qualifying and disqualifying criteria should be used to determine eligibility for a claim, and what methods or criteria should be used for regulatory monitoring and compliance?; (6) What criteria could be used to develop a health claim for foods that would provide truthful and not misleading messages to consumers that changes in dietary patterns are related to reductions in cancer risk (56 FR at 60577)?

In addition, FDA held public hearings on January 30 and 31, 1992, on all aspects of the proposed rules published in response to the 1990 amendments.

II. Summary of Comments and the Agency's Responses

The agency received approximately 100 comments (including those from the March 28, 1991, request) in response to its proposed rule on health claims for dietary fiber and cancer. Comments were received from consumers, consumer advocacy groups, state health departments, organizations of health professionals, the food industry, and Government agencies.

The agency has summarized and addressed the issues raised in these comments below. Data submitted in scientific articles that were not reviewed in the proposed rule or in any of the Federal Government consensus documents or Life Sciences Research Office (LSRO) reports are discussed in the agency's review of recent scientific evidence in section III of this document. A number of the comments received were more appropriately addressed in other documents, and these comments were forwarded to the appropriate docket for response.

A. General Comments

1. Several comments stated that there is sufficient scientific evidence to support a health claim that diets high in dietary fiber can reduce the risk of colon cancer. These comments maintained that it is well known that population groups who consume high-fiber diets have a lower incidence of cancer, and these comments cited the strength of international correlational data on per capita availability of fiber and risk of colon cancer. Other comments stated that FDA should allow a health claim regarding dietary fiber and cancer

because cancer is a major public health problem, and it is important for consumers to be well informed. Several comments stated that FDA failed to consider the rapid pace of scientific advances linking nutritional substances to the maintenance of long-term health and disease prevention.

FDA agrees that cancer is a significant public health problem and is a significant cause of death. Colorectal cancers are the second and third leading causes of cancer deaths in the United States for men and women, respectively (Ref. 46). As FDA described in its proposed rule (56 FR 60566), numerous human and animal studies have examined the possible role of dietary fiber intake in reducing the risk of developing colon cancer. Most correlational studies and many (but not all) case-control studies show that diets high in fiber-containing foods (whole grains, fruits, and vegetables) are associated with a reduced risk of colorectal cancer. Prospective epidemiologic studies are few in number and give mixed results. Animal studies indicate that certain types of dietary fiber, but not others, may be important in modulating the effects of chemical carcinogens.

FDA agrees that there is substantial evidence that diets high in fiber-rich foods, including whole grains, fruits, and vegetables, are associated with reduced risk of colorectal cancer. These diets differ, however, in levels of many nutrients and in types of dietary fiber, making it difficult to attribute the observed diet-disease relationship to a single nutrient. Overall, the available data are not sufficient to demonstrate that it is the total dietary fiber, or a specific fiber component, or specific vitamins and minerals (singly or interactively) that are related to reduction of cancer risk.

The agency disagrees with the comments that assert that international correlational data on fiber per capita availability and risk of colon cancer are sufficient to justify a health claim regarding dietary fiber and cancer. While the correlation coefficients of such studies are often large, these studies are very weak in controlling for confounding variables. Many of the countries with low incidences of colon cancer are undeveloped nations that differ in many ways from Western countries (for example, in prevalence of obesity, environmental pollution, genetic susceptibility, parasitic diseases, etc.). None of the international correlation studies reports actual food consumption; instead, each attributes consumption of fiber from averages of food disappearance. This approach does not account for food disappearance through loss or wastage (peeling, etc.) or for differing dietary habits among various socioeconomic groups within a single country. Thus, in its proposed rule, FDA tentatively found that a basis did not exist on which to authorize a health claim relating to an association between ingestion of dietary fiber and risk of cancer. In this final rule, FDA is not authorizing a dietary fiber and cancer health claim because, based on the agency's review of the scientific evidence, including scientific literature that became publicly available after the proposal's publication, and review of data in comments, the agency has concluded that the evidence is not sufficiently conclusive or specific for dietary fiber per se to justify such a health claim. The agency has concluded, however, that there is sufficient evidence to support a claim relating the ingestion of fruits, vegetables, and whole grain products to reduced risk of some cancers. These foods are also generally low in fat and are good sources of dietary fiber.

2. Several comments stated that FDA did not follow the congressional mandate to consider whether there is significant scientific agreement supporting specific health claims. The comments argued that the agency should have first identified the range of specific health claims that could be made about dietary fiber and cancer and then examined the scientific support for each claim. A related comment asserted that FDA's evaluation criteria for specific scientific studies were based on a fundamental misapprehension of its role under the 1990 amendments. The comments stated that FDA's proper role is to search the science for significant agreement, not decide the validity of studies.

FDA disagrees with these comments. The 1990 amendments did not instruct the agency to identify the wide range of health claims that might be made with respect to the 10 topics identified and then to evaluate all published literature relevant to the claims. Rather, the 1990 amendments instructed the agency to determine whether claims respecting the 10 areas, including "dietary fiber and cancer," meet the requirements of section 403(r)(3) or 403(r)(5)(D) of the act. The agency interpreted this directive in a straightforward and logical way. Indeed, FDA's chosen approach was necessary if the agency hoped to accomplish the congressional mandate within the prescribed timeframe and with its limited resources. Thus, FDA, in its proposed rule (56 FR 60566), focused its scientific review on those aspects of the dietary fiber and cancer relationship for which the strongest scientific evidence exists: dietary fiber and colorectal cancer.

The agency developed its proposed rule regarding dietary fiber and cancer in conformity with the standards mandated by the 1990 amendments. FDA's role is to evaluate the totality of the publicly available scientific evidence and to assess whether there is significant scientific agreement among qualified experts that the available evidence supports the proposed claim. This evaluation necessarily involves an assessment of the validity of studies rather than merely a search for scientific agreement.

3. Several comments stated that FDA rejected health claims for dietary fiber and cancer because of rigid application of a scientific standard higher than that mandated by the 1990 amendments and that this rejection will have unfortunate public health consequences because valuable health-related information will not be transmitted to the American population.

FDA does not agree that it has applied a scientific standard higher than the one set out in section 403(r)(3)(B)(i) of the act. As required by the statute, FDA evaluated possible health claims for dietary fiber and cancer by inquiring whether, based on the totality of publicly available scientific evidence (including evidence from well-designed studies), there is significant scientific agreement among qualified experts that the claim is supported. FDA is codifying the scientific standard of section 403(r)(3)(B)(i) of the act at 21 CFR 101.14(c) in the final rule on general requirements for health claims, which is published elsewhere in this **Federal Register**.

4. Several comments stated that FDA used different criteria to assess the relationship between dietary lipids and cancer and the relationship between dietary fiber and cancer.

FDA disagrees with this comment. In reviewing the scientific literature, FDA followed the standard mandated by the 1990 amendments. However, the strength and consistency of the data in these two areas led the agency to reach two different conclusions about permitting health claims.

Assessments of the relevant scientific data, in Federal Government reports and other authoritative documents, have consistently concluded that dietary fat contributes to the risk of cancer at certain sites. In developing its proposed rule on this relationship (56 FR 60764), the agency found that new evidence was consistent with these earlier conclusions. Based on the totality of the evidence, FDA concluded that diets low

in total fat are associated with a reduced risk of some types of cancer.

In contrast, authoritative scientific documents, including Federal Government reports, have concluded that a number of components of diets rich in fruits, vegetables, and grain products contribute to their beneficial effect on cancer. For example, in its summary on dietary fiber and cancer in the National Academy of Sciences' report "Diet and Health: Implications for Reducing Chronic Disease Risk"("Diet and Health") (Ref. 30), the Committee on Diet and Health stated that "[E]ven where the evidence is strongest, it is not possible to adequately separate the effects of fiber from those of other components of the diet (e.g., total calories, fats, vitamins, minerals, and nonnutritive constituents of fruits and vegetables) and nondietary factors (e.g., socioeconomic status)." Similarly, "Healthy People 2000: National Health Promotion and Disease Prevention Objectives" ("Healthy People 2000") (Ref. 46) notes that recommendations from the National Cancer Institute (Refs. 53 through 55), the Surgeon General's Report, the National Academy of Sciences' "Diet and Health," and "Nutrition and Your Health: Dietary Guidelines for Americans" support increased consumption of vegetables, fruits, and whole grains and cereals (Refs. 47, 30, and 45, respectively). In developing its proposed rule on dietary fiber and cancer, the agency found that new evidence did not alter these earlier conclusions. Rather, the agency found that the available scientific evidence was not sufficiently conclusive or specific for fiber per se to justify a health claim relating intake of dietary fiber alone to reduced risk of cancer.

5. Several comments stated that there were disparities in the agency's treatment of confounders, the weight given clinical studies, and emphasis on animal studies between the proposed rules on fat and cancer and on fiber and cancer. One comment stated that FDA criticized several of the fiber and cancer studies because it was not possible to separate the effects of dietary fiber from the effects of a reduced fat intake, but that the agency did not make this criticism of the fat and cancer studies.

FDA disagrees with these comments. In the fiber and cancer studies referred to in the comment, dietary fat was decreased and dietary fiber was increased; therefore, the effects could not be separated. In the majority of the fat and cancer studies, however, dietary fat was decreased and dietary fiber remained the same. Therefore, the reduction in risk of cancer observed in these studies could not have been due to an increased fiber intake.

FDA also disagrees that it relied excessively on animal studies in the fat and cancer proposal. As FDA noted in the proposed regulation on dietary fiber and colon cancer (56 FR 60566), in general, animal studies on fiber show no consistent protective effect. In contrast, animal studies on fat and cancer, taken as a whole, support a promoting effect of fat on carcinogenesis at several sites independent of the effect of energy intake. Human studies on fat are also generally supportive of a promoting effect of fat on carcinogenesis with respect to some types of cancer. The evidence on the relation between fat and cancer is further discussed in the document "Dietary Lipids and Cancer" published elsewhere in this issue of the **Federal Register**.

6. One comment stated that there are several clinical studies on fiber and few on fat and, therefore, the health claim on fiber and cancer should be approved.

FDA disagrees with this comment. The available clinical studies on fiber investigate its relationship to precursor lesions such as polyps, dysplasias, and abnormal cell morphology of the colonic epithelium, rather than to cancer itself. These studies are difficult to interpret, because at this time the actual risk factors for colorectal cancer are still incompletely understood. Moreover, it is not known how valid are markers such as secondary bile acid concentration, fecal mutagenicity, fecal weight, fecal deoxycholic acid, and activity of fecal bacterial enzymes as surrogates for the disease of colon cancer. Additional studies are needed to establish which, if any, of these factors affect the development of human colon cancer.

7. Some comments stated that FDA failed to justify its rejection of authoritative Federal Government reports (specifically, National Cancer Institute (NCI) recommendations containing the word "fiber").

FDA does not agree that, in developing its proposed rule regarding fiber and cancer, it rejected conclusions of Federal Government reports. Some comments, by citing only those portions of dietary recommendations that include the word "fiber," seek to attribute the protective effects of diets high in fruits, vegetables, and grain products to fiber per se. FDA believes that this emphasis distorts the meaning of sound dietary recommendations by failing to acknowledge the important contributions to reduced risk of disease of the wide variety of nutrients and non-nutritive substances present in diets high in fruits, vegetables, and grain products. Such an emphasis also focuses attention away from changes in overall dietary patterns and their potential contribution to reducing risk of chronic diseases.

To date, neither the Surgeon General's Report on "Nutrition and Health" (Ref. 47), the National Academy of Sciences' "Diet and Health" (Ref. 30), nor DHHS' "Healthy People 2000" (Ref. 46) has found the scientific evidence strong enough to attribute the protective effects against cancer of dietary patterns high in fruits, vegetables, and grain products solely to the fiber content of such diets. The recommendations in the Surgeon General's Report (the Report) include increased consumption of whole grain foods and cereal products, vegetables (including dried beans and peas) and fruits (Ref. 47). The Report states, "While inconclusive, some evidence also suggests that an overall increase in intake of foods high in fiber might decrease the risk for colon cancer. Among several unresolved issues is the role of various types of fiber, which differ in their effects on water-holding capacity, viscosity, bacterial fermentation, and intestinal transit time."

Similarly, the National Research Council's "Diet and Health" recommends, "Every day eat five or more servings of a combination of vegetables and fruits, especially green and yellow vegetables and citrus fruits. Also, increase intake of starches and other complex carbohydrates by eating six or more daily servings of a combination of breads, cereals, and legumes." (Ref. 30). The summary concludes:

> Studies in various parts of the world indicate that people who habitually consume a diet high in plant foods have low risks of atherosclerotic cardiovascular diseases, probably largely because such diets are usually low in animal fat and cholesterol. Some constituents of plant foods, e.g., soluble fiber and vegetable protein, may also contribute—to a lesser extent—to the lower risk of atherosclerotic cardiovascular diseases. The mechanism for the link between frequent consumption of vegetables and fruits, especially green and yellow vegetables and citrus fruits, and decreased susceptibility to cancers of the lung, stomach, and large intestine is not well understood because the responsible agents in these foods and the mechanisms for their protective effect have not been fully determined. However, there is strong evidence that a low intake of carotenoids, which are present in green and yellow vegetables, contributes to an increased risk of lung cancer. Fruits and vegetables also contain high levels of fiber, but there is no conclusive evidence that the dietary fiber itself, rather than other nutritive and non-nutritive components of these foods, exerts a protective effect against these

cancers. The Committee does not recommend the use of fiber supplements.

"Healthy People 2000" (Ref. 46) notes that recommendations from the National Cancer Institute, the Surgeon General's Report, the National Academy of Sciences' "Diet and Health," and "Dietary Guidelines for Americans" support increased consumption of vegetables, fruits, and whole grain breads and cereals (Refs. 47, 30, and 45, respectively).

The agency's decision to prohibit the use on the label or labeling of foods of health claims relating intake of dietary fiber to decreased risk of cancer is consistent with the conclusions of Federal Government and other authoritative reports. Moreover, the agency's determination in this final rule to authorize a health claim relating diets low in fat and high in fiber-containing grains, fruits, and vegetables to a reduced cancer risk is quite consistent with the conclusions of these reports.

8. Several comments criticized the agency for starting its review of the scientific literature with consensus documents and Government reports rather than conducting its own review of the older literature and, secondly, for focusing on the scientific evidence concerning the relationship between dietary fiber and colorectal cancer rather than on that between insoluble fiber and colorectal cancer.

FDA disagrees with these comments. In evaluating the publicly available evidence for each of the 10 health claim topics, FDA reviewed the evidence and conclusions reached in several Federal Government documents and in other reports from recognized scientific bodies (56 FR 60566). These authoritative documents represent comprehensive reviews and evaluations of the literature available at the time of their publication (generally from 1987 to 1989) and represent scientific consensus at that time. Although the reports may not have referenced a particular study described in the comment, it is improbable that the studies reviewed in the reports missed an important effect.

In preparing its proposed rule, FDA updated these reports by independently reviewing subsequently published studies. In addition, to ensure that its review of relevant evidence was complete, FDA requested in the **Federal Register** of March 28, 1991 (56 FR 12932), scientific data and information on the 10 specific topic areas. The agency also reviewed and considered comments received in response to that **Federal Register** notice in developing its proposed rules. In reviewing the totality of the publicly available evidence, FDA considered studies that addressed the relationship between dietary fiber and colorectal cancer and those that addressed the relationship between insoluble fiber and colorectal cancer.

9. One comment questioned the motivation behind the agency's tentative rejection of health claims for fiber and cancer. The comment stated that the National Cancer Institute did not endorse health claims on dietary supplements, and stated that health claims for fiber should not be prohibited based on a concern that dietary supplements will be able to bear claims. Comments from supplement manufacturers asserted that, if health claims are permitted on foods containing fiber, then fiber supplements should also be permitted to carry claims. The comment argued that there is no difference between fiber in foods and fiber in supplements and that all fiber supplements are safe, although data were not included to substantiate such a claim.

FDA does not agree that its motivation for rejecting health claims associating dietary fiber and reduced cancer risk was to prevent supplement manufacturers from making such claims. As the agency's proposal makes clear, FDA tentatively decided to deny health claims for dietary fiber and cancer because the currently available scientific evidence is not sufficiently conclusive or specific for fiber per se to justify such a claim, not because the agency wishes to preclude use of such a claim on dietary supplements.

B. Comments Regarding a Relationship Between Dietary Fiber and Cancer

10. Several comments stated that health claims for insoluble fiber, particularly grain fiber, should be allowed. Another comment stated that wheat bran and related products that affect gastrointestinal transit time and fecal weight may help prevent colon cancer when consumed with a diet low in saturated fat and high in plant foods. This comment argued that the fact that animal studies show a protective effect in the colon by fibers with bulking properties is more important than understanding the underlying mechanism. The comment stated further that only specific fibers shown in animal studies to be protective, such as whole grain wheat, should be permitted to carry label claims.

FDA disagrees with these comments. Animal data are not consistent in showing a protective effect for insoluble dietary fiber. Indeed, corn bran, a predominantly insoluble fiber source (78 percent neutral detergent fiber), has been shown in three animal studies to enhance chemical carcinogenesis in rodents (Refs. 59, 60, and 61). While it is true that animal feeding studies using wheat bran are the most consistent in showing protective effects, animal data cannot be applied directly to humans. Taken together, the evidence for a significant role of wheat fiber in humans is still controversial. The number of human studies breaking fiber down by type (soluble, insoluble, etc.) is too small to be considered more than preliminary. Only two studies published since 1987 consider fiber type, while seven consider total fiber by source (fruit, vegetable, or grain), and five consider total dietary fiber as a single entity. The authors of a recent study state in their conclusion, "The efficacy of grain fiber in reducing the risk of colon and rectal cancer remains in question. While our results indicate some protective effect for the colon for grain fiber, most other studies do not find a grain effect" (Ref. 9). For example, the 1988 study by Slattery et al. (Ref. 40) found no effect of grain fiber.

11. Another comment provided data from an animal study that showed that wheat bran is superior to cellulose in reducing the incidence of colonic tumors in rats treated with the colonic carcinogen 1,2 dimethylhydrazine (Ref. 67). The data show that, even among insoluble fibers, differences exist in their effects on tumorigenesis. The study also showed that cellulose was more effective in reducing fecal bile acid concentrations compared to wheat bran, although this difference was apparently not statistically significant. Elevated fecal bile acid concentrations are putative risk factors for colon cancer, although in this study the cellulose group, with its lower fecal bile acid concentration, actually had significantly more colon tumors than the wheat bran group. This may further call into question the importance of dilution of fecal bile acids by fiber, a potential mechanism of action cited in this and other comments.

FDA notes that such results support its tentative conclusion in the proposed rule that fibers (even insoluble fibers) have different effects. The importance of bile acid dilution as a mechanism for effects of fiber remains to be determined.

12. One comment provided that the 1989 study by West et al. (Ref. 48), reviewed in the proposal, did control for micronutrient intake.

FDA agrees that this was incorrectly reported in the proposed rule.

13. A comment stated that the 1989 intervention study by DeCosse et al (Ref.

7) is relevant to the fiber-cancer relationship.

FDA disagrees with this comment. The patients in this study had no colons and, therefore, metabolized fiber differently and developed lesions at a different site from colon cancer patients. For these reasons, FDA believes that this study does not contribute to understanding the fiber-cancer relationship.

14. A comment cited the study of Rosen et al. (Ref. 37) to support the role of grains in reducing the risk of colon cancer.

FDA disagrees with this comment. The comment did not mention that the referenced study examined mortality data from 1969 to 1978 and surveyed food expenditures for 1978 only. Thus, the individuals who died of colon cancer had been dead for up to 10 years when the food expenditure data was collected. It is a weakness of this study that only a single year's food survey (1978) data were used, while mortality figures from the previous 10 years are incorporated. It is possible that this type of food data collection would accurately reflect the diet of the group which died from colon cancer up to 10 years earlier.

15. Several comments stated that studies with statistically insignificant but generally favorable results should be regarded as supportive of the relationship between fiber and cancer risk reduction.

FDA disagrees with this comment. Lack of statistical significance indicates that such findings could have arisen by chance and thus cannot be used to support a causal relationship.

16. One comment stated that overestimation of fiber intake (by inaccurate dietary or analytical methods) will result in underestimation of risk reduction.

FDA disagrees with this comment. Fiber consumption may be overestimated by a consistent factor in both the control and cancer groups. Such overestimation would have the effect of multiplying the intake of both groups by a common factor; for example, it could increase the intake in both groups by 30 percent. The differences between groups would also be multiplied by this common factor, and should be no less readily apparent than without this factor of overestimation, provided fiber intake is overestimated in each group to the same extent. Only if fiber intake were consistently overestimated in the cancer group, but not in the control group, would there be an apparent reduction of a protective effect. Because the same survey and analytical methods were applied to both groups, this seems an unlikely occurrence.

FDA recognizes that imprecise measures of fiber intake will usually tend to reduce associations between fiber intake and risk. Imprecise measurements do not necessarily result in overestimation of fiber, but merely inaccuracy in reporting the fiber content of certain foods. Lack of accuracy will hinder demonstration of a true relationship if one indeed exists between fiber and colon cancer risk reduction.

17. One comment noted that lack of a known mechanism of action for the putative effects of fiber in colon cancer risk reduction should not prevent the acceptance of claims of fiber's usefulness for this purpose. The comment made an analogy to drugs, arguing that they are often approved simply on evidence of efficacy, without clear knowledge of their mechanism of action.

FDA does not believe that the comparison to drug approval is apt. Drugs are substances of known chemical composition. In contrast, it is not known what fiber component or components may be responsible for the effects observed in some epidemiological studies. Fiber is a complex mixture of cellulose, hemicellulose, pectic substances, or other polysaccharides. Some of these materials, when isolated, have been found to promote rather than inhibit chemical carcinogenesis in rodents. Certainly it has not been established which of the components (all of which are types of "fiber") may reduce the risk of colon cancer in humans. Thus, more is at issue here than the mechanism of action; the identity of the actual active agent, if any, is also obscure.

18. One comment noted that fat and fiber intake correlate inversely with one another in many studies, and that this correlation is often statistically significant.

FDA notes that correlations between two dietary variables within a study do not demonstrate that either is causally related to the study endpoint (cancer). Rather, the two measures are merely associated with one another, in such a way that when one increases, the other decreases, and vice versa. Therefore, such a finding does not imply that increased fiber intake is causally related to decreased cancer incidence.

19. A comment noted that increasing fiber intake may promote decreased energy intake and that adding fiber in purified form to foods is not known to be harmful. The comment cited a 13-week study of oat hull feeding in rats as support.

FDA disagrees with this comment and notes that decreased energy intake in response to high fiber intake has not been shown consistently in all animal studies in which fiber-fed groups generally had similar body weights compared to no-fiber groups. FDA also disagrees with the broad statement that adding purified fiber to foods is not known to be harmful. A 13-week study dealing with one specific type of fiber is not sufficiently long to address chronic safety issues about all types of fiber. Nor were the full battery of toxicological endpoints customarily examined in safety evaluations performed in this study.

C. Food Claims Versus Nutrient Claims

In its proposed rule, FDA specifically requested comments on how best to inform consumers of the general dietary guidance to increase consumption of fruits, vegetables, and whole grain products that are rich sources of dietary fiber and other nutrients. In response to this request, FDA received a wide range of comments expressing strong support for health claims for foods rather than only for specific nutrients. National cancer research and health organizations, consumers, and consumer advocacy groups recommended allowing claims for whole foods. Several comments from the food industry also supported health claims for whole foods. These comments are summarized below.

20. Many comments supporting health claims for foods recommended that only those foods high in fiber should be permitted to carry a claim and that claims should not be allowed if they give the impression that dietary fiber, as a single nutrient, is responsible for the reduction in cancer risk associated with diets high in fruits, vegetables, and grain products.

FDA agrees with this comment that a health claim should not give the impression that a single nutrient is responsible for the reduction in cancer risk. Where the evidence is strongest, it is not possible to separate the effects of fiber from those of other components of the diet, such as fat, total calories, and vitamins.

21. Another comment stated that because the public is advised to increase its daily intake of dietary fiber, FDA should "exert control where it is needed" to avoid abusive use of fiber in foods and supplements. The comment stated that specific foods (e.g., no-fiber foods to which fiber is added) and fiber supplements should not be allowed to bear health claims.

FDA has determined that a health claim relating dietary fiber to cancer is

not supported by the totality of the publicly available scientific evidence. The claim that the agency is authorizing deals instead with diets high in fruits, vegetables, and grain products and may be carried by fruits, vegetables, and grain products that, without fortification, qualify as "good sources" of dietary fiber. This claim respects the state of the scientific evidence; it does not represent a position that other foods, including supplements, may not be able to bear a fiber/cancer claim in the future, should appropriate evidence demonstrating the validity of such a claim be brought to the agency's attention.

22. Other comments supported narrowly worded statements concerning overall diets and their effect on risk of cancer.

FDA agrees with this comment that a health claim, as outlined in the final rule, "Labeling; General Requirements for Health Claims for Food," should be stated in context of the total diet. Certain statements about overall diets and their effects on disease or health-related conditions would be considered dietary guidance and not regulated as health claims. In this rule, FDA is authorizing a reference to certain substances (fat and fiber) as part of a statement relating diets high in fruits, vegetables, and grain products to cancer risk.

23. Some comments stated that, if claims are allowed for fiber-containing foods, the fat content should be disclosed on the label.

FDA shares the comments' concern about the fat content of foods bearing the authorized claim. For a food to qualify for a health claim under § 101.76, it must meet the requirements for a "low fat" food as defined under § 101.62.

24. Some comments provided recommendations for developing regulatory criteria. For example, several comments stated that all foods, whether fresh or processed, should meet the same standards. Other comments stated that fiber-only products should be carefully evaluated to ensure that they qualify as foods according to criteria defined in the proposed regulations.

FDA notes new § 101.76(c)(2)(ii) contains the criteria that food must meet to qualify for the authorized health claim. A food must be or contain a fruit, vegetable, or grain product; must be "low fat;" and must be a "good source" of fiber.

25. Several comments noted that FDA acknowledges that virtually all dietary guidelines for Americans have encouraged consumption of fiber-rich foods, including whole grain cereals, fruits, and vegetables, and that comprehensive government reviews and other reviews by recognized scientific bodies have concluded that dietary patterns that include fiber-rich foods are associated with reduced risk of colorectal cancer, coronary heart disease, and other chronic diseases. The comment asserted that FDA should authorize the use of health claims for the relationship between dietary fiber and cancer.

FDA disagrees that the evidence is sufficient to support a claim that dietary fiber, as a single nutrient, is responsible for the reduction in cancer risk. However, FDA is authorizing a claim relating diets high in fiber-containing grain products, fruits, and vegetables to reduced cancer risk.

26. The American Cancer Society commented that it is unclear what aspect of fiber-rich foods reduces the risk of colorectal cancer. According to the American Cancer Society, the evidence does show, however, that fiber-rich diets reduce the risk of cancer. In its nutrition guidelines, the Society recommends that people "eat more high fiber foods, such as whole grain cereals, legumes, vegetables, and fruits." This recommendation emphasizes the importance of the total diet rather than individual components of it. The American Cancer Society recommended the use of a general food claim at the point of purchase that does not mention fiber or specific cancer sites. The comment stated further that, although the American Cancer Society does refer to the cancer prevention possibilities of fiber-rich foods in its educational materials, the American Cancer Society does not think this reference should be stated on food labels, because it is still unclear which qualities of such foods actually reduce cancer risk. For example, many fiber-rich foods are also low in fat and high in antioxidant vitamins. The American Cancer Society believes that if a claim is allowed, it should not be used on food labels unless the food meets the requirements for a "high fiber" nutrient content claim.

The National Cancer Institute supports the use of health claims on whole foods and diets high in fiber-containing foods and low in fat. Their comment stated that there is substantial and sufficient evidence that consumption of diets high in fruits, vegetables, and cereal grains are associated with the reduced risk of some types of cancer, particularly colorectal cancer. The National Cancer Institute recommended that the statement "high fiber diets" or some similar term be included in the label claim. In contrast to the American Cancer Society, the National Cancer Institute also recommended that only foods that contain naturally occurring fiber be allowed to carry a claim relating consumption of vegetables, fruits, and grain products to reduced risk of cancer. The comment stated that there is no agreement among scientific experts that fiber from fortified foods and supplements has a similar protective effect. In addition, the National Cancer Institute expressed safety concerns relative to the consumption of large amounts of fiber from a single dietary source.

FDA agrees that dietary patterns with higher intakes of vegetables (including legumes), fruits, and whole grains are associated with a reduced risk of some types of cancer (see Refs. 15, and 21 through 23 in the proposed rule (56 FR 60566) and Ref. 56 in this document). Although the specific roles of the numerous potentially protective substances in plant foods are not yet understood, populations with diets rich in these foods experience many health advantages, including lower rates of some cancers. Currently, there is not scientific agreement about whether the observed protective effects against cancer are due to a combination of the nutrient components of the foods, including fiber, to other components of the diet (for example, minerals, vitamins, etc.), or to displacement of other foods in fiber-rich diets (for example, replacement of meats, fats). Rather, the evidence currently demonstrates that it is the dietary pattern, and not a single nutrient, that is important in the reduction in risk of diseases such as cancer. If the scientific evidence were sufficient to support a health claim regarding the relationship between dietary fiber and cancer, no distinction would be made between "naturally occurring" fiber and fiber supplements. The final rule on general requirements for health claims, published elsewhere in this issue of the **Federal Register**, treats dietary supplements and conventional foods consistently.

III. Review of the Recent Scientific Evidence

A. Human Studies

FDA has reviewed studies that became publicly available after the publication of its proposed rule and data submitted as comments. These studies are summarized in Table 1.

A case control study by Soltero et al. (Ref. 56) in Puerto Rico focused on prior cholecystectomy as a risk factor for right-sided colon cancer. A food frequency questionnaire was also

administered to the subjects (or next of kin, if subjects were deceased). Cholecystectomy was confirmed to be a significant risk factor for right-sided colon cancer. Subjects with cancer reported consumption of significantly more meat and poultry and less fiber (as crude fiber) and vegetables than controls. Differences in fat intake were not statistically significant. It was not clear from the report if fiber included all sources of fiber or only cereal fiber. A protective effect was also seen for vegetables; it cannot be determined whether the effect reported for fiber was due to fiber itself or to other nutrient constituents of fiber-containing foods.

Giovannucci et al. (Ref. 62) studied a cohort of 49,296 U.S. health professionals, 40 to 75 years of age, for 2 years. The authors recorded diet by questionnaire and assessed colonic adenoma incidence based on sigmoidoscopy biopsy reports. Intake of animal fat was found to be positively associated with polyp incidence. Fiber from either fruits, vegetables, or grains were all significantly protective, whether measured as crude fiber or dietary fiber. Vegetable-associated nutrients (potassium, β-carotene, vitamins C and E) were also protective, but in a combined statistical analysis they did not account for the independent effect of fiber. Three factors limit the applicability of these findings. (1) The total fat intake of most of the subjects was low by general population standards; (2) right-sided lesions in the colon were not considered, and therefore no conclusions can be drawn about right-sided colon cancer from these data; and (3) all of the study subjects were men. A large cohort study involving U.S. nurses, the majority of whom were female, published in 1990, showed no protective effect of fiber or its components on colon cancer (Ref. 49). Giovannucci et al. do not address the differences between these two studies.

Kune et al. (Ref. 63) studied dietary factors in a case-control study of colonic polyp patients. Forty-nine patients with histologically confirmed colonic polyps (greater than 1 centimeter in size) were interviewed about their dietary practices from the previous 20 years. Interview results were compared with those of 727 community controls. Consumption of fiber and vegetables was associated with a significantly reduced relative risk (in both sexes) of polyps, while consumption of milk, beef, and beer were all associated with significantly increased risk (in males only). The study combines fiber and vegetable consumption, making it difficult to assess any independent role of fiber. Micronutrient intake from vegetables (except vitamin C), exercise, and total energy intake are potential confounding variables that were not controlled.

Gregoire et al. (Ref. 64) examined rectal cell proliferation, fecal bile acid concentration, and fecal pH in a 5-day feeding study in normal, healthy volunteers. Groups of 10 or 11 subjects consumed either a low fat/low fiber, low fat/high fiber, high fat/low fiber, or high fat/high fiber diet. Fiber was derived from a bread containing 43 percent wheat bran, 45 percent wheat flour, and 2 percent gum tragacanth as fiber sources. Approximately 41 grams (g) per (/) day of fiber were consumed in the high-fiber groups, versus 6 to 7 g/day in low fiber groups. Statistical analysis for main effects of fiber on labeling index, fecal pH, and fecal bile acid concentration revealed no statistically significant effects.

Entry of fiber into the colon influences short-chain fatty acid production. Cell culture studies have suggested that altered concentrations of short-chain fatty acids within the colon may influence colonic carcinogenesis. Butyrate production may be especially protective. Clausen et al. (Ref. 65) studied fecal short-chain fatty acid composition in 16 controls, 17 patients with resected adenomatous polyps, and 17 patients with resected colonic cancer. An analysis of fresh feces from the three groups revealed no significant differences in types or relative amounts of fecal short-chain fatty acids. Feces were also incubated in vitro for 6 to 24 hours with added boluses of wheat bran or psyllium. Under these conditions, relatively less butyrate was produced by inocula from adenoma and carcinoma patients. The authors propose that reduced butyrate production in patients may be of significance in the etiology of the neoplasms, although the butyrate content of the feces from cases was similar to that of control subjects when not incubated in vitro. It cannot be determined whether the same effects in the in vitro incubations would occur in vivo if the subjects were fed wheat bran or psyllium. The role of butyrate and other short-chain fatty acids in human colon carcinogenesis has not been clearly established.

McGarrity et al. (Ref. 66) studied the effects of fat and cellulose fiber on the growth and biochemical characteristics of two human colon cancer cell lines implanted subcutaneously in nude mice. Mice received either a low fat/low fiber diet, a high fat/low fiber diet, or a high fat/high fiber diet. The added cellulose tended to eliminate the growth-enhancing properties of a high fat diet, but the effects were not statistically significant. Differences in weight gain among the different groups at least partially explained the differences in tumor growth observed. Results with implanted tumors at a noncolonic site cannot be directly generalized to spontaneous colon tumors, which are exposed to the colonic contents as well as to the systemic blood supply.

Reduced fecal bile acid content is thought to be a beneficial factor for colon cancer risk. One comment described preliminary results of a human dietary intervention study (Ref. 58) in this area that has not yet been published. In this study, female subjects consumed wheat, corn, or oat bran supplements in addition to their usual diets. Fecal bile acids, neutral sterols, and fecal enzymatic activities of enzymes that produce fecal mutagens or carcinogens were measured before and after the intervention. Wheat bran supplementation reduced the activity of all four "risk factor" enzymes studied, while oat bran produced significant reductions in three of four enzymes, and corn bran produced significant reductions in only two of four. Alterations in stool weight are probably responsible for some of these changes. Wheat bran supplementation significantly reduced total and secondary bile acid concentration in feces, while oat bran and corn bran did not.

B. Conclusions From New Studies

These additional studies provide further data on the possible link between consumption of dietary fiber consumption and reduced risk of colon cancer. With the exception of the study by Giovannucci et al. (Ref. 62), none of the studies provides evidence of an independent contribution of fiber itself (distinct from its presence in food) to risk reduction. Rather, the studies show a relationship between diets rich in fiber-containing foods and reduced risk of cancer. The Giovannucci et al. study is limited in its applicability, however, as only lesions of the descending colon were considered, and the subjects were men who already consumed a diet lower in fat and higher in vegetables than a typical U.S. diet.

The preliminary results of Reddy's study (Ref. 58) on the effects of amount and type of dietary fiber on colonic bacterial enzymes and bile acids in humans support FDA's observations that insoluble fiber has not consistently been shown to be the protective fiber fraction. Wheat bran and corn bran (both largely insoluble fibers) exerted opposite effects in this risk factor study, as they do in most published animal

carcinogenesis studies. It must also be noted that the risk factors measured in this study have only postulated significance in the etiology of human colon cancer at the present time.

Although the current scientific evidence does not support a specific health claim for dietary fiber and reduced risk of cancer, the data do support a relationship between diets high in fiber-rich foods and low in fat and a reduced risk of some forms of cancer. Therefore, as discussed below, FDA will allow a health claim on vegetables, fruits, and grain products relating diets high in these foods to a reduced risk of cancer, and specifying that these foods contain dietary fiber.

IV. Decision to Deny a Health Claim Relating Dietary Fiber to a Reduced Risk of Cancer

Overall, the currently available scientific evidence is not sufficiently conclusive or specific for fiber per se to justify use of a health claim relating the intake of dietary fiber to a reduced risk of cancer. A major limitation in designing and evaluating research studies has been the need for better defined measures of dietary fiber and standardized descriptions for source, type, and amount of dietary fiber. Commonly used analytical methodologies do not detect many of the characteristics that may vary among fibers and that may be related to biological function (e.g., particle size, chemical composition, water-holding capacity). The inability to detect many of the differences among fibers and the general lack of clear evidence as to the mechanisms of action of fibers raise questions about the ability of commonly used analytical measures of dietary fiber to adequately predict biological actions of specific fibers. Therefore, for these reasons, new § 101.71(a) is added to reflect FDA's decision not to authorize use of a health claim relating dietary fiber to a decreased risk of cancer.

FDA's decision is consistent with recent recommendations in the Institute of Medicine's report "Nutrition Labeling: Issues and Directions for the 1990s" (Ref. 57). This report notes that there has been great interest in the specific effects of dietary fiber on several chronic diseases. According to the report, the strongest argument for an increased consumption of dietary fiber is the important contribution it makes to normal bowel function. Clear scientific associations of fiber intake with the incidence of cancer have not been made. The report indicates that one reason for this may be the difficulty in designing appropriate experiments to test specifically for the effect of dietary fiber. Foods high in dietary fiber are also generally low in calories and total and saturated fatty acids and devoid of cholesterol; thus, determination of a specific fiber effect in a feeding study is difficult. Moreover, according to the report, foods have a variety of fiber components and each may have different actions. Chemically and physiologically, cellulose, lignin, hemicellulose, pectin and alginate (all relatively purified fiber types) behave differently. Wheat bran, oat bran, and rice bran (all heterogenous mixtures of fibers) are not similar in composition. It is also very difficult to analyze dietary fiber chemically, and thus it is hard to correlate the role of specific fiber components to health effects (Refs. 30 and 57).

Therefore, FDA is not authorizing the use on the labels and labeling of foods of health claims relating to an association between the ingestion of dietary fiber and a reduction in the risk of cancer. In reaching this decision, the agency considered all comments received in response to its proposed rule (56 FR 60566), and reviewed the scientific literature that became publicly available after the proposal's publication and data submitted with comments.

V. Decision to Allow a Health Claim on Foods Relating Diets Low in Fat and High in Fiber-Containing Grain Products, Fruits, and Vegetables to a Reduced Risk of Cancer

FDA has reviewed numerous authoritative documents, including Federal Government reports, as well as recent research on dietary fiber and cancer risk. In addition, the agency considered all comments received in response to its proposed rule. The agency has concluded that the publicly available scientific evidence supports an association between diets low in fat and high in fiber-containing grain products, fruits, and vegetables and reduced risk of cancer.

FDA agrees with the comments that argue that dietary patterns that are low in fat and high in fiber-containing grain products, fruits, and vegetables (including legumes), are associated with a decreased risk of some types of cancer. Although the specific role of total dietary fiber, fiber components, and the multiple nutrients and other substances contained in these foods are not yet fully understood, many studies have shown that diets high in fiber-containing foods are associated with reduced risk of some types of cancer.

Thus, the conclusion that diets low in fat and high in fiber-containing grain products, fruits, and vegetables, foods also generally low in fat, are associated with a reduced risk of cancer is consistent with the available scientific evidence. As discussed in the final rule on general requirements for health claims, published elsewhere in this issue of the **Federal Register**, statements about good nutrition that do not expressly or by implication refer to a substance are considered dietary guidance and not health claims. In this rule, FDA is authorizing the inclusion of a reference to dietary fiber in a statement about the value of grain products, fruits, and vegetables in reducing cancer risk. Thus, the health claim permitted under this regulation to be used on the label or labeling of certain foods associates diets low in fat and high in fiber-containing grain products, vegetables, and fruits with a reduced risk of some cancers.

VI. Description of and Rationale for Components of the Health Claim.

A. Relationship and Significance Statements

In new § 101.76(a), the summary of the relationship between diets high in fiber-containing grain products, fruits, and vegetables and reduced cancer risk is consistent with the conclusions reached in the review of the scientific evidence. It is not known whether it is fiber, per se, or some other substance in fruits, vegetables, and grain products that functions as the protective agent; or, if it is fiber, what types and characteristics of the heterogeneous family of fiber compounds are most beneficial. Yet, because of the usefulness of dietary fiber in identifying the types of foods most likely to correlate with reduced cancer risk, fiber is specifically identified as being characteristic of the protective dietary pattern. Thus fiber can serve as the identifying marker. Other components of the relationship statement, for example, risk factors, have been indicated, as in other authorized health claims.

New § 101.76(b), on the significance of the relationship between consumption of diets low in fat and high in fiber-containing grain products, fruits, and vegetables and reduced risk of cancer, includes the information that U.S. diets tend to be high in fat and low in grains, fruits, and vegetables. A discussion of current dietary guidelines on recommended servings of grain products, fruits, and vegetables is also provided.

B. Nature of the Claim

In new § 101.76(c)(2)(i), FDA is authorizing a health claim relating

substances in diets low in fat and high in fiber-containing grain products, fruits, and vegetables to reduced risk of cancer. In new § 101.76(c)(2)(i)(A), the agency is requiring, consistent with other authorized claims, that the relationship be qualified with the terms "may" or "might." These terms are used to indicate that not all persons can necessarily expect to benefit from these dietary changes.

In new § 101.76(c)(2)(i)(B), the agency, consistent with other authorized claims, is requiring that the claim not indicate that all cancers may be affected, but rather that the risk of "some types of cancer" or "some cancers" may be reduced. The relationship between dietary factors and various types of cancers is variable; in many cases, the available data are inadequate to specifically identify which cancers may be affected.

In new § 101.76(c)(2)(i)(C), the agency is requiring that the claim be limited to grain products, fruits, and vegetables that contain dietary fiber. As noted in the conclusions reached from the available scientific evidence, it is not known what fiber substance or other substances in grain products, fruits, and vegetables are responsible for their protective effect. A role for dietary fiber has been hypothesized and has biological plausibility. Intakes of fiber and other nutrients from grains, fruits, and vegetables are correlated with reduced cancer risk. By requiring that the characterizing nutrient be identified as characteristic of a dietary pattern rich in fiber-containing grains, fruits, and vegetables, without specifically attributing the cause to a nutrient, the claim is more consistent with the current scientific knowledge. The claim should also minimize consumer confusion, because its wording is similar to current dietary guidelines from the U.S. Government, including the National Cancer Institute.

New § 101.76(c)(2)(i)(D) requires that health claims indicate that development of cancer depends on many factors. This requirement is intended to prevent consumers from being misled that grain product, fruit, and vegetable intake is the only factor connected with cancer risk. In new § 101.76(c)(2)(i)(E), FDA, consistent with other authorized health claims, is prohibiting the attribution of a specific reduction in risk of cancer to diets low in fat and high in fiber-containing grain products, fruits, and vegetables. In new § 101.76(c)(2)(i)(F) and (c)(2)(i)(G), FDA is prohibiting, consistent with other authorized health claims, more specific use of dietary terms than is warranted by the current state of the scientific evidence. These requirements also standardize use of these terms, thus minimizing consumer confusion as they compare food labels across products, or as they compare a health claim to the nutrition information panel.

C. Nature of the Food

New § 101.76(c)(2)(ii)(A) requires that the food bearing the health claim be or contain a grain product, fruit, or vegetable. Because the claim relates to diets high in these foods, it would not make sense for it to appear on the labeling of another type of food. A health claim that appears on a food that meets all the requirements in § 101.76(c)(2)(ii), but contains only a trivial amount of grain product, fruit, or vegetable, could be considered misleading and might misbrand the food under section 403(a) of the act. FDA, consistent with the requirements for the health claim on dietary fat and cancer (published elsewhere in this issue of the **Federal Register**), is requiring in new § 101.76(c)(2)(ii)(B) that foods bearing the health claim be "low fat" foods, or alternatively, belong to a class of products that is "low in fat." Low fat diets are associated with reduced cancer risks. Low or negligible fat is also one of the characterizing features of diets rich in grain products, fruits, and vegetables. Because the effect of fat is not readily separated from the effect of other nutritive components of grain products, fruits, and vegetables, it is being made a qualifying nutrient.

In new § 101.76(c)(2)(ii)(C), FDA is requiring that grains, fruits, and vegetables, bearing the authorized health claim qualify as a "good source" (greater than or equal to 10 percent of the daily reference value (DRV)) for dietary fiber. The requirement that these foods contain 10 percent of the DRV for dietary fiber is being set as a specific alternate to the 20 percent (i.e., "high") requirement for qualifying nutrients in the final rule on general requirements for health claims, published elsewhere in this **Federal Register**. This alternate level was deemed useful to assure that most grain products, fruits, and vegetables, would be eligible for this health claim, because these foods in general have been correlated with reduced cancer risk, and because they are significant sources of dietary fiber in the U.S. dietary pattern. Without this alternate level, very few grain products, fruits, and vegetables, would qualify for the health claim, which would be contrary to the available scientific evidence and to the purpose of health claims.

This section also requires that foods qualify as a good source of fiber based on their natural level of fiber. This means that foods which require fortification with dietary fiber, in order to meet the qualifying criteria for the health claim, cannot bear the claim. This requirement is consistent with the scientific basis for the claim, that is, that grains, fruits, and vegetables, in their native form correlate with reduced cancer risk. Because there are not sufficient data that specifically identify dietary fiber, or particular components of fiber, as causal and because this nutrient is being used as a marker for the substance or substances in grain products, fruits, and vegetables, that provide the observed protective effect, it is the native composition of the foods that identifies their usefulness. At the same time, this requirement does not prohibit fortification of qualifying foods with dietary fiber, once the qualifying level has been met naturally.

D. Optional Information

Under new § 101.76(d), similarly to other authorized health claims, health claims may identify additional risk factors for cancer. The regulation specifies the factors that may be listed; all are risk factors about which there is general scientific agreement. This additional information can provide a context that is useful for an understanding of the relationship of the diet to the disease, but manufacturers are cautioned that it should not be presented in a way that is misleading to the consumer. A health claim may also indicate that reductions in fat intake and consumption of fruits, vegetables, and grain products are part of a total dietary pattern that is consistent with the latest "Nutrition and Your Health: Dietary Guidelines for Americans," published jointly by the U.S. Department of Agriculture and the U.S. Department of Health and Human Services (Ref. 45). Consistent with other health claim regulations, the claim may also include information on the prevalence of cancer in the United States. In order to ensure that this information is valid, the agency is requiring that it come from one of three specified authoritative sources.

E. Model Health Claims

In new § 101.76(e) FDA is providing several model health claims to illustrate the requirements of new § 101.76. FDA is not prescribing specific language for claims, but certain elements are required, and these models include the required elements.

VII. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a

type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

IX. References

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List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.71 is amended by adding new paragraph (a) to read as follows:

§ 101.71 Health claims: claims not authorized.

* * * * *

(a) Dietary fiber and cancer.

3. New § 101.76 is added to subpart E to read as follows:

§ 101.76 Health claims: fiber-containing grain products, fruits, and vegetables and cancer.

(a) *Relationship between diets low in fat and high in fiber-containing grain products, fruits, and vegetables and cancer risk.* (1) Cancer is a constellation of more than 100 different diseases, each characterized by the uncontrolled growth and spread of abnormal cells. Cancer has many causes and stages in its development. Both genetic and environmental risk factors may affect the risk of cancer. Risk factors include: A family history of a specific type of cancer, cigarette smoking, overweight and obesity, alcohol consumption, ultraviolet or ionizing radiation, exposure to cancer-causing chemicals, and dietary factors.

(2) The scientific evidence establishes that diets low in fat and high in fiber-containing grain products, fruits, and vegetables are associated with a reduced risk of some types of cancer. Although the specific role of total dietary fiber, fiber components, and the multiple nutrients and other substances contained in these foods are not yet fully understood, many studies have shown that diets low in fat and high in fiber-containing foods are associated with reduced risk of some types of cancer.

(b) *Significance of the relationship between consumption of diets low in fat and high in fiber-containing grain products, fruits, and vegetables and risk of cancer.* (1) Cancer is ranked as a leading cause of death in the United States. The overall economic costs of cancer, including direct health care costs and losses due to morbidity and mortality, are very high.

(2) U.S. diets tend to be high in fat and low in grain products, fruits, and vegetables. Studies in various parts of the world indicate that populations who habitually consume a diet high in plant foods have lower risks of some cancers. These diets generally are low in fat and rich in many nutrients, including, but not limited to, dietary fiber. Current dietary guidelines from Federal government agencies and nationally recognized health professional organizations recommend decreased consumption of fats (less than 30 percent of calories), maintenance of desirable body weight, and increased consumption of fruits and vegetables (five or more servings daily), and grain products (six or more servings daily).

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met.

(2) Specific requirements. (i) *Nature of the claim.* A health claim associating diets low in fat and high in fiber-containing grain products, fruits, and vegetables with reduced risk of cancer may be made on the label or labeling of a food described in paragraph (c)(2)(ii) of this section, provided that:

(A) The claim states that diets low in fat and high in fiber-containing grain products, fruits, and vegetables "may" or "might" reduce the risk of some cancers;

(B) In specifying the disease, the claim uses the following terms: "some types of cancer," or "some cancers";

(C) The claim is limited to grain products, fruits, and vegetables that contain dietary fiber;

(D) The claim indicates that development of cancer depends on many factors;

(E) The claim does not attribute any degree of cancer risk reduction to diets low in fat and high in fiber-containing grain products, fruits, and vegetables;

(F) In specifying the dietary fiber component of the labeled food, the claim uses the term "fiber", "dietary fiber" or "total dietary fiber"; and

(G) The claim does not specify types of dietary fiber that may be related to risk of cancer.

(ii) *Nature of the food.* (A) The food shall be or shall contain a grain product, fruit, or vegetable.

(B) The food shall meet the nutrient content requirements of § 101.62 for a "low fat" food.

(C) The food shall meet, without fortification, the nutrient content requirements of § 101.54 for a "good source" of dietary fiber.

(d) *Optional information.* (1) The claim may include information from paragraphs (a) and (b) of this section, which summarize the relationship between diets low in fat and high in fiber-containing grain products, fruits, and vegetables, and some types of cancer and the significance of the relationship.

(2) The claim may identify one or more of the following risk factors for development of cancer: Family history of a specific type of cancer, cigarette smoking, overweight and obesity, alcohol consumption, ultraviolet or ionizing radiation, exposure to cancer causing chemicals, and dietary factors.

(3) The claim may indicate that it is consistent with "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office.

(4) The claim may include information on the number of people in the United States who have cancer. The sources of this information must be identified, and it must be current information from the National Center for Health Statistics, the National Institutes of Health, or "Nutrition and Your Health: Dietary Guidelines for Americans," USDA and DHHS, Government Printing Office.

(e) *Model health claims.* The following model health claims may be used in food labeling to characterize the relationship between diets low in fat and high in fiber-containing grain products, fruits, and vegetables and cancer risk:

(1) Low fat diets rich in fiber-containing grain products, fruits, and vegetables may reduce the risk of some types of cancer, a disease associated with many factors.

(2) Development of cancer depends on many factors. Eating a diet low in fat and high in grain products, fruits, and vegetables that contain dietary fiber may reduce your risk of some cancers.

Dated: November 3, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

Note: The following table will not appear in the annual Code of Federal Regulations.

BILLING CODE 4160-01-F

TABLE

DIETARY FIBER AND CANCER

Study	Study Design	Subjects	Methods	Results	Comments
Kune et al, 1991 (Ref. 63).	Case-control	Cases: 49 patients who had one or more histologically confirmed adenomatous polyp larger than 1 cm in diameter previously removed by endoscopy. Controls: 727 community controls.	50 patients from Melbourne, Australia, who had histologically confirmed adenomatous polyps removed, were selected randomly from a pool of 223. Dietary assessment was done through dietary questionnaire and a quantitative diet history, relying upon subject recall for prior 20 years.	Those with adenomatous polyps were found to have a lower fiber/vegetable intake ($p = 0.04$). Increased consumption of milk, beef, and beer were all significant risk factors in males.	Study combines fiber and vegetable consumption. Confounders were not considered in the model, such as smoking, urban v. rural, exercise, total energy intake, micronutrients other than Vitamin C. Colorectal polyps are used as a proxy for colorectal cancer.
Clausen et al, 1991 (Ref. 65).	Correlational	16 healthy control subjects with no history of GI disease; 17 patients with resected colonic adenomas; 17 patients with resected colonic cancer.	Freshly passed feces was homogenized with isotonic NaKCl for study in an anaerobic fecal incubation system. No patient showed signs of recurrence at the time of fecal sampling, which was at least 3 months after surgery. Patients were excluded from the group with former adenomas if they had previously had abdominal surgery, and from the group with former colonic cancer if the cancer operation had resulted in colostomy. Furthermore, intake of antibiotics within the previous two weeks caused exclusion. Both normal subjects and patients were on a ordinary Danish diet. Fecal short chain fatty acids were measured in both freshly passed feces and following incubations in vitro for 6 to 24 hours. In vitro incubations included trials with added carbohydrate substrates.	Without in vitro incubation, the total concentrations and ratios of short chain fatty acids and the concentrations of individual acids including butyrate in fecal suspensions from 16 normal subjects, 17 patients with resected colonic adenomas, and 17 patients with resected colonic cancer were not significantly different. The ratio of butyrate production to total short chain fatty acid production from fiber sources added to the in vitro fecal inoculum was significantly reduced in patients with colonic cancer and adenomas compared with healthy controls after 6 hours incubation ($p<.05$) and more significantly reduced when the incubation time was extended to 24 hours ($p<.01$). The authors feel that subjects characterized by a colonic flora with a relatively low butyrate formation may have an increased risk of developing colonic adenomas and cancer.	Subjects are somewhat matched by age and sex, but not completely. Polyp and cancer patients were characterized by relatively less butyrate production from fiber substrates in vitro than healthy controls. In vivo, without incubations fecal short chin fatty acid concentrations were similar in both controls and cases. It cannot be assessed whether in vivo consumption of the fiber substrates would result in findings similar to those reported in vitro.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Gregoire et al, 1991 (Ref. 64).	Clinical trial.	43 healthy volunteers, ages and sex distribution not reported.	Volunteers were randomly allocated, after stratification by age and sex to one of 4 dietary groups: A. low fat, low fiber B. low fat, high fiber C. high fat, low fiber D. high fat, high fiber The source of fat is butter, mayonnaise, dressing, cream, Bernaise sauce, and ground beef. The source of fiber is Fibread (9.3 g wheat fiber per slice) Three day food records kept by subjects just prior to intervention period. Cell proliferation was assessed with tritiated thymidine labeling of 3 rectal biopsies. Fecal pH and fecal bile acid concentrations were measured as well.	A short-term increase in dietary fat and decrease in dietary fiber does not result in a large increase in cell proliferation rate. Changes in fecal pH and fecal bile acid concentrations were not significantly different.	During the intervention, dietary variables other than the added fat and fiber were not controlled. The rate of colonic proliferation is a possible intermediary towards colon cancer, not the end point.
Soltero et al., 1990 (Ref. 56).	Case control study in Puerto Rico.	200 patients treated for right-sided colon adenocarcinoma. Neighborhood controls matched for age and sex.	Subjects (or next of kin, if dead) were interviewed with a quantitative food frequency questionnaire regarding the diet 1 year prior to diagnosis. Fiber was calculated from USDA Handbook #8 (crude fiber).	Cholecystectomy was a risk factor for right sided colon cancer. Meat and poultry intake were significantly greater in cancer cases than controls. Fiber and vegetable intakes were significantly greater in controls than in cancer cases. No significant association with fat intake and cancer.	Major focus of the study was on cholecystectomy and colon cancer. Both fiber and vegetables noted as protective, and the relative contribution of each to risk reduction cannot be determined. It is not clear if all sources of fiber were considered, or only cereal fiber (discrepancy between text and table 5).

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Giovanucci et al., 1992 (Ref. 62).	Prospective study among U.S. health professionals.	49,296 health professionals, ages 40 to 75 years, in 1986. 170 documented cases of rectal or colonic adenomatous polyps. Controls--7,284 subjects who had colonoscopy 1986 to 1988.	Subjects received a food frequency dietary questionnaire by mail two years after enrollment. Analyzed for crude fiber, dietary fiber and fat. Fiber sources: vegetables, fruits, or grain.	Animal fat intake significantly associated with polyps. Red meat and dairy fat significantly associated with polyps. All sources of dietary fiber associated with ↓risk. Also, other plant nutrients (potassium, β-carotene, vitamin C, vitamin E) all inversely associated with polyp risk. These associated nutrients did not cancel out fiber's effect when entered in multiple logistic regression.	Intake of meat and fat relatively low compared to U.S. population. This may limit applicability of fiber findings. Right sided adenomas were excluded from analysis. Inference cannot be made about the impact of fiber on right sided colonic tumors. All subjects were men.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 91N-0099]

RIN 0905-AB67

Food Labeling: Health Claims and Label Statements; Dietary Fiber and Cardiovascular Disease

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing its decision not to authorize the use on the label or labeling of foods of health claims relating to an association between dietary fiber and cardiovascular disease (CVD). However, FDA is authorizing a health claim relating diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain dietary fiber (particularly soluble fiber), to a reduced risk of coronary heart disease (CHD). This action is in response to provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) that bear on health claims, and was developed in accordance with the final rule on general requirements for health claims, published elsewhere in this issue of the **Federal Register**.

On the basis of the totality of the publicly available scientific evidence, including recently available evidence, the agency has concluded that there is significant scientific agreement among qualified experts that a claim relating diets low in saturated fat and cholesterol, and high in fruits, vegetables, and grain products that contain soluble fiber, to reduced risk of CHD is supported. The evidence is not sufficient to attribute the reduction in risk to soluble fiber or to a specific type or characteristic of soluble fiber, or to other components of these diets.

EFFECTIVE DATE: May 8, 1993.

FOR FURTHER INFORMATION CONTACT: Joyce J. Saltsman, Center for Food Safety and Applied Nutrition (HFS-165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5916.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 27, 1991 (56 FR 60582), FDA proposed to deny the use on food labeling of health claims relating diets high in dietary fiber to reduced risk of CVD. The proposed rule was issued under provisions of the 1990 amendments (Pub. L. 101-535) that bear on health claims and in accordance with the proposed general requirements for health claims for food (56 FR 60537, November 27, 1991). As amended in 1990, the Federal Food, Drug, and Cosmetic Act (the act) provides that a food is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition unless the claim is made in accordance with sections 403(r)(3) or (r)(5)(D) of the act (21 U.S.C. 343(r)(3) or (r)(5)(D)).

Section 3(b)(1)(A) of the 1990 amendments specifically requires that the agency determine whether health claims respecting 10 nutrient/disease relationships meet the requirements of section 403(r)(3) or (r)(5)(D) of the act. The relationship between dietary fiber and CVD is one of the claims required to be evaluated. In the proposed rule published in the **Federal Register** of November 21, 1991 (56 FR 60582), FDA limited its review of the science to those aspects of the dietary fiber/CVD relationship for which the strongest scientific evidence and agreement already existed: dietary soluble fiber and CHD.

In the proposed rule, FDA requested written comments on its tentative determination not to authorize a health claim for dietary fiber and CVD. FDA also requested comments on the following issues: (1) Should the agency permit a claim on the label or in labeling of foods that states that diets high in fruit, vegetables, and whole grains are associated with a reduced risk of certain forms of cancer and CVD?; (2) If such statements should be permitted, what criteria should be used to identify foods that are eligible for such statements?; (3) What measures should the agency adopt to assure that consumers are not misled as to the benefit of consuming a specific product?; and (4) Does FDA have the authority to allow and should it allow health claims for foods as well as nutrients?

On January 30 and 31, 1992, FDA held public hearings on all aspects of the proposed rules published in response to the 1990 amendments, including health claims for dietary fiber and CVD. In addition, because of new evidence identified from literature searches and new data submitted with comments to the proposed rule, FDA reopened the comment period on dietary fiber and CVD for 30 days (57 FR 32751, July 23, 1992).

In response to its proposed rule on dietary fiber and CVD, the agency received approximately 130 comments from consumers, consumer advocacy groups, State health departments, organizations of health professionals, the food industry, and Government agencies. A number of comments were received that were more appropriately answered in other dockets, and these were forwarded to the appropriate docket for response.

Most of the comments specific to the proposal for a health claim for fiber and CVD provided explanations in support of or in opposition to provisions of the proposed regulation. Some of the comments contained relevant scientific studies not included in the agency's proposed rule. These additional studies and those identified through literature searches that had not been previously reviewed in the proposal (56 FR 60582) are included in the agency's review below. The agency has summarized and responded to issues raised in the comments in section III. of this document.

II. Updated Review of Scientific Evidence

FDA, to ensure that it had not overlooked new and significant scientific data, reviewed human studies published since the publication of the proposed rule that it had identified in a standard literature search. In addition, FDA carefully reviewed all relevant scientific data submitted as comments. The availability of the new data was announced in a notice of reopening of comment period (57 FR 32751).

A. Human Studies

Detailed summaries of studies discussed below are presented in Table 1. FDA's explanation for separately evaluating studies on mildly to moderately hypercholesterolemic individuals and normocholesterolemic individuals is found in its proposed rule (56 FR 60587). Multiple sources of soluble fiber, including oat bran and other cereal brans, legumes, pectin, psyllium, and guar gum, were used in these studies.

1. Hypercholesterolemics: "typical" or "usual" diets

Leadbetter et al. (Ref. 83) evaluated the hypocholesterolemic effects of increasing intakes of β-glucan, the major type of dietary soluble fiber in oat bran. A four-by-four Latin square design was used in this randomized intervention study with 40 hypercholesterolemic (total serum cholesterol 250 to 348 milligram/deciliter (mg/dL)) men and women, ages 25 to 64, in New Zealand. Subjects added 0, 30, 60, and 90 grams/day (g/day) oat bran to their usual diet

for 1-month intervals. There was no wash-out between periods. Oat bran was provided in weighed packages and detailed advice and recipes were provided on how to incorporate it into the diet. The total dietary fiber content of the regular diets, without oat bran, ranged from 23 to 27 g/day. Results showed no significant effect of oat bran on serum cholesterol at any dose. There was no dose-related trend and no correlation between bran dose and changes in serum cholesterol. The authors stated that the oat bran used in this study was lower in soluble fiber (3.7 to 4.2 percent β-glucan) than oat bran used in studies showing a significant lowering of serum cholesterol with oat bran supplementation.

Cara et al. (Ref. 84) evaluated the hypocholesterolemic properties of wheat germ in 10 hypercholesterolemic men and women (serum cholesterol 254 to 367 mg/dL), ages 35 to 68 years. Subjects consumed their regular diets for 1 week, then added 30 g/day wheat germ (2.9 g dietary fiber) for 4 weeks. At the end of the treatment period, subjects were monitored for an additional 4 weeks with no supplementation. Their base diet included 13.6 g/day dietary fiber and 6 g/day alcohol. Serum cholesterol decreased significantly (8.6 percent) after wheat germ intervention and returned to baseline during the 1 month followup period. Dietary soluble fiber and total saturated fat before and during the treatment period were not reported. The authors speculate that the high vegetable protein content of wheat germ could account for the observed results.

Karlander et al. (Ref. 85) evaluated the hypocholesterolemic properties of beet fiber in 13 hypercholesterolemic noninsulin-dependent diabetics mellitus (NIDDM) men and women (mean serum cholesterol of 275 mg/dL). Five subjects were on chronic beta blockers and diuretics and eight were on diet treatment with sulfonylurea (SU). This was a controlled, randomized intervention trial with cross-over design. The study was divided into three 6-week periods with a run-in period followed by either fiber intervention (20 g/day beet fiber) or the subject's regular diet for 6 weeks, then cross-over to the other diet. Obese subjects were given dietary advice to aid in weight control. Results showed no significant difference in total serum cholesterol between control and fiber periods for subjects advised to reduce energy intake. The SU group showed significantly decreased (10 percent) serum cholesterol during the fiber phase (total cholesterol decreased from 275 to 247 mg/dL). The SU group had a slight but significant loss of body mass during the run-in period only. There was no effect on serum triglycerides.

Spiller et al. (Ref. 87) evaluated the cholesterol-lowering properties of guar gum compared to oat bran in a 3-week, intervention trial with cross-over. Thirteen men and women, mean age 62 years, with mild to moderate hypercholesterolemia (serum cholesterol 204 to 276 mg/dL), were randomized to receive either 15 g (11 g dietary fiber, of which there was 10 g soluble fiber) of guar gum per day or 77 g/day (11 g dietary fiber, 5 g soluble fiber) oat fiber source, divided into three servings. The fibers were provided in weighed packets with instructions to mix the fiber with water or juice and consume before each main meal. After 21 days, subjects switched to the other fiber source. There was no wash-out between test periods. Blood samples were collected on days 14 and 21 during treatment periods. Results showed a significant reduction in serum cholesterol, compared to baseline, for both groups. Guar reduced serum cholesterol 11 percent and oat fiber 6 percent. Maximum cholesterol reduction was experienced after 14 days on the test fiber. No significant change occurred in serum cholesterol between days 14 and 21 on either test fiber, with serum cholesterol values increasing slightly but not significantly. Factors confounding these results include small sample size, the absence of a wash-out between test periods, and short treatment periods. Dietary intakes of soluble fiber were not reported.

Kawatra et al. (Ref. 88) reported significant reductions in total serum cholesterol and low density lipoprotein (LDL)-cholesterol in 20 overweight Indonesian men and women with mild to moderate hypercholesterolemia consuming guar gum. Subjects consumed 15 g/day guar gum with their normal diet for 6 weeks. The guar was consumed 15 minutes before the main meal in the form of biscuits (10 g guar) and mixed (5 g guar gum) with a flavored drink. Total serum cholesterol decreased 16.7 percent and LDL-cholesterol decreased 26.5 percent. Intake of total dietary fiber, dietary soluble fiber, and saturated fat were not reported.

Tinker et al. (Ref. 89) evaluated the cholesterol-lowering properties of prunes in a randomized, cross-over trial. Forty-one men, ages 29 to 79, with mild to moderate hypercholesterolemia (serum cholesterol 201 to 290 mg/dL) consumed either grape juice (360 milliliter (mL)/day) or 12 prunes (100 g/day) for 4 weeks followed by cross-over to other diet for an additional 4 weeks. Prunes provided 6 to 7 g of total dietary fiber and 3.6 to 4.2 g of soluble fiber as pectin. Base diets included 18 g of total dietary fiber during the grape juice period and 24 g of fiber during the prune period. Four to five percent of the energy was from alcohol. There was no significant difference between serum cholesterol on the prune diet and on the grape juice diet.

A final report by Earll et al., July 1986 (Ref. 90), was submitted with one of the comments. This was an intervention study with seven free living hyperlipidemic (serum cholesterol ranged from 261 to 346 mg/dL) male and female patients. Subjects were asked to consume 24 g/day of corn fiber (containing less than 2 g soluble fiber) for 6 weeks, then 48 g/day corn fiber for an additional 6 weeks with their regular diet. The test period was followed by an 8-week wash-out period. Actual consumption of corn fiber was slightly less according to records kept by the subjects. Total cholesterol was reduced, on average from 298 to 253 mg/dL (significant), although much smaller changes were seen in two subjects, and one subject had an increase in serum cholesterol during the study period. In all but one of the subjects, serum cholesterol remained above 200 mg/dL with fiber intervention, suggesting dietary therapy was not adequate. The dietary intakes of the subjects before and during the test period were not recorded.

Whyte et al. (Ref. 104) reported significant reductions in serum cholesterol in 23 men with mild hypercholesterolemia (total cholesterol ranged from 209 to 259 mg/dL) consuming oat bran. Subjects consumed 123 g/day oat bran or 54 g/day wheat bran cereal with their regular diets for 4 weeks followed by cross-over to the other fiber cereal. All subjects consumed wheat cereal during a 3-week baseline period prior to randomization to test groups. Total dietary fiber and fat intake were approximately the same between groups. Total serum cholesterol and LDL-cholesterol, when consuming oat bran, decreased 4 percent and 5.5 percent, respectively, compared to wheat bran. The authors note that one of their earlier studies with 12 g of oat bran showed significant decreases in serum cholesterol of 6 percent compared to 12 g of wheat bran. According to their analyses, both oat brans were similar in composition (Ref. 104). The smaller decrease in serum cholesterol reported in this study as compared to some other oat bran studies, not conducted by these authors, may be due to the difference in β-glucan

content of different strains of oats. This 4-week study does not address long-term effectiveness of oat bran intervention.

Uusitupa et al. (Ref. 100), in a randomly-allocated, double-blind parallel group trial, tested the effects of guar gum on 39 individuals with NIDDM (mean serum cholesterol of groups: 253 and 237 mg/dL). The test group received 5 g of guar gum three times per day (estimated total of 10 g soluble fiber) before meals for 3 months, while the control group received 5 g of wheat flour 3 times per day before meals. After 3 months, the control group was switched to guar and both groups were followed for an additional 10 months. At the end of 3 months, the guar group showed a significant lowering of serum total cholesterol. Over the remaining 10 months, the group which began as the test group had an increase in total cholesterol, although it remained significantly lower than prior to the trial. The group which began as the control group, but switched to guar, demonstrated the lowest serum cholesterol during month 5 (208 mg/dL). This was followed by increasing serum cholesterol to a maximum at month 11 (242 mg/dL). After 12 months, serum cholesterol for this group was 233 mg/dL. Significant weight loss occurred in both the control and treatment groups to a similar degree. The dietary intakes for both groups were not reported.

Spencer and Gee (Ref. 109) evaluated the cholesterol-lowering properties of apple juice supplemented with 10 g of dietary fiber (70 percent soluble fiber, predominantly from gum arabic) versus plain apple juice. Thirty-one mildly hypercholesterolemic men (serum cholesterol between 200 and 270 mg/dL) consumed their regular diets in this 6-week cross-over, blinded trial. With both ordered groups totalled, there was a significant decrease in serum total cholesterol and LDL-cholesterol during the period of consumption of fiber-enriched juice. When order of presentation is considered, there were inconsistencies in the changes. The group which began the trial with the placebo did not show any change from baseline in serum cholesterol during the placebo phase, whereas the group which received the placebo during the second half of the trial maintained the lower cholesterol level which occurred during the fiber supplementation period. Cholesterol intake was significantly higher in the juice-only group.

Niemi et al. (Ref. 99), in a double-blind, cross-over trial, reported significant lowering of serum cholesterol in a group that received 15 g/day guar gum (estimated total of 10 g soluble fiber) as a supplement for 12 weeks when compared to the group which received cellulose, the placebo. The 16 women and 6 men chosen as subjects were all (NIDDM) between the ages of 40 and 76. Nineteen of these subjects were on medication for their diabetes. Although the patients were advised to maintain their normal diets, no dietary measurements were reported to verify this.

Kirsten et al. (Ref. 97) evaluated the hypocholesterolemic properties of guar gum in 13 men and women with type IIa and IIb hyperlipidemia (serum cholesterol concentration >251 mg/dL). The study was divided into three phases: the 30-day pretreatment phase (baseline), the 60-day treatment, and the 60-day post-treatment period. During the treatment phase, subjects consumed 4 g of guar gum, mixed with water or juice before breakfast, lunch, and dinner (12 g guar/day, estimated—8 g soluble fiber). Subjects were only instructed to avoid cholesterol-rich foods during the study period. Both total serum cholesterol and LDL-cholesterol decreased significantly compared to pretreatment levels. During the post-treatment period, serum cholesterol returned to baseline and LDL-cholesterol increased above baseline. The dietary intakes of the subjects during each phase of the study were not reported.

Cerda et al. (Ref. 105) evaluated the hypocholesterolemic effects of grapefruit pectin in a double-blind, placebo-controlled, cross-over study. Twenty-seven hypercholesterolemic men and women (mean serum cholesterol of 275 mg/dL) consumed 15 g of grapefruit pectin (27 tablets, 9 per meal) or 15 g of flour (also in tablet form) per day for 4 weeks followed by a 4-week wash-out before cross-over. During the pectin period total cholesterol decreased by almost 8 percent and LDL-cholesterol by 11 percent (both significantly lower compared to baseline). There was no change in serum cholesterol during the placebo period. The dietary intake of the subjects during each period of the study was not reported. The short test periods do not address long-term usefulness of pectin.

Haskell et al. (Ref. 106) evaluated the hypocholesterolemic properties of four isolated, purified soluble fibers in four separate trials. All subjects had serum cholesterol levels between 200 and 280 mg/dL and were randomized to 1 of the four studies. Study one was a 12-week intervention trial using a powdered soluble fiber mixture providing 17.2 g/day of soluble fiber. The powder consisted of acacia gum (9.7 g), psyllium (4.9 g), and guar gum (2.6 g). The soluble fiber mixture was tested against a fructose placebo (15 g/day). Results showed no statistically significant changes from baseline to 6 or 12 weeks within or between groups. Study two was a 4-week intervention testing 15 g/day of acacia gum powder against 15 g/day fructose powder. There was no significant change from baseline or compared to the placebo. Study three was an 8-week cross-over trial using 10 g/day of guar (estimated 6.7 g soluble fiber) as a control and a 15 g/day fiber mixture of pectin (3.9 g), psyllium (6.3 g), guar (3.3 g), and locust bean gum (1.5 g). Each test period was 4 weeks. Results showed both the guar and the fiber mixture reduced serum cholesterol (approximately 10 percent and 8 percent, respectively), LDL-cholesterol (approximately 14 percent and 12 percent, respectively), and high density lipoprotein (HDL)-cholesterol (about 6 percent) significantly. Study four was a 4-week dose-response study with increasing amounts of soluble fiber from a mixture of pectin, psyllium, guar, and locust bean gum. Three groups received either 5 g, 10 g, or 15 g/day of the mixture. Results showed that the serum cholesterol and LDL-cholesterol of the group consuming 15 g/day was significantly lower than the placebo.

A 1984 study by Anderson et al. (Ref. 110) was submitted with comments in support of a long-term hypocholesterolemic effect of soluble fiber from oat bran and beans. Ten men, ages 46 to 66, with serum cholesterol above 260 mg/dL were randomly assigned to oat bran or bean-supplemented diets for 21 days following a 7-day baseline period on a metabolic ward. The base diet was a "typical" American diet with 38 percent of calories as fat and 450 mg cholesterol. To this diet, the subjects added either 100 g of oat bran or 100 g of dried beans per day. Both of these diets provided 18 g of total soluble fiber and 48 to 50 g of total plant fiber per day. Before discharge, the subjects were instructed on the use of a high fiber (50 g of total fiber per day) maintenance diet with oat or bean product supplements at home. The high fiber diet was also low in fat (30 percent of calories as fat), low in saturated fat (10 percent of calories), and low in cholesterol (150 mg/day). Ten men were followed on their home diets for 24 weeks and 4 for 99 weeks. Results of the metabolic ward phase of the study showed that the oat bran and bean diets lowered serum cholesterol significantly (23 percent) over the 3-week period compared to baseline. At 24 weeks (the followup phase), serum

cholesterol levels were significantly (26 percent) lower than baseline. Cholesterol levels in the four men followed for 99 weeks were 23 percent lower than baseline (significant at p<0.0025). Reductions in LDL-cholesterol were also significant during both phases of the study. HDL-cholesterol decreased significantly (20 percent) during the metabolic ward phase but increased during the long-term followup. All 10 subjects lost approximately 4 pounds (lb) (significant at p<0.0025) during the metabolic ward phase of the study. The investigators reported that changes in body weight were not significantly correlated with the changes in serum cholesterol. An additional 4 lb of weight was lost during the 24-week phase of followup.

An unpublished study (Ref. 119) evaluated the cholesterol lowering properties of oat gum in hypercholesterolemics (mean serum cholesterol of 255 mg/dL). Instant oat gum (3.6 g) or a placebo (maltodextrin) were mixed with a noncarbonated diet fruit drink (250 mL) and consumed twice a day at each main meal for 4 weeks. There was a 3-week wash-out between treatment periods and after the last oat gum period. Subjects were randomly assigned to start the treatment period with either the oat gum beverage or the placebo. Results showed significantly lower serum cholesterol after 4 weeks on oat gum compared to both the baseline (p = 0.02) and the placebo (p = 0.001). Although subjects were asked to maintain their weight, subjects' weights were not reported.

Bridges et al. (Ref. 120) evaluated the effect of oat bran on serum cholesterol and serum acetate in hypercholesterolemic men admitted to a metabolic ward. Animal studies have shown that both acetate and propionate inhibit cholesterol synthesis (Ref. 120). The 20 subjects were divided into two groups: Wheat bran group (mean serum cholesterol of 252 mg/dL) and oat bran group (mean serum cholesterol of 305 mg/dL). Following 1 week on a typical American diet, the diets were supplemented for 21 days with either 110 g of oat bran per day or 40 g of wheat bran. Results showed that the oat bran group experienced significantly lower (p = 0.05) serum cholesterol than the wheat bran group. However, in the wheat bran group, the baseline cholesterol level had been higher than in the oat bran group. There was a significant (p = 0.001) weight loss in both groups. The weight loss appeared to be greater in the oat bran group. LDL-cholesterol was significantly lower (p = 0.005) in the oat bran group as compared to the group's pretreatment values. There was no significant difference in LDL-cholesterol between groups. Serum acetate values were significantly higher in the oat bran group than in the pretreatment diets. Wheat bran did not change serum acetate significantly compared to the pretreatment diets.

Kashtan et al. (Ref. 121) evaluated the effects of wheat bran and oat bran supplements on blood lipids and lipoproteins in 84 subjects with mild hypercholesterolemia. This was a controlled, parallel, double-blind study in which subjects consumed either oat bran supplements (with 11 to 17 g dietary fiber and an estimated 5 to 8 g of soluble fiber) or a wheat bran cream of wheat mixture (11 to 17 g of dietary fiber) each day for 14 days. Defined diets were delivered to the subjects' homes. The diets provided one of four energy amounts: 1,600, 2,000, 2,400, and 2,800 calories, with 37 percent of energy as fat, 47 percent carbohydrate, and 16 percent protein. Results showed mean serum cholesterol decreased significantly (-10.8 percent, p = 0.001) in the oat group compared to the wheat group (-4.7 percent). However, the baseline cholesterol was higher among the oat bran group. The wheat bran group also experienced significantly decreased serum cholesterol compared to their baseline (p <0.001). LDL-cholesterol decreased significantly compared to baseline for both groups (p = 0.03 for the wheat bran group and p <0.001 for the oat group). The short test period of 2 weeks in this study makes interpretation of the results difficult.

Ranhotra and coworkers (Ref. 122) studied lipidemic responses in 17 hypercholesterolemic men consuming foods high in soluble fiber. This was a 6-week intervention study with a 6-week control period prior to the test period. Subjects consumed their usual diet during the control period and kept daily records of intake for 4 weeks. Subjects were then given a list of foods that were identified as good sources of soluble fiber and a diet supplement containing 30 g each of rice bran and oat bran, and were instructed to incorporate foods on the list into their usual diet. Each subject served as his own control. Results showed that only 6 (34 percent) of the 17 subjects were responders to the soluble fiber intervention. The authors reported that not all subjects consumed the supplement daily and that intakes of soluble fiber varied greatly among the participants. Serum cholesterol values decreased from 1 percent to 17 percent compared to individual control levels in those responding to soluble fiber. However, the authors did not perform a statistical analysis of the results, and the results in this study are too inconsistent in direction and magnitude to support an effect of soluble fiber on serum cholesterol.

Zhang et al. (Ref. 123) studied the mechanism of cholesterol lowering in nine subjects with ileostomies. This was a randomized, controlled, cross-over study design. Subjects were instructed to consume their own food, which was modified to be low fiber, and were assigned to either a low fiber diet (supplemented with wheat-flour bread) or a high fiber diet (supplemented with oatbran bread) for 3 weeks followed by cross-over to the other fiber bread for another 3 weeks. Ileostomy effluents were collected on sampling days in both dietary periods. Subjects were also divided into two subgroups according to the amount of bile acids excreted in the ileostomy effluents. Results showed subjects with low bile acid excretion had significantly increased daily excretion of total bile acids on the high fiber diet as compared to the low fiber diet. There were no significant differences in daily excretion of total bile acids between the high fiber period and the low fiber period in subjects with high daily bile acid excretion. There was no baseline serum cholesterol measurement. Compared to the low fiber period, serum cholesterol and LDL-cholesterol decreased significantly (p = 0.01 and p = 0.05, respectively) in all nine subjects on the high fiber diet. Subgroup analysis showed that subjects with low daily bile acid excretions had significantly reduced serum cholesterol on the high fiber diet than on the low fiber diet. Subjects with a high daily excretion of bile acids showed no significant difference in serum cholesterol between the test periods. Conclusions about fiber mechanisms in lowering serum lipids in subjects with ileostomies may not apply to the general population.

2. Hypercholesterolemics: Step 1 or 2 diets

A study by Israelsson et al. (Ref. 86) was submitted with a comment. This placebo-controlled, double-blind, cross-over intervention study used 30 g/day beet fiber or bread. Twenty-seven hypercholesterolemic (serum cholesterol 263 to 297 mg/dL) women, 55 to 56 years old, were chosen from a CVD screening program. Subjects consumed a moderate cholesterol, low fat diet with increased polyunsaturated fatty acids/saturated fatty acids (PUFA/SFA) for a 1-month run-in period and were then randomized to the fiber group or placebo for 1 month followed by cross-over to the other diet. The beet fiber provided 6 g soluble fiber, 16.5 g

insoluble fiber, and 22.5 g total dietary fiber. Subjects decreased alcohol intake after the run-in period. No data on saturated fat or soluble fiber intakes were provided. Results showed a significant reduction in serum cholesterol in the fiber group compared to the placebo after 2 weeks, but not after 4 weeks. LDL-cholesterol showed a modest but significant reduction after 4 weeks of fiber intervention. HDL remained constant or increased significantly after 1-month intervention. The ratio of LDL:HDL was significantly reduced at the end of the test period. The short test period of this study does not address long-term effectiveness of beet fiber.

Bremer et al. (Ref. 91) evaluated the cholesterol lowering effects of oat bran and wheat bran in a randomized, single-blind, cross-over, placebo-controlled intervention trial. The fibers were incorporated into breads. Twelve hyperlipidemic men and women (total serum cholesterol 220 to 348 mg/dL) were stabilized on a American Heart Association (AHA) phase II diet (total fat 25 to 30 percent of energy, saturated fat <8 percent of energy, polyunsaturated fat 5 to 10 percent of energy, cholesterol <250 mg/day) for 3 months prior to intervention. There was a 2-week run-in prior to test during which subjects added additional bread to their diets. Subjects were randomized to one of the two fiber groups for 4 weeks, followed by 2-week wash-out, then cross-over to other fiber group. The bread (10 to 12 slices/day) was added to the diet in place of other carbohydrate foods. Subjects had a mean intake of 44.6 g/day of oat bran (range of 34.2 to 68.4 g/day). Total dietary fiber intake during the oat period was 32.2 g, and 34.1 g during the wheat period. Results showed no significant differences in total serum cholesterol or LDL-cholesterol between the oat and wheat periods. Authors account for the lack of observed response on serum cholesterol from oat bran as due to the lower soluble fiber content of New Zealand oat bran compared to oat bran used in other studies.

Anderson et al. (Ref. 92) evaluated the hypocholesterolemic effects of two bulk laxatives, relative to psyllium and a placebo (cellulose), in mild to moderately high hypercholesterolemic (total serum cholesterol 200 to 300 mg/dL) men and women. The laxatives were evaluated at the manufacturer's recommended dosages. Of the 163 subjects screened, 105 completed the 16-week study. Subjects were instructed in and consumed the AHA Step 1 diet (total fat 30 to 33 percent of energy, saturated fat 10 percent of energy, carbohydrate 46 percent of energy, cholesterol <300 mg/day) for 8 weeks followed by an 8-week parallel treatment with diets supplemented with one of three fiber supplements or placebo. Fiber sources used were the following bulk laxatives: psyllium (10.2 g/day), methylcellulose (6 or 10.2 g/day), calcium polycarbophil (4 g/day), and cellulose placebo (4 g/day). The authors note that psyllium and methylcellulose were most effective in lowering serum cholesterol. There was no significant difference between psyllium and methylcellulose in lowering serum cholesterol. Soluble fiber was not controlled in this study. Subjects on psyllium had the highest soluble fiber intake. Side effects were reported for each laxative.

An unpublished manuscript entitled "High soluble fiber foods reduce serum lipids even when diets are already low in saturated fat and cholesterol" (Ref. 93) was received as part of a comment. This 4-week, cross-over, metabolic study in 12 hyperlipidemic (mean total cholesterol of 272 mg/dL) subjects compared a psyllium cereal/low fat diet (9.35 g psyllium/day = ≤3 oz of psyllium cereal) with a similar diet substituting wheat bran for the psyllium cereal. The low fat diets were the same in both phases of the study, low in saturated fat (<4 percent of energy) and cholesterol (<50 mg/day) and high in carbohydrate (>60 percent of energy). The psyllium cereal was significantly more effective in lowering total and LDL-cholesterol than the wheat bran cereal. Mean total cholesterol reduction was from 272 mg/dL to 249 mg/dL, and from 192 mg/dL 172 mg/dL for LDL cholesterol. Preliminary subgroup analysis by the authors of the study suggested that patients with both elevated cholesterol and triglycerides (Type IIb) showed no reduction in LDL cholesterol, while patients with only Type IIa (isolated elevation of cholesterol) benefited. Additional concerns are raised by this study regarding the usefulness of psyllium in Type IIb patients.

An unpublished manuscript entitled "High fiber foods reduce serum lipids even on diets low in saturated fat and cholesterol" (Ref. 94) was received as a comment. This was a cross-over study with 11 hyperlipidemic volunteers. Each 16-week test period was separated by a 2-month wash-out period during which subjects consumed only the Step 2 diet (total fat <20 of energy, saturated fat <7 percent of energy, cholesterol <100 mg/day, and carbohydrate >60 percent of energy). During one metabolic phase, subjects were fed foods considered good sources of soluble fiber (e.g., legumes and psyllium-containing cereals) as part of the Step 2 diet. During the second phase, wheat bran-containing foods were fed. Results showed that both the soluble- and insoluble-fiber groups lost weight during the 4-month test period. The insoluble-fiber group lost significantly more than the soluble-fiber group. Although, blood lipids fell on both diets, total cholesterol, LDL- and HDL-cholesterol values were significantly lower (6.3 percent, 8.6 percent, and 5.7 percent, respectively) in the soluble-fiber group than in the insoluble-fiber group. The soluble fiber diet emphasized foods shown in other studies to reduce serum cholesterol, i.e., dried beans, peas, other legumes, oat bran, and a psyllium-containing cereal. The actual difference in soluble fiber content between the soluble and insoluble fiber diets was only about 3.2 g/day, on average. The authors felt that the specific foods they fed contribute to lowering of serum cholesterol, but expressed concern that not all soluble fibers show this effect, and that no mechanism of action is apparent. They, therefore, expressed "concern over lipid lowering claims for direct dietary fibers."

An intervention study by Anderson et al. (Ref. 95) with 44 hyperlipidemic (serum cholesterol 200 to 300 mg/dL) men and women was conducted using a randomized, double-blind, and parallel design. Subjects consumed a Step 1 diet and 3.7 ounce (oz)/day (on average) of either a wheat bran cereal or a psyllium cereal for 6 weeks. The psyllium cereal provided 10.7 g/day of psyllium. The psyllium group had a lower total cholesterol by about 8 percent and LDL cholesterol by nearly 13 percent by the end of the study. Mean total cholesterol, however, was still higher than 200 mg/dL despite these reductions. Both groups had comparable weight loss of about 1 (lb) pound. Because this study had a short test period, it did not address the long-term usefulness of psyllium in reducing serum cholesterol. In a parallel design, nonblinded clinical trial with 59 men and women with total cholesterol between 215 and 396 mg/dL, Neal and Balm (Ref. 98) placed all subjects on Step 1 diets for 7 weeks. The control group continued on the Step 1 diet, and the test group received 20.4 g of psyllium per day in the form of Metamucil immediately after breakfast and the evening meal for 13 weeks. After the treatment period, the psyllium group had a decrease in total cholesterol of 7.1 percent, while the control group had a 1.6 percent decrease. The difference between the test and control

groups was 5.5 percent, a significant decrease. Although there was a 5.1 percent decrease in LDL in the psyllium group compared to the control, this decrease was not significant. The authors failed to report the amounts of total fat, saturated fat, and total soluble dietary fiber consumed during each period.

Two short-term studies by Wolever et al. (Refs. 101 and 102) evaluated the effectiveness of psyllium in lowering serum cholesterol (Ref. 101) and its effectiveness when psyllium was taken with meals or between meals (Ref. 102). These studies were done with men and women, some of whom were on lipid-lowering drugs, who were instructed on a Step 2 diet. The test periods were for 2 weeks. In both studies, serum cholesterol was lowered significantly at the end of the 2 weeks.

O'Connor et al. (Ref. 103) conducted a well-controlled multicenter, double-blind randomized, parallel group, placebo-controlled trial with men and women between the ages of 18 and 70 years with a diagnosis of mild to moderate primary hypercholesterolemia (see Table 1). A five fiber supplement, containing guar and pectin and providing 7.5 g of soluble fiber and 2.5 g of insoluble fiber, was administered either once or twice a day for 15 weeks with a Step 1 diet. The placebo group received 5.2 g of insoluble fiber with no soluble fiber before breakfast and dinner. All nutrients were kept constant except for fiber. Serum cholesterol and LDL-cholesterol were significantly reduced compared to placebo in all studies (see Table 1, studies B301 and B302 in). An extension of this study evaluated the long-term usefulness of the five fiber supplement for an additional 36 weeks (total of 51 weeks). Significantly reduced levels of total and LDL-cholesterol were maintained (5.3 percent and 8.4 percent, respectively) compared to baseline. This study shows both the ability of a particular soluble fiber product for reducing blood lipids and the long-term benefits of soluble fiber supplementation with a low fat diet.

An unpublished study (Ref. 108) evaluated the hypocholesterolemic effect of psyllium in 23 hypercholesterolemic men (mean total cholesterol greater than 240 mg/dL). Using a double-blind, double cross-over design, the subjects were randomly assigned to either the psyllium-wheat bran-psyllium group or to the wheat bran-psyllium-wheat bran group for 8, 5, and 5 weeks, respectively. Subjects consumed a total of 10 g of soluble fiber/day from psyllium and 2 g of soluble fiber per day from wheat bran. All subjects consumed a Step 1 low fat diet as the base diet. Results showed significant cholesterol and LDL-cholesterol lowering (4.3 percent) with psyllium compared to the wheat phase of the test. Initial cholesterol values for each group were not given.

A 1987 study by Turnbull and Leeds (Ref. 111) was submitted with comments from the food industry as further evidence for a hypocholesterolemic effect of soluble fiber from oat bran. In this study, 17 free living men and women aged 23 to 73 years (serum cholesterol levels above 232 mg/dL) were given varying degrees of instruction on a low fat diet (<35 percent calories from fat). All subjects followed this diet for a 1-month run-in period. Eight subjects were followed intensively during the run-in period and fiber periods through blood sampling and diet histories. Subjects were then randomly assigned to receive either 150 g/day oats (from cereal and muffins) or 100 g/day wheat flour biscuits for 1 month followed by cross-over to the other fiber diet for an additional month. The oat products provided 5.4 g of soluble fiber per day. The wheat products provided 3.1 g/day. Results during the run-in period showed a significant loss of weight and reduction in serum cholesterol in the group of eight subjects studied intensively during the first month. At the start of the first test period (whether oat or wheat) all subjects had a mean fat intake of 34 percent of calories. During the oat period, the subjects' energy intakes increased and fat intake increased to 35 percent. Mean body weight, however, remained constant. Combining all results from the oat-wheat and wheat-oat periods, serum- and LDL-cholesterol fell significantly ($p = 0.02$ and $p = 0.003$, respectively). During the wheat period, the subjects' caloric intake increased with a mean body weight increase of 0.3 kilogram (kg). Total fat consumption during the wheat period was 36 percent of calories. Mean serum cholesterol of the combined period showed a nonsignificant increase (1.6 percent) in serum cholesterol during the wheat period. LDL-cholesterol showed a nonsignificant increase. In the eight subjects followed intensively throughout the study, the results showed that most of them had further reductions in total and LDL-cholesterol on the oat diet beyond the low fat diet alone. In a later study (Ref. 126) of the same design and using the same levels of oats and wheat flour, the authors reported favorable changes in apolipoprotein A1 and no change in apolipoprotein B in subjects on the oat diet.

The purpose of the study by Fukagawa et al. (Ref. 114) was to evaluate the effects of a very high carbohydrate high fiber (HCF) diet on peripheral-tissue insulin responsiveness in a group of healthy young men (ages 18 to 24 years, Group A) and in a group of older men and women (ages 67 to 86 years, Group B). The young men had normal serum cholesterol (199 mg/dL) and the older adults were hypercholesterolemic (237 mg/dL). The subjects were studied while consuming their usual ad libitum diet and after consuming a HCF diet for 21 to 28 days. The older group was admitted to the metabolic ward for the duration of the study. The younger subjects only ate their meals on the metabolic ward. The study was not blinded or placebo controlled. Test diets provided the following: Group A— 23.6 g/day soluble fiber, 88.2 g of plant fiber/day, 134 mg dietary cholesterol, 14 percent energy as fat, 3 percent energy as saturated fat, 69 percent of energy as carbohydrates; Group B— 17 g of soluble fiber, 67.7 g of plant fiber/day, 90 g of dietary cholesterol, 15 percent energy as fat, 3 percent energy as saturated fat, and 70 percent energy as carbohydrates. Results showed a significant reduction in serum cholesterol in both groups after 4 weeks (Group A: 26 percent; Group B: 45 percent). The results of this study are inconclusive for an effect of fiber on serum cholesterol (which was not the objective of the study) because the subjects' ad libitum diets were significantly higher than the test diet in fat (37 to 42 percent of calories compared to approximately 14 percent on the test diet), saturated fat (15 to 17 percent of calories versus 3 percent of calories), and lower in carbohydrates (40 to 45 percent of calories versus 68 to 70 percent of calories). In addition, there was no control group.

Anderson et al. (Ref. 118) evaluated the cholesterol-lowering benefits of psyllium-enriched cereal in subjects with mild to moderate hypercholesterolemia (serum cholesterol range of 200 to 300 mg/dL). Subjects consumed their usual diets for 1 week before being randomly assigned to receive psyllium-flake or wheat bran flake cereal for 6 weeks. Subjects were also instructed on a Step 1 diet and asked to adhere to it for 6 weeks. Soluble fiber intake during the treatment period was 5.9 g per day for the wheat bran group and 15.1 g/day for the psyllium group. Results showed significantly reduced serum- and LDL-cholesterol in the psyllium group compared to the wheat group. Serum

cholesterol was reduced 8.36 percent (p = 0.01) and LDL-cholesterol 12.9 percent (p = 0.01) in the psyllium group. There was no significant change in serum- or LDL-cholesterol in the wheat group.

3. Normocholesterolemics: "typical" or "usual" diets

Resnicow et al., 1991 (Ref. 96), measured total serum lipids in a population of 31 Seventh Day Adventists, ages 5 to 46 years, who had consumed a pure vegetarian diet for at least 6 months prior to taking of blood samples. Diets of vegans were compared to those of omnivore controls. Blood samples were not taken from the controls and blood values for these subjects were derived from the Lipid Research Clinics Population Studies Data Book. Results showed that the adult vegans consumed significantly less energy and energy from fat (31 percent versus 38 percent of calories), total fat, saturated fat, monounsaturated fat, cholesterol, and protein. They also consumed significantly more fiber (45 g/day versus 20 g/day) than the omnivores. Total dietary soluble and insoluble fibers were not assessed. Foods consumed in greater frequency by vegans included almonds, cashews, and their nut butters, dried fruits, citrus fruits, soy milk, and greens. Total serum cholesterol for vegans was approximately 23 percent lower (139 mg/dL versus 182 mg/dL) than expected values for omnivores.

One study submitted with comments evaluated the effect of glucomannan, a pectin-like gel fiber derived from purified tubers of *Amorphophallus koniac* K. Koch, on serum cholesterol and weight reduction in obese patients consuming their normal diets (Ref. 117). Weight loss and serum cholesterol decreased significantly in the test group compared with the placebo group at the end of the 8-week trial. After 4 weeks on the test product, subjects had a mean weight loss of 4.9 lb and mean serum cholesterol reduction of 20.9 mg/dL. After another 4 weeks, weight loss was only 0.6 lb and serum cholesterol was reduced only 0.8 mg/dL. Because weight loss and serum cholesterol are closely correlated, the effect of glucomannan on serum cholesterol cannot be determined from this study.

An unpublished study studied the mechanism of serum cholesterol reduction by oat bran (Ref. 124). This was a 2-month metabolically-controlled intervention trial with nine normocholesterolemic men. A single isotope was used to determine bile acid kinetics during the oat bran period. During the first month, subjects consumed a constant diet provided in a metabolic unit. The fat content of the diet was 35 percent of the energy. The total soluble fiber content of the low fiber diet ranged from 3.0 to 4.9 g/day and for the high fiber period 9 to 12 g/day. During the second month, this same diet was supplemented with 100 g of oat bran per day. Results showed significantly lowered serum cholesterol during both periods. Serum cholesterol was 14 percent lower compared to the prestudy period during the low fiber period and 22 percent lower during the high fiber period. Serum cholesterol during the high fiber period was also significantly lower than that of the low fiber period (an additional decrease of 9 percent). Bile acid excretion approximately doubled during the high fiber period.

4. Normocholesterolemics: low fat diets

Nervi et al. (Ref. 107) reported than an intake of 120 g/day of legumes for 30 to 35 days significantly lowered serum cholesterol (from 162 to 143 mg/dL) in 20 Chilean young men compared to responses of men on a control diet. The men consumed beans, peas, or lentils each day as part of a diet that provided 33 percent of calories from fat and 12.5 g of total fiber. The study was designed to evaluate the hypothesis that legumes may be a risk factor for cholesterol gallstones in certain subpopulations. The authors reported significantly increased biliary cholesterol saturation and modification of bile acid composition during the legume diet period.

5. Other studies

Evidence for the cholesterol-lowering effect of soluble fiber from oats was evaluated using meta-analysis (Ref. 125). In this study, after pooling the raw data from 5 investigators who had looked at the effect of consumption of oat products on blood total cholesterol, a modest reduction (average decrease of 5 to 6 mg/dL) on blood total cholesterol levels was found. The decrease in blood total cholesterol was largest in those trials with initially higher blood total cholesterol levels, particularly where an intervention dose of 3 g or more of soluble fiber from oats was used. To assess whether other dietary factors, i.e., dilution of saturated fat and calorie intakes by the oatmeal or oat bran addition to diets, might have been responsible for the drop in blood total cholesterol levels, the authors used the experimentally derived, predictive equation of Keys to see if dietary changes in fat components of the test diets could account for the observed decreases in serum cholesterol. The fat and saturated fat changes did not appear to be responsible for the drop in serum cholesterol levels, thus suggesting that some other factor in the test diets (e.g., the soluble fiber fraction) was responsible for the observed effects. The authors concluded, therefore, that incorporation of oats (a rich source of soluble fiber, primarily as β-glucan) into diets causes a modest decrease in average blood cholesterol. The authors also suggested that there was a dose-response relationship between the amount of soluble fiber from oats and the reduction in blood cholesterol levels, with intakes of soluble fiber from oats above 3 g/day showing more effect than lower intakes. Additionally, the authors noted that other components in oats may play a role in the observed cholesterol reduction and suggested the need for long-term clinical trials (6 months or more) with multiple doses to verify their conclusions from the meta-analysis.

6. Summary of human studies

The human studies reviewed above suffered from many of the same design flaws noted in the proposed rule on health claims for dietary fiber and cardiovascular disease (56 FR 60582 at 60591). Some studies were conducted with very small sample sizes (Refs. 84, 85, 87, 90, 91, 93, 94, 97, 110, 111, 114, 122, 123, 124, and 126). Another limitation was short study times (Refs. 87, 101, 102, 110, 114, 120, 121, and 123). Inadequate control of confounding factors, such as concomitant weight losses and changes in other dietary components which may have affected results, plagued some studies (Refs. 86, 96, 107, 108, 110, 117, 119, and 120). The absence of adequate dietary intake data to assure that dietary changes other than differences in soluble fiber intakes had not occurred was a problem for a number of studies (Refs. 84, 86, 87, 88, 90, 91, 95, 97, 99, 105, 106, 119, and 123).

Several studies were suggestive of positive effects of soluble fiber intakes on blood cholesterol levels. One study provided evidence of a relationship between consumption of foods high in soluble fiber and reduced levels of blood total- and LDL-cholesterol levels (Ref. 118). In a comparison of a breakfast cereal fortified with psyllium, a rich source of soluble fiber (12 g of psyllium/day from 114 g/day of a psyllium-containing cereal) to a wheat bran cereal which contributed negligible amounts of soluble fiber, the psyllium-containing cereal was associated with lower blood total- and LDL-cholesterol levels after 6 weeks than were observed in subjects following a diet containing wheat bran

cereal. In another study (Ref. 104), consumption of 123 g of oat bran cereal (contributing 10.3 g soluble fiber daily) versus consumption of 54 g of wheat bran cereal per day (contributing 3.4 g of soluble fiber daily) was associated with lower blood total- and LDL-cholesterol levels after 4 weeks. Dietary intakes of fat and saturated fat were estimated to be similar across treatments. On the other hand, some studies found no relationship between intakes of high soluble fiber diets and blood total- or LDL-cholesterol levels (Refs. 83 and 91). Several explanations for the lack of a relationship in these studies were offered by the authors, including the possibility that the oat bran used was low in soluble fiber content (Refs. 83 and 91). The study by Neal and Balm (Ref. 98) showed significantly lower blood total-cholesterol levels with consumption of a psyllium-fortified cereal, but the decline in LDL-cholesterol levels compared to the control was not statistically significant. A small body weight loss in both groups may have confounded the relationships. However, since it is the LDL-cholesterol, rather than the total-cholesterol, that is the desired endpoint for evaluating beneficial changes, the lack of statistical significance for serum LDL-cholesterol levels limits this study's usefulness.

Finally, the meta-analysis on the cholesterol-lowering effect of oat products was useful and suggested a benefit from oat consumption. However, the authors noted that, while grams of soluble fiber were chosen to represent the dose of oat product, it is entirely possible that other components of oats, as well as the way in which the oat product is prepared, may also play a role in reduction of blood LDL-cholesterol levels. The authors recommended that, because there are several components of oats which could provide beneficial effects on blood cholesterol levels, future clinical studies should test multiple doses of oat products with the simultaneous measurement of other possible active components, including soluble fiber, β-glucan, and tocotrienols.

The most definitive results linking soluble fiber intakes to beneficial changes in blood cholesterol levels were for studies in which dietary supplements of guar (Refs. 99 and 100), gum arabic (Ref. 109), psyllium (Ref. 92), or a combination of soluble fiber sources (Ref. 103) were given. Some of these studies (Refs. 99, 100, and 109) also, however, failed to provide adequate information on dietary intakes, thus limiting the ability to rule out possible confounding effects from other dietary changes that may have occurred concomitantly with addition of these supplements. A series of well-conducted clinical trials were done to design and test the effectiveness of fiber mixtures (guar, pectin, psyllium, and locust bean) on blood cholesterol levels (Refs. 103 and 106). Early studies in one series (Ref. 106) showed no benefit from acacia gum alone or a mixture of acacia gum, psyllium and guar (Studies 1 and 2). Only when a mixture of pectin, psyllium, guar and locust bean was given were beneficial effects seen (Study 4). These results strongly suggest that benefits of fiber supplements are not readily predicted by an analytical definition of soluble fiber, but rather vary, in some unknown way, among different sources or combinations of sources, of soluble fiber. Thus, generalizing results from one fiber source to another must be done cautiously.

B. Animal studies submitted with comments

FDA received a number of animal studies submitted as comments. FDA has reviewed these studies as described below.

1. Relationship between specific soluble fibers and plasma cholesterol

Ney et al. (Ref. 127) evaluated the effect of soluble oat fiber on blood very low density lipoprotein (VLDL), low density lipoprotein (LDL), and high density lipoprotein (HDL) levels by feeding male rats cholesterol-raising diets (diets which contained 1 percent cholesterol and 0.2 percent cholic acid as the stimulus for increasing blood cholesterol levels) and 6 percent dietary fiber from cellulose (control) or from three oat products with increasing levels of soluble fiber: Oat bran, high fiber oat flour or a processed oat product. Compared to the cholesterol-fed cellulose control, all oat fibers lowered plasma total cholesterol by 25 to 45 percent, lowered VLDL + LDL cholesterol levels by 40 to 60 percent, and raised HDL-cholesterol by 25 to 40 percent (all significant at $p = 0.01$). This pattern of changes in blood lipid components is associated with decreased risk of heart disease. The processed oat product, which contained 40 percent more soluble fiber than oat bran or oat flour, resulted in a lipoprotein profile similar to that obtained without the cholesterol-raising stimulus of dietary cholesterol and cholic acid. The oat product with the highest soluble fiber content was, therefore, more effective with ingestion of the cholesterol-raising diet than was the oat bran or oat flour with lower amounts of soluble fiber. The authors suggested that these data, which show greater benefits as the soluble fiber content increases, support the suggestion that soluble fiber is the component of oat fiber responsible for the cholesterol-lowering effect of oat-containing diets.

Nishini et al. (Ref. 128) evaluated the effect of dietary fibers from oat bran, wheat bran, cellulose, and pectin on plasma lipoproteins, apolipoproteins and enzymes involved on cholesterol metabolism in non-fasted rats. The animals were fed experimental diets estimated to contain 8 percent dietary fiber by weight. Results showed that pectin-fed animals (i.e., animals receiving the highest soluble fiber) had significantly lower serum cholesterol, HDL-cholesterol, and apolipoprotein A-1 levels compared to the fiber-free control. Total cholesterol levels in the wheat-bran-fed (primarily insoluble fiber) or oat bran-fed (mixed soluble/insoluble fiber) animals were not significantly different from the fiber-free control. No data were given on the soluble fiber content of the diets, although the pectin diet would be expected to have the highest level of soluble fiber. Results showed that blood lipid distributions are affected differently by dietary fibers, and that changes among lipid components frequently occurred without a change in overall cholesterol concentrations.

Prentice et al. (Ref. 129) compared the effects of ground and rolled caryopses of barley and rolled oats to ground corn on hepatic cholesterol and fatty acid synthesis in chickens. Approximately 7 to 8 percent of the barley and oat cereals was β-glucan; corn had less than 1 percent β-glucan. Both barley and oats decreased plasma total cholesterol by 32 percent and 25 percent, respectively. The authors attributed the effect on serum cholesterol to the higher soluble fiber content of barley and oat diets.

Summaries of unpublished animal studies (Ref. 130) suggested that oats may be effective in lowering plasma cholesterol compared to controls fed white flour, wheat flour, or corn starch. However, the data were preliminary and, thus, had limited usefulness.

Other summaries of unpublished animal studies (Ref. 136) suggested that rolled oats (75 percent by weight in diet) significantly lowered serum cholesterol in chicks. Extruded oat bran, equivalent to 47 percent of oat bran by weight in the diet, significantly depressed ($p = 0.05$) serum cholesterol in chicks. Oat gum at 0.05 percent and 0.10 percent by weight in the diets of rats significantly lowered serum cholesterol. Data comparing several oat fractions fed to chicks suggested that oat gum may be

the active cholesterol depressant component, and that ground rolled oats and instant oatmeal are equal in effect to the defatted, defibered oat flour. The oat oil also had a depressive effect. Additionally, pectin (high soluble fiber) was found to significantly lower serum cholesterol in rats. These studies were done in the mid-1970's and did not have analyzed values for soluble fiber content of the respective diets. Methods and data were not well described, making results difficult to interpret.

Qureshi et al. (Ref. 131) reported the effects of diets supplemented with either corn (61.5 percent by weight of the base diet), wheat (75 percent of the diet), barley (73.5 percent), oats (74.5 percent), or rye (73.5 percent) on serum cholesterol in chickens. This was part of a study to investigate the effects of dietary cereals on the metabolic regulation of lipid metabolism in chicken livers. Compared to corn, barley and oats lowered serum cholesterol 45 percent and 32 percent, respectively. Presumably, barley and oats were higher in soluble fiber content than was corn. However, no fiber content data were presented. Additionally, body weights for animals consuming the barley and oats diets varied, making it difficult to ascribe the effects to fiber per se.

Ranhotra and co-workers (Ref. 132) evaluated the effect of oat bran and oat bran concentrate on serum lipids in rats. Animals were fed experimental diets containing oat bran (5.57 percent soluble fiber) or oat bran concentrate (13.75 percent soluble fiber). Results showed the high soluble fiber content of the oat bran concentrate was associated with a significantly lower serum cholesterol level, but that the oat bran diet (which contained lower amounts of soluble fiber) and the diet free of soluble fiber were not associated with lower serum cholesterol levels.

Shinnick et al. (Ref. 133) evaluated the ability of various sources and forms of oat fiber to lower plasma and liver cholesterol in male rats fed a diet with 6 percent dietary fiber as cellulose (0 percent soluble fiber), oat bran (7 percent soluble fiber), high fiber oat flour (8 to 10 percent soluble fiber), or one of four processed high fiber oat flours (8 to 12 percent soluble fiber). All diets were supplemented with 1 percent cholesterol and 0.2 percent cholic acid to stimulate increased levels of blood total cholesterol. Results showed that all oat products significantly lowered serum cholesterol compared to the control. In a second experiment, diets containing 4 percent dietary soluble fiber in a processed oat flour significantly lowered serum cholesterol. The processed oat flours had higher soluble fiber fractions than the less processed oat products.

In a study published in 1983, Rogel and Vohra (Ref. 135) reported no effect from five varieties of oats (oat bran or oat hulls) fed for 4 weeks on the serum cholesterol levels of quail. No data on soluble fiber were given.

Kritchevsky et al. (Ref. 138) evaluated the cholesterol-raising effects of oat and wheat bran on blood cholesterol levels in rats in a three-week feeding study in which semipurified diets containing 0.5 percent cholesterol and 10 percent oat bran, wheat bran or cellulose were fed to male rats. Weight gains varied among the diets. Results showed that, under these study conditions, there were no effects of diet on any of the serum lipids. No data on soluble fiber content of the diets were provided.

Kahlon et al. (Ref 140) evaluated the effects of rice brans (full-fat or defatted), oat bran, or rice-wheat bran combinations on cholesterol in hamsters. The control diet contained 10 percent cellulose and 0.5 percent cholesterol. Test diets were composed of the control diet plus one of the brans. The oat bran contained 8 percent dietary soluble fiber versus 2 to 3 percent soluble fiber in the other brans. Results showed that rice bran (with fat) and oat bran resulted in significantly lower plasma cholesterol than the control diet. Defatting rice bran resulted in loss of its cholesterol-lowering properties, suggesting that it is the lipid portion rather than the fiber portion of rice bran which is responsible for its cholesterol-lowering effects.

In another study, rats were fed a diet containing 1 percent cholesterol and 0.2 percent cholic acid with added cellulose, oat gum, chitosan, or cholestyramine (5 percent of the diet). Cholestyramine, oat gum, and chitosan all significantly lowered blood and liver cholesterol levels, with the greatest effect with cholestyramine, a commonly used cholesterol-lowering drug. Oat gum, at 5 percent of the diet, reduced serum cholesterol by 23 percent (Ref. 141).

Forsythe et al. (Ref 142), in a study published in 1978, evaluated the influence of source and particle size of dietary fibers on hypocholesterolemic effects in rats. The sources of fiber were cellulose, wheat bran, wheat midlings, oat bran, oat flour, sugar beet pulp, soybean hulls and psyllium seeds. There were significant differences in weight gain and food intake among dietary treatments. No fiber decreased serum cholesterol compared to the fiber-free group.

Significantly lower values of plasma total cholesterol and liver cholesterol in rats fed fiber sources known to contain soluble fibers (oat bran, oat gum, and pectin) compared to rats fed cellulose (insoluble fiber) were reported by Chen et al. (Ref. 143). Rats were fed a base diet containing 1 percent cholesterol and 10 percent by weight of one of the four fiber types. The greater effect of oat gum compared to oat bran was interpreted by the authors to suggest that the plasma and liver cholesterol-lowering effects of oat bran are due to its gum fraction.

Chen and Anderson (Ref. 144) examined the effects of fiber-supplemented diets on total and LDL-cholesterol in rats. Rats were fed one of five experimental diets containing sucrose and 10 percent plant fibers. The diets were as follows: sucrose and cellulose, sucrose-cholesterol with cellulose, sucrose-cholesterol-pectin, sucrose-cholesterol-guar gum, and sucrose-cholesterol-oat bran. Results showed that fiber-fed rats had significantly lowered plasma cholesterol than rats that received cellulose; the lowest concentrations were observed in the pectin-treated group. No data were given on the soluble fiber content of the test diets, although the pectin would presumably contain the highest concentration of soluble fiber.

Chen and Anderson (Ref. 146), in two experiments, examined the effects of guar gum or wheat gum on the plasma and liver lipid levels of rats. In the first experiment, animals were fed one of three diets for three weeks: diet plus sucrose and 10 percent cellulose; sucrose, 15 percent wheat bran, and 4 percent cellulose; and sucrose and 45 percent wheat bran. Each diet provided 10 g of plant fiber. In experiment two, animals were fed one of four diets: diet plus sucrose, sucrose plus cholesterol, sucrose plus cholesterol and wheat bran, or sucrose, cholesterol, and guar gum. The wheat and guar diets provided 7 g of plant fiber; the other two diets provided 4 g of plant fiber. Results from experiment 1 showed that the two wheat bran diets (high in insoluble fiber) significantly raised plasma cholesterol compared to the control. Results of experiment 2 showed the guar diet (high in soluble fiber) significantly lowered serum cholesterol compared to those fed the sucrose-cholesterol or sucrose-cholesterol-wheat bran diets. Plasma cholesterol was similar between the sucrose-cholesterol and wheat groups.

Wilson et al. (Ref. 148) examined the influence of different soluble fibers upon the metabolism of lipids in genetically hyperlipemic, obese Zucker rats. Four diets were tested: a non-fiber diet (no added fiber), a 0 percent soluble fiber diet (cellulose fiber), an oat bran

diet (33 percent soluble fiber), and a pectin-citrus fiber diet (100 percent soluble fiber). Except for the control, the fibers provided 10 percent of the total diet weight. Results showed non-significant decreases in total plasma cholesterol in the oat bran and pectin groups compared to the no-fiber and cellulose groups. However, the pectin group (the highest soluble fiber group) had changes in blood lipid components associated with reduced risk of heart disease: significantly lower LDL-cholesterol and significantly higher HDL-cholesterol.

Welch et al. (Ref. 149) evaluated the hypocholesterolemic effects of oat bran fractions. Oat bran was separated into five fractions: oil, insoluble fraction (rich in starch and insoluble fibre), protein-rich, oat gum, and soluble residue. These were fed to chicks. Results showed that, compared to the control, only the diets containing oat bran, oat gum, or the protein fractions significantly lowered plasma cholesterol. Oat gum was the only fraction which had the same effect in reducing plasma cholesterol levels as did the native oat bran. Thus, oat gum was concluded to be the main cholesterol-lowering component of oat bran. Beta-glucan was the main component of the gum fraction. However, the protein fraction also had a beneficial effect on plasma cholesterol levels, although of a lesser magnitude than the gum portion.

Five sources of dietary fiber were compared for their effect on blood and liver cholesterol in beef-fed C57BL/6 male mice (Ref. 150). Mice were fed one of the following fiber supplements (7 percent dietary fiber) with the experimental diet: soybean fiber, rice bran (full fat), oat bran, barley bran, and mixed bran (one-third each of rice, barley, and oat brans). Results showed significantly lower plasma total cholesterol compared to the control in the rice bran and soybean fiber groups.

Ginter et al. (Ref. 151) reported that addition of 5 percent citrus pectin (a high soluble fiber source) and 0.5 percent ascorbic acid to a high-fat diet fed to guinea pigs prevented cholesterol accumulation in blood serum and the liver.

Kakis et al. (Ref. 152) reported reduced serum cholesterol and HDL levels in all psyllium-fed (a soluble fiber) animals as compared to wheat bran-fed (a relatively high insoluble fiber source) animals after a three week experimental period. Relative to the appropriate wheat bran control, psyllium had a graded serum hypocholesterolemic effect that varied from a high of 41 percent at low dietary cholesterol concentrations to 26 percent at high dietary cholesterol concentrations. However, HDL cholesterol (in mg percent and as a percent of total cholesterol), the "beneficial blood cholesterol," was lower in the psyllium groups than in the respective wheat bran controls. Thus, the overall benefit of psyllium was not clear from this study.

Life Sciences Research Office's (LSRO) 1982 report to FDA on the health aspects of psyllium seed and other food ingredients (Ref. 153) was submitted with comments. Summaries of studies with beagles fed psyllium-supplemented diets consistently showed lowered serum cholesterol compared to controls.

2. Animal studies: dose-response relationship between soluble fiber and plasma cholesterol

Shinnick et al. (Ref. 134), following evaluation of several approaches to improve the cholesterol-fed rat model used to evaluate the hypocholesterolemic potential of foods, fed nine levels of a high fiber oat flour (HFOF) derived from oat bran to male Sprague-Dawley rats. Ingestion of increasing amounts of HFOF, containing 0 to 10 percent dietary fiber, by rats in which high blood cholesterol levels had been produced with 1 percent cholesterol and 0.1 percent cholic acid, resulted in a significant inverse relationship between serum cholesterol levels and HFOF intake for serum and liver cholesterol levels. Similar results were obtained for liver cholesterol levels. The authors suggested that, although this study does not distinguish among the components of HFOF that may contribute to the cholesterol-lowering effect, the observed dose-response relationship in the rat model is suggestive that larger intakes of soluble oat fiber sources may be accompanied by greater reductions in serum cholesterol levels in humans.

Turley and co-workers (Ref. 147) conducted a dose-response study to three levels of psyllium supplementation in the diets of hamsters. Results were compared to two other nonabsorbable polymers known to have cholesterol-lowering effects (i.e., cholestyramine and surfomer). Animals were fed diets containing 0 percent, 1 percent, 4 percent, or 7.5 percent psyllium. Results showed significantly lowered plasma cholesterol compared to the control group in animals consuming 4 percent and 7.5 percent psyllium. The group consuming 7.5 percent psyllium had the lowest plasma cholesterol, although the authors did not report any significant difference between the 4 percent and 7.5 percent psyllium groups. While all three polymers were effective in reducing plasma total and LDL-cholesterol levels, each exerted different quantitative and qualitative effects on bile acid and cholesterol metabolism, suggesting that mechanisms of action may vary by fiber type.

3. Animal studies: relationship between β-glucan and plasma cholesterol

Three cultivars of hull-less barley containing β-glucans were evaluated for their hypocholesterolemic responses in chickens (Ref. 137). The authors identified the Arizona cultivar of barley as a waxy-starch genotype of high molecular weight and with a high β-glucan content. The Washonupana cultivar was second highest in molecular weight and is also described as a waxy-starch type genotype. The third cultivar, Franubet, has the lowest molecular weight and is not waxy in texture. These latter two genotypes have normal β-glucan contents. Both the Arizona and Washonupana varieties produce highly viscous slurries in water, and this viscosity was greatly reduced by addition of the enzyme, endo-β-glucanase, which destroys the β-glucan. Results of feeding studies in rats showed that both the Arizona and Washonupana cultivars reduce serum cholesterol in chickens. The Franubet variety had no effect. The authors interpreted these results to mean that the cholesterol-lowering properties of the Arizona and Washonupana cultivars were probably a function of their viscous β-glucan content.

Klopfenstein and Hoseney (Ref. 139) evaluated the cholesterol-lowering effect of β-glucan-enriched bread. Oat, barley, wheat, and sorghum breads were made with and without β-glucan from each type of grain (e.g., oat β-glucan was processed into oat bread) and fed to rats for 35 days. Breads containing β-glucans from oats and barley adversely affected weight gains and feed efficiencies. Results showed lowered serum and liver cholesterol in rats fed the β-glucan-enriched bread than those fed the control breads. Given differences in weight gains, results are difficult to interpret.

Fadel et al. (Ref. 145) evaluated the hypocholesterolemic effects of β-glucans in different barley diets fed to chickens and the influence of β-glucanase on the hypocholesterolemic effects. The animals were divided into five groups and fed one of five diets: a corn-diet, Washonupana (WSNP) barley, WSNP with β-glucanase, Fraubet (FNBT) barley, FNBT with β-glucanase. Results showed significantly lowered serum

cholesterol only in chicks fed the WSNP diet. LDL-cholesterol levels for all barley fed chicks were significantly lower than that of the corn diet-fed chicks. Only the WSNP fed chicks had serum cholesterol significantly lower than WSNP fed chicks with supplemental β-glucanase. There was no significant difference in total cholesterol in FNBT and FNBT plus supplemental β-glucanase fed chicks. β-glucan in the Washonupana barley has hypocholesterolemic effects and addition of the β-glucanase to this diet reverses the hypocholesterolemic effects. However, the lack of similar finding with added β-glucanase to the Franubet variety suggests that β-glucans may differ among different varieties.

4. Summary of results from animal studies

The animal studies received as comments, and reviewed above, provide evidence to support the likely effectiveness of soluble fibers relative to the cholesterol-lowering characteristics of diets high in some cereals. However, the animal studies, like the human studies, fail to provide adequate specifications characterizing the test fiber sources. Indeed, similarly to many human studies, many animals studies did not analyze experimental diets for soluble fiber content, nor provide descriptions of the physical characteristics or commercial sources of the soluble fibers used as test substances.

Results from the animal studies showing effectiveness of increasing levels of oat products are suggestive, but not conclusive, evidence of a dose response for soluble fiber (Refs. 127, 132, 134). A specificity for the gum portion of oats, the major source of soluble fiber in oats—and specifically, of beta-glucan as the predominant soluble fiber source—is suggested by several studies (Refs. 127, 129, 132, 134, 137, 141, 143, 145, and 149). However, the solubility (and possibly, the effectiveness) of beta-glucan is apparently variable, and can be affected by such factors as plant variety (Refs. 137 and 145), or food processing such as baking of bread (Ref. 154). These results, therefore, suggest that analysis of the beta-glucan content per se may not be sufficient to characterize the active soluble fiber content of foods.

Other soluble fibers were also shown to have serum cholesterol-lowering effects in animals, including pectins (Ref. 128, 143, 144, 148, and 151), psyllium (Refs. 147 and 152), and guar gum (Ref. 146). However, in the psyllium study (Ref. 152), adverse effects on HDL-cholesterol levels were observed, raising the issue that individual fibers need to be evaluated as to their overall effect on all relevant blood lipid components, not simply limited to blood total or LDL-cholesterol levels. The various fiber sources also appear to have different mechanisms of action and different relative magnitudes of effect (Refs. 128 and 147), thus suggesting that caution is necessary before generalizing from one type of dietary fiber to another.

C. Conclusions from new studies

FDA reviewed over 40 human studies that became available since publication of its proposed rule, and a number of animal studies submitted as comments. The most commonly studied soluble fiber sources were oat bran, pectin, guar gum, and psyllium. Other fibers studied were wheat germ, beet fiber, and gum arabic. A few studies evaluated the effects of mixtures of soluble and insoluble fibers or food sources of soluble fibers.

FDA evaluated results from these studies in light of studies reviewed in the proposal and conclusions from Federal government and other authoritative reviews. In the proposal, FDA noted that, although most reviews by authoritative scientific bodies had concluded that diets rich in water-soluble fiber fractions were associated with cholesterol-lowering effects in humans, it was not possible to conclude that the observed effects were due to the soluble fiber or to other components associated with consumption of foods rich in soluble fiber. FDA also noted that there was some evidence that different types of soluble fiber have different effects, and that the analytical measure of soluble fiber may not be adequately predictive of its physiological effects. Thus, FDA concluded that:

> Overall, the available data are not sufficient to demonstrate that it is the total soluble dietary fiber, or a specific measurable and quantifiable subcomponent, that is related to lower blood cholesterol levels. (56 FR 60582 at 60592).

The newer evidence available since the proposed rule and reviewed above do not change the conclusions reached by the earlier review. If, however, additional information becomes available to demonstrate that a specific soluble fiber-containing product, a soluble fiber-containing ingredient, or a more highly specified form of foods soluble fiber is effective in lowering bloood LDL-cholesterol and does not adversely affect other risk factors for cardiovascular disease (e.g., blood HDL-cholesterol levels), then FDA encourages manufacturers to petition for a health claim for their particular product. The same science will be applicable, regardless of whether the petition is for a single supplement-type product, a clearly specific ingredient, or a specific type of soluble fiber contained in foods.

III. Comments

A. Food Claims Versus Nutrient Claims

1. In the proposal on general requirements for health claims (56 FR 60537), FDA specifically requested comments on issues relating to health claims on the label or labeling of foods which targeted foods rather than nutrients, criteria to identify foods eligible for such claims, and possible measures to assure that consumers are not misled as to the benefit of consuming specific products.

A variety of comments submitted in response to the proposed rule on dietary fiber/CVD supported claims on foods. Specifically, relative to a claim for dietary fiber and heart disease, a few comments stated that FDA does have the authority to regulate claims about foods as well as nutrients and that the agency should allow a generic health claim on fruits, vegetables, whole grain and similar types of foods, stating that generous intakes of such foods in diets may help lower the risk of heart disease and certain forms of cancer. Other comments stated that, at this time, a scientific basis does not exist on which to authorize a specific claim for dietary fiber and heart disease, and that a food claim was more appropriate. Other comments suggested that such claims be developed in concurrence with "The Surgeon General's Report on Nutrition and Health," (Surgeon General's Report) (Ref. 63) and objectives identified in "Healthy People 200: National Health Promotion and Disease Prevention Objectives," (Healthy People 2000) (Ref. 64), and should focus on the total diet.

A number of comments stated that the amount of fat in the American diet should be lowered and the amount of dietary fiber increased through a variety of food choices from among all the food groups. Several comments favored a limited claim at point of purchase for foods that would help increase dietary fiber intake and lower fat intake. A number of comments noted that an appropriate health statement on food labels should emphasize that eating a variety of food sources of dietary fiber daily (cereals, grains, fruits, and vegetables) can decrease the risk of certain forms of cancer and heart disease. A number of comments stated that food claims, if allowed, should not give the impression that a single

nutrient (for example, dietary fiber) is responsible for the reduction in risk of heart disease. Several comments suggested that a health claim regarding dietary fiber and heart disease be made only on fruits, vegetables (fresh or processed), or whole grains and not on products that combine these foods with other ingredients (such as bread products or sauce). Other comments favored use of claims on foods but not supplements.

One comment stated that FDA should allow a fiber health claim because virtually all dietary guidelines for Americans have encouraged consumption of fiber-rich foods, including whole grain cereals, fruits, and vegetables, and that comprehensive government and other reviews by recognized scientific bodies concluded that dietary patterns that include fiber-rich foods are associated with reduced risk of colorectal cancer, heart disease, and other chronic diseases.

As the agency has discussed, in the final rule on general requirements for health claims published elsewhere in this issue of the **Federal Register**, statements about good nutrition that do not, expressly or by implication, refer to a substance are considered dietary guidance and not health claims. In this rule, the agency has concluded that the scientific evidence is sufficient to support a health claim that refers to a substance contained in certain fruits, vegetables, and grain products and relates those foods to a reduced risk of heart disease. Specific reference to the fact that these foods contain soluble fiber is authorized, since this nutrient serves as a useful marker for the broad product categories of foods which correlate with reduction in blood LDL-cholesterol levels, and consequently, with reduced risk of heart disease. Thus, the agency has been persuaded by the comments that the totality of the evidence supports a health claim which identifies foods whose use is protective against heart disease and whose selection can be facilitated by reference to the marker nutrient, soluble fiber. Because soluble fiber is usually considered a useful adjunct to, but not a replacement for, a diet low in saturated fat and cholesterol (Ref. 66), the agency is also requiring this information in the label claim.

B. General Comments

2. Several comments supported a health claim for dietary fiber and heart disease, stating that there is sufficient scientific evidence to support such a claim or that a claim is warranted because heart disease and, hence, CVD are major public health problems. Other comments stated that because such a claim would help Americans become aware of the importance of fiber, and because it is well known that population groups who consume high fiber diets have a low incidence of heart disease, these claims should be allowed. Several comments stated that FDA should consider the rapid pace of advances in knowledge that link nutritional substances to good health and disease prevention. Other comments stated that a claim regarding dietary fiber and CVD should not be allowed because overall health depends on a number of factors, such as exercise and lifestyle characteristics.

FDA agrees that CVD and, consequently, CHD are significant public health problems. The agency, in the proposal, tentatively concluded that diets high in fiber-rich foods, including whole grains, fruits and vegetables, are associated with reduced risk of CHD, and thus CVD. In the proposal, the agency also noted that these diets differ in levels of many nutrients, such as saturated fat and vegetable protein, and in types of dietary fiber, making it difficult to ascribe, from observational studies on whole diets, the observed nutrient and disease relationship to a single dietary component (56 FR 60582 at 60592 and 60593).

Several new studies that became available after publication of the proposal were suggestive of positive effects of soluble fiber intakes on blood total- and LDL-cholesterol levels, risk factors for heart disease. However, FDA has also concluded, as noted in the proposal, that the effectiveness of these fibers may be affected by other dietary components (e.g., the level of saturated fat and cholesterol in the diets), as well as by physical characteristics (e.g., particle size or water-holding capacity), or by the fiber source itself. Thus, while the agency has concluded that not all soluble fibers, i.e., as identified by the AOAC method for soluble fiber determination, are effective in lowering cholesterol, and other components of fiber-rich foods, i.e., vegetable proteins or lipids, may contribute to the cholesterol-lowering effect observed. In addition, the hypocholesterolemic effectiveness of some soluble fibers has been reported in studies in which the source of soluble fiber was consumed as an adjunct to a low saturated fat, low cholesterol, and low total fat diet.

3. Several comments stated that FDA is not following the congressional mandate to consider whether there is significant scientific agreement supporting specific health claims. Specifically, the comments argued that the agency should have placed its inquiry in the proper context by first identifying the range of specific health claims that could be made about dietary fiber and CVD, and then examining the scientific support for each claim.

FDA disagrees with this comment. The 1990 amendments did not require the agency to identify the wide range of health claims that might be made with respect to the 10 topics identified in the act and then to evaluate all published studies relevant to the claims. Rather, the 1990 amendments instructed the agency to determine whether claims respecting the 10 areas, including "dietary fiber and cardiovascular disease" meet the requirements of section 403(r)(3) or (r)(5)(D) of the act. The agency interpreted this directive in a straightforward and logical way. Indeed, FDA's chosen approach was necessary if the agency hoped to accomplish the congressional mandate within the required timeframe. Thus, FDA, in its proposed rule (56 FR 60582), focused its review of the science on those aspects of the dietary fiber and CVD relationship for which the strongest scientific evidence exists: Soluble fiber and CHD.

4. Some comments stated that FDA's denial of a health claim for dietary fiber and CVD, because of rigid application of a scientific standard higher than that mandated by the 1990 amendments, would have unfortunate public health consequences.

FDA disagrees with the comment that the agency is applying a standard higher than that mandated by the 1990 amendments. To ensure the validity of health claims, Congress enacted a scientific standard in section 403(r)(3)(B)(i) of the act. FDA intends to authorize any claim shown to meet that standard; specifically, any claim for which, based on the totality of the publicly available scientific evidence, there is significant scientific agreement, among experts qualified by training and experience to evaluate such claims, that the claim is supported by the evidence. FDA also disagrees that applying the scientific standard mandated in section 403(r)(3)(B)(i) of the act will have unfortunate public health consequences. FDA believes that for health claims to be truly educational and provide public health benefits, they must be scientifically valid and not misleading. The issue of the scientific standard is discussed in more detail in the final rule on general requirements for health claims, published elsewhere in this issue of the **Federal Register**.

5. Some comments stated that FDA used disparate criteria in assessing the relationship between lipids and CVD

and dietary fiber and CVD, but did not elaborate on this issue.

FDA disagrees with these comments. In reviewing the scientific literature for the development of its proposed rules for health claims, FDA followed the standard mandated by the 1990 amendments.

Federal Government reports and other authoritative documents have consistently concluded that there is a strong relationship between the total amount and types of dietary fat and other lipids in the diet and the risk of heart disease. In developing the proposed rule on lipids and CVD, the agency found that new evidence supported these conclusions. The weight of the evidence showed that diets low in saturated fat and cholesterol are associated with reduced blood total- and LDL-cholesterol and a lower risk of CHD.

In contrast, Federal Government reports and other authoritative documents did not reach similar conclusions that the scientific evidence supported a claim that dietary fiber per se is associated with the reduced risks of CVD. The available evidence showed an association between consumption of diets high in fruits, vegetables, and grain products—diets which are generally high in fiber—and risk of heart disease. For example, in its recommendations in the NAS report "Diet and Health" (Ref. 48), the committee on Diet and Health "agree[d] with most other expert groups in proposing that the intake of vegetables, fruits, and other sources of complex carbohydrates should be increased and that the intake of sugars should be limited." The committee further noted that "the strength of the evidence does not justify making specific recommendations pertaining to dietary fiber at this time. The committee's recommendation to emphasize the consumption of vegetables, fruits, and other sources of complex carbohydrates would, however, indirectly result in increased consumption of dietary fiber."

In developing its proposed rule on dietary fiber and CVD, the agency found that the evidence available at the time the proposal was developed did not alter these conclusions. The agency found that the scientific evidence was not sufficiently conclusive or specific for dietary fiber per se versus other components in the diet to justify use of a health claim relating intake of dietary fiber to reduced risk of CVD.

6. One comment stated that FDA failed to comply with the 1990 amendments (section 403(r)(4)(C) of the act) in that it has rejected the conclusion of authoritative Federal Government reports without justifying its decision to do so as the act requires. The comment stated that the National Cholesterol Education Program (NCEP) has concluded that soluble fiber may help reduce blood cholesterol levels. The comment refers to the NCEP 1989 consumer pamphlet (Ref. 5), which recommends breads, pasta, rice, cereals, dried peas and beans, fruits, and vegetables as good sources of complex carbohydrates (starch and fiber). The comment quotes from the pamphlet that these foods are "excellent substitutes for foods that are high in saturated fat and cholesterol. The type of fiber found in foods such as oat and barley bran, some fruits like apples and oranges, and in some dried beans may even help reduce blood cholesterol levels" (Ref. 5). The comment also noted that the NCEP expert panel report, "Population Strategies for Blood Cholesterol Reduction" (Ref. 66), supports the recommendation to consume vegetables, fruits, breads, legumes, and whole grain cereals. The comment quotes the NCEP report that "Dietary fiber supplements are not a panacea for blood cholesterol problems. Foods rich in soluble dietary fiber are, however, a useful addition to a low saturated fatty acid, low fat, and low cholesterol eating patterns* * *" and:

> "Oat bran exhibits hypocholesterolemic properties due to its appreciable content of oat gum. Soluble fibers such as pectin, guar gum, locust bean gum, or psyllium in large quantity supplementation have been shown to lower total and LDL-cholesterol levels. The absolute effect on LDL-cholesterol concentrations is modest even when the amount of soluble fiber such as oat bran is consumed in appreciable amounts (60 g). This effect, however, represents a useful adjunct to an eating pattern low in saturated fatty acids and cholesterol" (Ref. 65).

FDA disagrees that, in developing its proposed rule regarding fiber and CVD, it rejected conclusions of Federal Government reports. Comments, through repetition of those portions of the text that accompanies dietary recommendations and that includes the words "soluble fiber," are attributing greater significance to the statements relating soluble fiber to heart disease risk than was given to these results by the expert panels. This selected emphasis distorts the meaning of the authoritative reports in question by failing to acknowledge important contributions to reduced risk of disease by the wide variety of nutrients and nonnutritive substances present in diets high in fruits, vegetables, and grain products. Such an emphasis also focuses attention away from changes in overall dietary patterns and their potential contributions to reducing risk of chronic diseases.

In the NCEP report (Ref. 65) cited by the comment, the expert panel noted the hypocholesterolemic effects of some soluble fibers, but recommends "a habitual pattern of eating that is consistently low in saturated fatty acids, total fat, and cholesterol." NCEP further recommended that "all healthy Americans recognize that no single food or supplement is the answer to achieving a desirable blood cholesterol level" (Ref. 65). NCEP's recommendation to Americans is to "eat a greater quantity and variety of fruits, vegetables, breads, cereals, and legumes" (Ref. 65). These food choices "will help to meet nutritional needs for minerals, vitamins, dietary fiber (including soluble fiber), and complex carbohydrates, and to replace calories from fat." Thus, the NCEP acknowledges the importance of a dietary pattern that focuses on reducing fats in the diet in order to reduce serum cholesterol. It did not attribute a protective effect from CVD to dietary fiber alone.

Neither the Surgeon General's report on "Nutrition and Health" (Ref. 63), the National Academy of Sciences (NAS) "Diet and Health: Implications for Reducing Chrinic Disease Risk"(Diet and Health) (Ref. 48), nor (The Department of Health and Human Services (DHHS)) "Healthy People 2000" (Ref. 64) found the scientific evidence strong enough to attribute the protective effects against CVD of dietary patterns high in fruits, vegetables, and grain products exclusively to the soluble fiber content of such diets. Specifically, the Surgeon General's report on "Nutrition and Health" (Ref. 63) recommends increased consumption of whole grain foods and cereal products, vegetables (including dried beans and peas) and fruits. The report states that:

> "the association shown in epidemiologic and animal studies between diets high in complex carbohydrates and reduced risk for CHD and diabetes mellitus is, however, difficult to interpret. The fact that such diets tend also to be lower in energy and fats, especially saturated fats and cholesterol, clearly contributes to this difficulty. Some evidence from clinical studies also suggest that water-soluble fibers from foods such as oat bran, beans, and certain fruits are associated with lower blood glucose and blood lipid levels" (Ref. 63).

The section concludes with the statement, "Current evidence suggests the prudence of increasing consumption of whole grain foods and cereals, vegetables (including dried beans and peas), and fruits" (Ref. 63).

Similarly, the Executive Summary of the National Research Council's "Diet

and Health" recommends, "Every day eat five or more servings of a combination of vegetables and fruits, especially green and yellow vegetables, and citrus fruits. Also, increase intake of starches and other complex carbohydrates by eating six or more daily servings of a combination of breads, cereals, and legumes" (Ref. 48). The summary continues "Studies in various parts of the world indicate that people who habitually consume a diet high in plant foods have low risks of atherosclerotic CVD's, probably largely because such diets are usually low in animal fat and cholesterol. Some constituents of plant foods, e.g., soluble fiber and vegetable protein, may also contribute—to a lesser extent—to the lower risk of atherosclerotic cardiovascular diseases." The Committee does not recommend the use of fiber supplements.

"Healthy People 2000" states that recommendations from the National Cancer Institute, the Surgeon General's report on "Nutrition and Health," NAS' "Diet and Health," and "Dietary Guidelines for Americans" support increased consumption of vegetables, fruits, and whole-grain breads and cereals (Ref. 64). "Healthy People 2000" also states that further research is needed to clarify whether the effect on blood lipids is an independent effect, and if so, to quantify the relationship (Ref. 64).

Therefore, in its proposed decision not to authorize the use on the label or labeling of foods of health claims relating intake of dietary fiber to decreased risk of CVD, the agency's tentative conclusion was consistent with those of Federal Government and other authoritative reports.

FDA's position was also consistent with recommendations in the Institute of Medicine's report "Nutrition Labeling: Issues and Directions for the 1990s" (Ref. 81). In this report, the authors note that:

"there has been a great deal of interest in the specific effects of dietary fiber on several chronic diseases. The strongest argument for an increase in consumption of dietary fiber is the important contribution it makes to normal bowel function. Clear scientific associations of fiber intake with the incidence of heart disease, certain types of cancer, and diabetes mellitus have not been made. One reason may be the difficulty in designing appropriate experiments to specifically test for the effect of dietary fiber. Foods high in dietary fiber are also generally low in calories and total and saturated fatty acids and devoid of cholesterol; thus, determination of a specific fiber effect in a feeding study is difficult. Moreover, foods have a variety of fiber components and each may have different actions. Chemically and physiologically, cellulose, lignin, hemicellulose, pectin and alginate (all relatively purified fiber types) behave differently. Wheat bran, oat bran, and rice bran (all heterogeneous mixtures of fibers) are not similar in composition. It is also very difficult to analyze dietary fiber chemically, and thus it is hard to correlate the role of specific fiber components to health effects * * *" (Ref. 81).

The Institute of Medicine's report (Ref. 81) also provided specific recommendations, including: (1) "FDA and USDA should require the disclosure of fiber content per serving in grams on the nutrition information panel under the term total dietary fiber"; and (2) "FDA and USDA should discourage labeling of soluble or insoluble fiber contents until methodologies approved by the agencies allow for the adequate and reproducible quantification of the soluble and insoluble fiber contents of a variety of foods" (Ref. 81).

Therefore, FDA is not rejecting the conclusions of these government reports. In its final rule, § 101.76, the agency is permitting a claim relating dietary consumption of fruits, vegetables, and grain products, i.e., good sources of fiber, with reduced risk of heart disease.

7. One comment criticized FDA for misinterpreting the conclusions of the Government of Canada's 1985 "Report of the Expert Advisory Committee on Dietary Fiber" to the Department of Health and Welfare (Ref. 46). The comment stated that the committee expressly advocated health claims for soluble fiber and CHD.

FDA agrees that the Canadian report in question noted hypocholesterolemic effects of some soluble fiber sources, but FDA disagrees that the Department of Health and Welfare supports health claims on soluble fiber in Canada. In its comments to FDA regarding the proposed rule, dietary fiber and CVD, the Canadian Department of Health and Welfare stated its opposition to health messages. Its comment stated that health messages and claims for heart disease and cancer, among other diseases, are not permitted under the Canadian Food and Drugs Act. These diseases are considered to require medical diagnosis and treatment under medical supervision, and thus products bearing messages about them are regulated as drugs. The 1985 report suggested that, if a company desired to use a health claim, then that company should present the evidence of the product's effectiveness based on acceptable test protocols (Ref. 46).

8. One comment stated that FDA failed to note, in the proposed rule, epidemiological studies cited in the NAS' "Diet and Health" that found an inverse association between dietary fiber and CHD, even after adjusting for the possible confounding effects of calories and fat (Ref. 48).

FDA disagrees with this comment. One study was cited in "Diet and Health" that showed a protective effect of dietary fiber from cereals on risk of CHD independent of caloric intake. Results of a study by Khaw and Barrett-Connor (Ref. 31) (reviewed by FDA in the proposal) found an inverse association between fiber intake and ischemic heart disease mortality independent of calories among other dietary components. However, "Diet and Health" also states that the authors used 24-hour dietary recall to assess intake, a method which has limited applicability in the assessment of the usual dietary intake of individuals in the United States (Ref. 48). Results from the 1982 epidemiological study by Burr (Ref. 82), also cited in "Diet and Health," showed a lower risk of CHD in 10,943 vegetarians than in nonvegetarians, but their decreased risk could not be accounted for by increased fiber consumption, because many other components of the diet also differed between these two groups. Therefore, FDA did not misinterpret the conclusions of "Diet and Health" that there is no conclusive evidence that it is dietary fiber, rather than other components of fiber-rich foods, that reduces risk of CVD.

9. One comment disagreed with the indication in the proposed rule that a "risk/benefit" argument was not a sufficient or appropriate basis on which to authorize a health claim for food labels. The comment stated that, although the data for dietary fiber do not support the hypothesis for reduced risk of CVD, the "potential benefits far outweigh the potential disadvantages."

FDA disagrees with this comment. Congress enacted a scientific standard for health claims in section 403(r)(3)(B)(i) of the act. Claims must meet the statutory requirements; that is, based on the totality of the scientific evidence, there must be significant scientific agreement, among experts qualified by training and experience to evaluate such claims, that the claim is supported by such evidence. The concept of "potential benefits outweighing potential disadvantages" is not an acceptable substitute for the scientific standard mandated by Congress.

C. Specificity of the Relationship Between Soluble Dietary Fiber and Heart Disease

10. Several comments stated that FDA's refusal to authorize a health claim on dietary fiber and CVD is based

on the agency's determination to treat all dietary fiber as a group, rather than considering each fiber source individually. The comment stated that dietary fiber is composed of a diverse group of materials, as the agency observed, and each has its own physiological effects. The comment noted that certain water soluble fibers have been documented to reduce serum cholesterol, thereby lowering the risk of CHD.

FDA disagrees with this comment. In the proposed rule (56 FR 60582), FDA limited its review of the science to those aspects of the dietary fiber and CVD relationship for which the strongest scientific evidence exists: soluble dietary fiber and CHD. FDA also noted, however, that soluble fiber was a heterogenous family of fibers which vary in both chemical and physical characteristics. After reviewing the totality of the evidence, the agency is persuaded that even if soluble fiber alone is effective in reducing risk of heart disease, greater specificity than that identified by existing analytical methods is needed in order to predict the effectiveness of soluble fiber in foods.

11. LSRO submitted its document, "Dietary Fiber and Cardiovascular Disease" (Ref. 40), as a comment. In this final report, LSRO stated that it remains to be determined whether the observed effects of dietary fiber on serum cholesterol reduction result strictly from the fiber or from other components of the fiber-rich food or from a combination of these factors. The report stated that studies suggest that soluble fiber, a specific type of dietary fiber, is hypocholesterolemic, while insoluble fiber is not. Further, when foods are used, foods rich in β-glucans seem to have a more hypocholesterolemic effect. The report states that there is no indication of optimum level or even a dose-related effect, and notes that there are suggestions as to optimum level of intake for "better health" (e.g., normal bowel function) but not for prevention of disease. In addition, there are no data relating to transience of fiber effects, although this is amenable to experimental testing. The LSRO report also noted that generalization to the U.S. population is difficult. Presumably, persons at high risk, such as those with a family history of hyperlipidemia or heart disease, would benefit most.

The LSRO report also states that it is unclear whether the lipid-lowering effects observed in some studies are the result of the fact that most high fiber diets are low in fat. According to the report, most of the available evidence suggests that isolated polysaccharides, such as pectin, guar gum, locust bean gum, oat gum, and psyllium mucilloid, have the ability to lower serum cholesterol levels; however, there are no data to indicate that a fiber present in a food is the same as when it has been extracted and purified. The data suggest that diets high in fiber-rich foods can influence lipidemia, but this effect is probably due to overall changes in the diet caused by the addition of fiber sources rather than simply to a direct effect of fiber.

One comment stated that FDA failed to cite LSRO's (Ref. 39) conclusions regarding hypocholesterolemic effects of some soluble fibers.

FDA agrees that the results of clinical studies suggest that soluble fiber is hypocholesterolemic, while insoluble fiber is not. FDA also agrees that the effect of fiber-rich foods on serum lipids is related to the total diet, i.e., one that is low in saturated fat and cholesterol and high in soluble fiber-rich foods, such as vegetables, fruits, and grain products.

FDA disagrees that the agency failed to consider the conclusions of this report. Both of LSRO's reports (Refs. 39 and 40) concluded that soluble fibers were related to reduced blood cholesterol levels, but the LSRO report (Ref. 40) also concluded, as noted above, that it remains to be determined whether the observed effects of dietary fiber on serum cholesterol reduction result strictly from the fiber or from other components of fiber-rich foods or from a combination of these factors. Data available since LSRO's report (Ref. 40) provided some additional information as to the effect of soluble fiber on blood cholesterol reduction.

12. One comment stated that FDA failed to note part of the World Health Organization's (WHO) report (Ref. 71) on the relationship between soluble fiber and blood cholesterol levels (and hence CHD). The comment quotes the report, "[o]ther dietary components, such as dietary fibre, have an effect on serum cholesterol in experimental studies and are correlated in intercountry comparisons. As with fatty acids, the different forms of dietary fibre may have different effects on serum cholesterol" (Ref. 71). The comment concludes that, although the WHO report did not analyze the relevant science, it acknowledges the evidence that soluble fibers have hypocholesterolemic effects.

FDA disagrees with the comment that it failed to note the WHO statements regarding soluble fiber. Although the WHO report states that "different forms of dietary fiber may have different effects on serum cholesterol," it does not identify which form of dietary fiber affects serum cholesterol; the term "soluble fiber" was not used in the report (Ref. 71).

13. Several national health organizations with expertise in heart disease agreed with FDA's proposed conclusion, that, at this time, there is insufficient evidence to link dietary fiber, per se, to CVD. The comments stated that the proposal is consistent with the conclusions of all previous expert groups. The comments stated that the association between fiber and blood lipids is specific to soluble fiber and that specificity to fiber class is unresolved. The amount of soluble fiber necessary to produce blood cholesterol lowering is unclear; nor is it known whether (and if so, how much) the response differs by type of soluble fiber (i.e., β-glucan versus pectin). Furthermore, the comments state that FDA's review of the scientific literature (56 FR 60574) mentions the tumor-enhancing effect of soluble fibers in animal studies. They recommended that FDA not allow health claims that link fiber to risk of CVD's. The comments stated that there are insufficient data to warrant such a claim and that it is misleading to permit a claim that singles out a particular food or foods in diets. The comments stated that if there were sufficient data to make a claim, it should be stated in the context of a low fat, low cholesterol diet. It would also be necessary to specify the type of fiber, e.g., soluble fiber, in the case of CVD.

FDA agrees that a health claim for a dietary component should be stated in the context of the total daily diet and, in this case, should be specific to the type of dietary fiber. The agency has been persuaded, based on its review of the comments and its review of the scientific literature, that questions remains as to whether the cholesterol-lowering effect observed with some soluble-fiber food sources (e.g., oats) is due to the soluble fiber component or to a combination of other components associated with these foods.

14. One comment questioned the motivation behind the agency's tentative rejection of health claims for fiber and CVD. The comment stated that FDA does not want any health claims on dietary supplements and that the agency should not preclude claims because of concern that dietary supplement manufacturers will then be able to make such claims. Comments from supplement manufacturers stated that, if health claims are permitted on fiber-containing foods, then fiber supplements should also be permitted to carry a claim because there is no difference between fiber in foods and

fiber in supplements and all fiber supplements are safe. Other comments stated that FDA should authorize health claims on supplements because supplements offer an alternative to consumers who might otherwise not eat sufficient amounts of fiber in their diets.

FDA disagrees with the comment that it does not want health claims on fiber supplements and with the suggestion that it rejected dietary fiber and CVD health claims because of concern that supplement manufacturers would then be allowed to make such claims. FDA has applied the law equally to supplements and conventional foods.

As the agency's proposed rule stated, FDA proposed to deny a health claim for dietary fiber and CVD because the agency tentatively concluded that the available scientific evidence was not sufficiently conclusive or specific for dietary fiber per se. FDA notes that the comment claimed that there is no difference between fiber in foods and fiber in supplements but submitted no data were submitted to support this statement. Indeed, several expert reports (Refs. 39, 40, and 46) concluded that there is no evidence that fiber, when isolated and/or processed in foods, has the same physiological effects on serum cholesterol as consumption of the native fiber from fiber-rich foods. These reports note that the predictive capability of analytically determined values for soluble fiber and physiologic activity has not been established, and effectiveness may vary by source of fiber or by physical characteristics not detected with chemical methods of analysis (e.g., particle size or water-holding capacity). They also note that safety may vary between native and isolated sources of fiber.

D. Comments Regarding a Relationship Between Specific Soluble Dietary Fibers and CVD

15. One comment submitted a review of available literature for particular fibers. The comment stated that several of these fibers are "effective as cholesterol lowering agents and in addition, they are safe to use provided a few reasonable precautions are taken." The comment identified fibers such as locust bean gum, guar gum, oats, pectin, and psyllium mucilage as materials with hypocholesterolemic effects. Less well-tested fibers that have some hypocholesterolemic effects (for example, barley, acacia gum, dried beans, and karaya gum) were also mentioned. The comment stated that wheat fiber requires more study to determine its effects. The comment notes that, since dietary fiber represents a diverse group of materials, FDA should consider allowing health claims and statements on individual dietary fiber materials. The comment also recommended separate health claims on fibers with "hypocholesterolemic" activity, because each of these fiber materials also has a different dose-response. The comment provided some criteria on which to base the individual fiber claims.

FDA agrees that the scientific literature shows that dietary fiber is a complex group of dietary substances with differing chemical, physical, and physiological properties, and that not all soluble fibers are alike in their hypocholesterolemic properties. FDA disagrees with the recommendation to allow individual health claims on various soluble fibers, but does concur that the effectiveness of individual fibers in foods may be documented for specific food products or for fibers whose physical and chemical characteristics are well specified (e.g., oat brans meeting specified parameters). Thus, if manufacturers can document, through appropriate studies, that the soluble fiber in their particular food is effective in lowering LDL-cholesterol, and has no adverse effects on other heart disease risk factors (e.g., HDL-cholesterol), then FDA encourages manufacturers to petition for a health claim for their particular product or ingredient. Additionally, if new evidence becomes available which more clearly identifies what type of soluble fiber is effective, this also would be appropriate for a petition.

16. Another comment stated that part of FDA's difficulty in interpreting data on dietary fiber and CVD results from the consideration of soluble fiber as a single nutrient instead of as a class of diverse substances. The comment stated that data exist to support at least one soluble fiber, β-glucan, as the substance responsible for the majority of the cholesterol-lowering effects observed with some fiber sources. Another comment stated that there is a preponderance of literature supporting oat bran and its hypocholesterolemic effects and that the active mechanism behind oat bran's effectiveness is the β-glucan component. The comment suggested that the agency allow foods to be identified that contribute to eating patterns that reduce the risk of disease.

FDA agrees, as discussed in the proposal, that dietary fiber is a diverse group of substances and not all soluble fibers are alike in their hypocholesterolemic properties. FDA also agrees, based on new data submitted as comments, that there is evidence to suggest that β-glucan has hypocholesterolemic properties. However, as noted in the meta-analysis (Ref. 125), other components of oats, such as tocotrienols and oat oil, may play a role in the reduction of blood LDL-cholesterol levels. However, FDA is authorizing a claim on fruits, vegetables, and grain products—foods that are good sources of soluble fiber and other substances that may have cholesterol-lowering properties.

17. Comments from a health professional organization stated that several studies have shown that soluble fibers, such as those in oat, beans, psyllium, and guar, appeared to lower serum cholesterol, at least when given in large amounts. The comment further stated that weight loss observed in some studies may possibly be far more important than fiber in contributing to cholesterol reduction.

FDA agrees that weight loss associated with test diets may affect the ability to differentiate between the effects of the test substance (i.e., soluble fiber) versus the well-documented effect of weight loss on blood total- and LDL-cholesterol. This was discussed in the meta-analysis submitted as a comment (Ref. 125). Several studies observed reductions in blood cholesterol levels in studies in which loss did not occur. For example, in a study by Marlett et al. (Ref. 124), submitted with another comment, there was no significant weight loss in either the control or soluble fiber (oat bran) groups during the fiber intervention period. Serum cholesterol was significantly lower in the oat bran group than in the control group. Spiller et al. (Ref. 87) reported no weight changes in two groups receiving either guar gum or oat fiber. Both groups experienced significantly lowered serum cholesterol. In two other studies (Refs. 118 and 120), there was no significant difference in the weight loss between subjects consuming oat bran (Ref. 120) or psyllium cereal (Ref. 118) and those consuming wheat bran. The oat bran group had significantly lower serum cholesterol than the wheat group and compared to the control period. Thus, while the agency agrees that weight loss may be a confounding factor, the new evidence is consistent with the concept that consumption of diets high in certain soluble fiber-rich foods, independent of body weight, has a beneficial effect on blood cholesterol levels.

E. Comments Regarding FDA's Interpretation of Specific Studies

Some comments cited references that were already reviewed by FDA or the consensus documents, or were studies of questionable relevance to human CVD (e.g., studies evaluating

postprandial glucose response of fiber diets). Some abstracts were also cited that do not provide sufficient information for evaluation. Review articles that provided no new data were also included with some comments.

18. One comment stated that the study by Kahn et al. (Ref. 25) showed significant decreases in relevant parameters in the test groups versus baseline and that the authors concluded that soluble fiber "appears to be quite effective" in lowering those parameters. In the proposed rule, FDA reported that there was no significant difference in serum cholesterol between the test group and the control group.

FDA notes that it did report that a significant difference in serum cholesterol existed between baseline and intervention values if the results are examined without consideration of the immediate versus delay constraint of the design. The agency initially concluded that the study did not support an effect of oat bran on serum cholesterol lowering because of the lack of statistical significance when examining only the difference between the immediate intervention group and its control. FDA believes that the study design should have been modified to overcome this problem of the time delay in comparing the groups. However, after further review, FDA agrees with the authors (Ref. 25) that, after correcting for the time delay, the study does show that oat bran supplementation reduced serum cholesterol.

19. One comment criticized FDA for calling a "p value" of 0.052 in the paper by Anderson et al. (Ref. 5) "nearly significant." The comment suggested that a more precise term would be "borderline significant."

FDA acknowledges that the term "borderline significant" is more commonly used professionally, but considers that this does not negate the need for caution in reviewing the results of this paper.

20. One comment stated that FDA failed to report the modest effect, from a study by Bell et al. (Ref. 12), of a pectin-enriched cereal on serum cholesterol.

FDA disagrees with this comment. Of the two fiber-enriched cereals (one enriched with psyllium and the other with pectin) tested by Bell et al. (Ref. 12), FDA reported that only psyllium demonstrated a significant reduction in cholesterol. The agency correctly stated that the psyllium-enriched diet demonstrated significant lowering of total- and LDL-cholesterol, but that the pectin did not.

21. A comment disagreed with FDA's statement that the study by Davidson et al. (Ref. 15) did not demonstrate significant reductions from baseline levels in total cholesterol with daily intakes of up to 2 oz of oatmeal (1.2 to 2.4 g β-glucan/day) or 1 oz oat bran (2.0 g β-glucan/day) in persons on a Step 1 diet.

FDA correctly reported that only the higher fiber intake groups showed statistically significant effects. The small sample size may have prevented seeing an effect in the lower doses. FDA agrees that, based on the results of this study, an intake of soluble fiber (in this case, β-glucan from oats) of about 3 g per day or more was beneficial in that it resulted in a significant lowering of serum cholesterol in persons consuming a low-fat diet.

22. A comment asked FDA to consider a result from a study by Newman et al. (Ref. 50) which used β-glucan from barley and compared it to wheat fiber. The cholesterol levels of the high β-glucan group did not differ significantly from baseline after four weeks. The author explains this lack of significance by citing the small sample size and small amounts of β-glucan consumed.

FDA does not necessarily disagree with this comment, but considers that it was correct in not assessing the results as positive (i.e., a true difference exists) because a statistically significant effect was not demonstrated.

23. One comment stated that FDA failed to consider significant the results by Van Horn et al. (Ref. 68). In this study, the investigators tested the effects of oat-bran intervention on serum cholesterol levels in subjects with normal or mildly elevated serum cholesterol levels. The authors reported a difference ($p = 0.074$) in serum cholesterol between the oat group and the control after 8 weeks.

FDA did not consider this result significant because the small sample size was not a problem in this study and the p values reported are one-tailed. Such values allow leeway over the more conventional and conservative two-tailed tests.

24. One comment stated that FDA did not properly interpret the results of a study by McIntosh et al. (Ref. 44), which compared the cholesterol-lowering effect of β-glucan from barley to that of wheat fiber.

FDA disagrees with this comment. Although there was a significant difference between cholesterol levels of the two groups, this was largely due to a rise in total cholesterol that occurred in the wheat group compared to baseline. In this case, it is not possible to know whether wheat acted as a placebo, or whether wheat itself is cholesterol-raising. However, because the group fed barley did not show a significant lowering of cholesterol from their own baseline level, the agency does not find that a positive effect of barley was demonstrated.

25. Another comment addressed a study by Burr et al. (Ref. 13) that examined whether there was a change in mortality rates between men given dietary advice to increase fiber intake or to reduce fat intake. The comment was specifically concerned with FDA's conclusion that the study was not able to show a difference between mortality rates in the two groups. The comment stated that the results show that increasing fiber intake is no less effective than decreasing fat intake in the prevention of CHD.

FDA disagrees with this comment. Because there was no group in this study which acted as a control (no changes in diet), the study does not provide evidence that either diet in the studies is effective or that neither is effective. The agency finds that the study does not add to the evidence of the effects of fiber.

26. One comment stated that a study by Little et al. (Ref. 42) that shows that lowering fat is responsible for significant lowering of total cholesterol, while increasing fiber is not, did not specify the type of fiber (i.e., soluble versus insoluble) and should not be considered as part of the fiber-CHD evaluation.

FDA disagrees with this comment. The agency considered any fiber study which might be relevant to the health claim. However, the weight given to study results was influenced by several factors, including the quality and usefulness of the information on soluble fiber intakes.

27. One comment noted that the study by Demark-Wahnefried et al. (Ref. 16) showed a significant drop in total serum cholesterol in all three of the following dietary groups: A high fiber, low-fat diet; a low-fat diet alone; and a regular diet with fiber added. The comment contended that, because there was no significant difference between any of the groups, this study showed that increasing soluble fiber intake is as effective as reducing fat intake.

FDA disagrees with this comment. This study does not support a conclusion that soluble fiber is as effective as reducing fat intake. These results showed that the cholesterol-lowering effect of a low-fat diet was not further enhanced by the addition of fiber. Additionally, there was a significantly decreased consumption of fat and cholesterol in all groups; this is consistent with the hypothesis that fat displacement is one mechanism by

which high fiber diets lower total cholesterol.

28. Another comment also criticized FDA's review of the Demark-Wahnefried et al. study (Ref. 16). The comment stated that, according to the Keys equation for predicting changes in blood cholesterol levels from changes in intakes of fatty acids, only 40 percent of serum cholesterol's lowering is explained by changes in dietary fat.

FDA disagrees with this comment. The agency's evaluation of this study pointed out the lack of significant difference between cholesterol lowering on the regular diet plus oats or the low fat, low cholesterol diets. The study did not estimate how much, if any, of the remaining 60 percent is attributable to oat bran.

29. One comment stated that FDA misinterpreted the results of the study by Keenan et al. (Ref. 26) by failing to note that the control group decreased its soluble fiber intake over the study period, thus accounting for the return to baseline for serum cholesterol in this group by the end of the study.

FDA disagrees that it misinterpreted the results of this cross-over study, in which the authors compared the hypocholesterolemic effects of oat- or wheat-supplemented Step 1 diets with a control group on the Step 1 diet only. Although FDA recognizes the problem with the control group, the agency correctly reported that there was a lack of significance in the change in serum cholesterol in the oat-wheat group during the oat phase. Recognizing that the control group decreased its soluble fiber over the study period may suggest redoing the study with a better control of soluble fiber in this group.

30. Another comment also disagreed with FDA's criticism that the study by Keenan et al. (Ref. 26) did not have a placebo. The comment stated that the wheat group was considered a placebo because it has been well documented that wheat has virtually no cholesterol lowering properties. A similar comment was made regarding FDA's criticism of a study by Swain et al. (Ref. 57) in which wheat was also used as a placebo.

FDA has expressed concern about the use of wheat as a placebo due to its inconsistent effect on serum cholesterol in some reports. Although the study by Keenan demonstrated an increased total cholesterol in the "oat-wheat" group of 6 percent above baseline during the wheat period, in Swain's study the wheat group showed a 7 percent decrease in serum cholesterol. Based on these studies and other reviews, FDA now believes that these variations in serum cholesterol may be a function of the amount and method of administration of the wheat and must be reviewed with caution. Rather than discounting the use of wheat as a placebo, FDA believes that the placebo, whether it is wheat or another fiber, must be evaluated individually for each study.

31. One comment suggested that the FDA failed to note that the study by Davidson et al. (Ref. 15) was specifically designed to determine whether β-glucan has a dose-response effect on serum cholesterol after reducing and controlling for fat intake. Subjects in this study consumed a Step 1 diet with two levels of oat bran incorporated into the diet. FDA disagrees that it failed to note this point. The authors of the study stated that there is a "lack of continued dose response" (Ref. 15). In addition, the authors say that "the impact of fat substitution on serum cholesterol reduction with oat cereals cannot be completely excluded" due to the lack of isocaloric control for the higher-dose treatment groups (Ref. 15).

32. Another comment on the Davidson et al. study (Ref. 15) stated that FDA's criticism of the lack of a control group was not valid due to the 6-week wash-out period. The comment states that, during this wash-out period, the serum cholesterol values of all treatment groups returned to baseline levels, suggesting that the hypocholesterolemic effects observed were the result of oat β-glucan supplementation.

Although the wash-out period is not the equivalent to a true control, FDA agrees that, considered with the evidence from the intervention period, the decrease in serum cholesterol suggests an effect of β-glucan at the higher levels of intake.

33. One comment criticized FDA for failure to note regarding the study by Bell et al. (Ref. 11) that the psyllium group on the Step 1 diet had significant reductions in total cholesterol levels as compared to the placebo (wheat fiber) controls.

FDA disagrees with this comment. The problem with this study is that, during the second 8-week test period, the psyllium group's total cholesterol had risen to only 1.5 percent below the baseline level. The significant difference still exists between placebo and test group because the mean serum cholesterol level of the placebo group actually increased to a level higher than baseline. The agency believes that these results weaken the support for cholesterol-lowering effectiveness over time on this diet.

34. One comment stated that the study by McIvor et al. (Ref. 45), showing no effect of guar gum on serum cholesterol in a population of overweight noninsulin dependent diabetics, should not have been discussed in the proposed rule. The comment explained that this was not a typical population group (diabetics consume large amounts of fiber products to help with carbohydrate metabolism), and the objective of the study was to test the safety of guar. In addition, the comment states that the diets were uncontrolled so the results could be confounded by additional fat from the granola-type bars in which the guar gum was incorporated.

FDA disagrees with this comment. Although overweight diabetics may not be a typical group, FDA did not eliminate the noninsulin diabetics from the criteria for evaluating fiber studies; insulin-dependent diabetics are excluded, however. Although the objective of the study was not to evaluate cholesterol-lowering effects, this information was presented and FDA considered it to be relevant. In addition, adding fiber to a diet without changing the overall diet is probably a very typical form of consumer behavior. The agency also notes that it did not say that fiber intake had no effect in this study, but rather that the results are "inconclusive."

35. One comment addressed FDA's review of the study by Lo and Cole (Ref. 43), in which pooled periods only show a significant difference between the placebo and soy fiber groups. The comment stated that the placebo's effects on total cholesterol were insignificant, while soy's effects were significant.

FDA disagrees with this comment. As shown in table IV of the paper, the 2 percent decrease in serum cholesterol reported after soy fiber consumption in Group B is not significant. FDA questions the inconsistency of the results (i.e., after the placebo effect is gone, is Group B more representative of the effect?). The order of treatment effects on the results should have been considered in the conclusion.

36. One comment criticized FDA's review of the study by Superko et al. (Ref. 56), which FDA discounted as demonstrating significant differences between fiber groups. The comment stated that FDA has failed to consider the significant reductions in serum cholesterol levels between baseline and test group consuming guar gum.

FDA disagrees with this comment. While it is true that at 4 weeks there was a significant difference between total cholesterol levels from baseline, at 8 weeks the p value dropped to 0.15, which is not statistically significant. When FDA calculated the difference

between the placebo to guar supplementation at the 4 and 8 week intervals, neither was significant as defined by a p value of 0.05 or less.

37. One comment stated that FDA incorrectly reported results in the study by Beling et al. (Ref. 10). The comment stated that FDA reported nonsignificant reductions in serum cholesterol between the group using oat-enriched cereal and the control group.

FDA agrees with this comment. After reexamining the results, FDA notes that they show a significant difference between the two groups, thus adding support to a cholesterol-lowering effect of soluble fiber-rich foods in combination with consumption of a low-fat diet.

38. Another comment stated that the weight loss differences reported in the study by Beling et al. (Ref. 10) were not significant between groups, so effects of weight change should be similar. The comment also stated that it is not possible to completely "blind" a study that uses ready-to-eat cereal.

FDA agrees with the comment.

39. One comment stated that FDA criticized the lack of baseline fiber intake data in the study by Gold and Davidson (Ref. 19), but did not explain the significance of that assertion.

FDA considers baseline fiber intake data necessary to determine if the effect seen could have resulted from fat displacement in the diet.

40. One comment criticized FDA's evaluation of a study by Stewart et al. (Ref. 55) and stated that FDA failed to consider the effect after adjustment when reporting the study as nonconclusive of an effect. The study by Stewart and colleagues (Ref. 55) noted that the psyllium supplement administered had a nonsignificant effect on total serum cholesterol when dose was not considered, but a significant effect after adjusting for dose.

FDA disagrees with this comment. Referring to both Figure 1 and Table 4 in the study, the linear trend is driven by the higher dose values, which have very small numbers compared to the overall study population. In addition, the author has excluded the 739 control subjects in the dose-specific analysis for a dose of 0 (no psyllium intake), which, if included, would most likely eliminate any trend. The results of the study do not support any overall effect of psyllium on serum cholesterol.

41. One comment stated that FDA unnecessarily distinguishes studies using separate fiber supplements from those using fiber-enriched foods.

FDA disagrees with this comment. FDA is applying a consistent legal standard to its consideration of studies on fiber supplements and studies of fiber-rich foods. However, from a scientific standpoint there is reason to believe that the use of fiber at higher intakes and higher concentration (i.e., a fiber supplement taken as a single dose prior to meals) may well differ from the typical intake of fiber from foods (i.e., smaller amounts of fiber consumed throughout the day). If an effect is seen when fiber is consumed at higher intakes and higher concentrations, it cannot be assumed that there is a linear dose-response effect that will translate into significant effects at more usual levels of intake. Conversely, if an effect is seen when fiber is consumed with more typical intake from foods, it may not automatically translate into an effect from fiber supplements. Additionally, isolated fibers (as used in supplements) may vary in chemical and physical characteristics from native or less processed fibers. Since a mechanism of action for soluble fiber in reducing blood LDL-cholesterol levels has not been identified, it is possible that processing of soluble fibers may affect their ability to lower blood cholesterol levels.

F. Comments Regarding Applicability to the General Population/Public Health Aspects

42. One comment criticized FDA for including, in the dietary fiber-CVD proposal, the criterion that studies must be conducted in persons who generally represent the healthy U.S. population, i.e., adults with cholesterol readings below 300 mg/dL. The comment stated that this criterion eliminated many valid studies that demonstrate significant scientific agreement for a claim about the relationship between soluble fiber and CHD; and secondly, that these studies remain useful to demonstrate soluble fiber's hypocholesterolemic effects at lower doses, for longer durations, in conjunction with reduced-fat diets.

FDA agrees that populations at higher risk may provide a more sensitive group for identifying a nutrient/disease relationship. However, extrapolation of results from a high risk group to the general population must be done with caution and generally requires some confirmatory studies in the general population. FDA included, in its review, studies on persons considered to be at high risk, i.e., with levels of blood total cholesterol between 200 and 300 mg/dL. FDA, thus, included a large segment of the general population whose risk levels fall in this range, but excluded the much smaller segment of persons with blood total cholesterol levels above 300 mg/dL, because these people often have multiple and serious health problems, making it difficult to generalize results beyond the particular study populations. According to the National Center for Health Statistics (Ref. 79), only 5 percent of the U.S. adult population of men and women have serum cholesterol levels 300 mg/dL or higher. Results of two studies (Refs. 9 and 59) showed that subjects with a mean serum cholesterol level ≤300 mg/dL had significantly lowered serum cholesterol at the end of the test period compared to baseline. Final serum cholesterol levels, however, was still greater than 300 mg/dL. Thus these individuals remained severely hypercholesterolemic and at high risk for CVD.

It is also important to note that the hypocholesterolemic effect in these two studies (Refs. 9 and 59) and many of the other studies attenuated with time, and serum cholesterol levels increased toward baseline. Thus, the agency does not agree with the comment that such results are necessarily useful to demonstrate a long-term hypocholesterolemic effect of soluble fiber at lower doses. Interpretation of results depends on how well compliance with the test regimen was accomplished.

Of the other 33 studies reviewed in the proposed rule (56 FR at 60596 through 60609), the mean blood total cholesterol was in the mid- to upper-200's (mg/dL) because many of the subjects had individual serum cholesterol levels greater than 300 mg/dL. These studies were included in the evaluation of the relationship between dietary fiber and CVD if they met the other evaluation criteria.

43. Another comment criticized FDA for separately evaluating studies using "typical" or "usual" American diets (i.e., approximately 37 percent of calories from fat) and those using a reduced fat (Step 1) diet. The comment stated that the agency should have given equal weight to studies whether they involved a "typical" American diet or a reduced fat (Step 1) diet.

FDA disagrees with this comment. As stated in the proposed rule (56 FR 60582 at 60587), "Responses of blood cholesterol levels to dietary treatment are affected by many factors, including initial (baseline) blood cholesterol levels and dietary factors (i.e., the level of saturated fat and cholesterol in the diet)." Because serum cholesterol is responsive to dietary intakes of saturated fat and cholesterol, FDA separated the studies on the basis of whether fiber effects were being evaluated as part of a typical American diet or as part of a reduced fat diet.

Results of fiber studies become confounded when the test diet is not adequately controlled, or not assessed at all, and when subjects make their own changes to their diets by consuming less total and saturated fat. In such cases, the true effects of fiber, if any, cannot be adequately determined. Although the agency grouped studies based on type of diet, it did give them equal weight based on the evaluation criteria.

44. One comment stated that FDA failed to consider studies reporting only modest reductions in serum cholesterol as strong evidence of soluble fiber's effectiveness. The comment refers to the public health significance of even a small reduction in serum cholesterol; i.e., a 1 percent reduction in serum cholesterol levels predicts approximately a 2 percent reduction in CHD (Ref. 41).

FDA disagrees with this comment. FDA recognizes that changes in serum cholesterol in fiber-feeding studies are generally small. However, if, due to the sample size of the study, this change is not sufficient to demonstrate statistical significance beyond that which may occur by chance (generally accepted by epidemiologists and biostatisticians as $p<.05$), it cannot be concluded that a true effect has been observed.

45. Another comment stated that there is no scientifically valid basis for excluding studies involving subjects whose blood cholesterol levels exceed 300 mg/dL.

FDA disagrees with this comment. As stated above, 5 percent of the U.S. population have serum cholesterol levels greater than 300 mg/dL (Ref. 79). It is important to remember that "the magnitude of plasma lipid response is frequently related to the initial plasma lipid status of the experimental subjects. Persons with higher plasma lipids initially usually experience the greatest plasma lipid response to diet intervention" (Ref. 33). What may cause an effect to look significant may be driven largely by the magnitude of the change, which is more likely to be observed in those individuals with very high serum cholesterol levels. To base conclusions on one group that will respond to a much greater extent than another is misleading as to those persons with normal to moderately elevated serum cholesterol levels, who comprise 95 percent of the adult population.

46. One comment noted that population compliance was essential to the success of dietary intervention for improved public health and that adding fiber to the diet is more acceptable to consumers than removing fat.

FDA agrees that compliance is an important factor, but, with respect to fiber and CVD, it must first be established that addition of fiber alone to the diet is an effective means of reducing serum cholesterol.

G. Comments Regarding Issues of Study Design, Confounders, Fat, etc.

47. One comment stated that FDA criticized studies that do not control for the effects of low dietary fat when examining increased dietary fiber consumption and cholesterol reduction.

FDA disagrees with this comment. Although many studies provide compelling evidence of the effect of a combined low-fat, high fiber diet on lowering serum cholesterol, FDA examined the scientific evidence to determine whether a specific relationship existed between soluble dietary fiber and risk of heart disease, and whether sufficient scientific evidence was available to support a health claim for dietary fiber and heart disease.

48. Another comment criticized FDA's evaluation of a study by Van Horn et al. (Ref. 67) for inappropriately discounting the correlation of fiber intake with serum cholesterol by pointing out that many other nutrient intakes besides fiber showed correlations with cholesterol levels. The comment stated that dietary fiber had correlations with CHD that were as statistically significant as those for fat and CHD, and this argues for a finding that significant scientific agreement supports a claim about the relationship between fiber and CHD.

FDA disagrees with this comment. FDA again emphasizes that many other nutrient intakes in addition to dietary fiber show statistically significant correlations. In a cross-sectional survey analyzed in this manner, one of the first things that must be considered when many factors show significance is whether they are highly correlated with each other. If this is the case, displacement of fat in the diet by fiber is one explanation for the observed effect.

49. Another comment argued that, although FDA has stated there may be other micronutrients or components in vegetables, cereal, fruits and berries other than soluble fiber that may have contributed to the cholesterol-lowering effects of some soluble fiber-containing foods, the agency has failed to identify them.

FDA agrees that it did not identify other components in foods that may have serum cholesterol lowering effects. Its point in this statement was that attribution of effects to soluble fiber per se, when foods contain a wide range of vitamins, minerals, and other substances, is misleading. The authors of the meta-analysis (Ref. 125) also noted that other components of oats may play a role in the cholesterol-lowering properties observed in human studies.

50. Another comment criticized FDA's evaluation of a study by Van Horn et al. (Ref. 69).

FDA stands by its evaluation of the Van Horn study. FDA criticized the study because there are significant changes in diet between the control and test group in total fat intake, saturated fat intake, and monounsaturated fat intake, and the authors did not demonstrate that these changes did not contribute to the cholesterol-lowering effect observed.

51. Another comment suggested that weight loss is not a confounder, but rather a result of fiber's ability to effect weight reductions independently of changes in caloric or fat intake.

FDA disagrees with this comment. Although this may be a possible mechanism of action, no studies reviewed have provided clear evidence of this.

52. One comment stated that confounding variables and lack of a mechanism of action are not a valid basis for denying a link between ingestion of fiber and reduced risk of heart disease which experimental evidence shows in fact exists.

FDA disagrees with the comment's description of the basis for its proposed action. If factors such as weight loss, changes in diet, lifestyle changes, and/or exercise, which are known to influence serum cholesterol, are not controlled in a clinical study, or if analytical methods for determining the soluble fiber content in food sources are not clearly established, the specificity for an effect of soluble fiber on serum cholesterol cannot be determined. In its proposal, FDA made a tentative decision to deny a health claim regarding dietary fiber and CVD for a number of reasons, including confounding factors identified in many of the clinical studies reviewed, but not because there is no recognized mechanism(s) of action for hypolipidemic effects of different soluble fibers. For a more thorough discussion of FDA's proposal to deny a health claim on dietary fiber and CVD in the proposed rule, see 56 FR 60582 at 60591 through 60592. FDA believes that, for health claims to be educational and result in changed eating habits, the claims should be truthful and not misleading.

H. Conclusions From Comments

FDA agrees with many of the comments that a problem in determining the relationship between dietary fiber and heart disease is the fact that dietary fiber is a diverse group of chemical substances that may be associated with different physiological functions, and that the analytical methodology to identify the soluble fiber content of a food may not be predictive of the likely physiological effect.

IV. Decision to Deny a Health Claim Relating Dietary Fiber to Reduced Risk of CHD

Overall, the currently available scientific evidence is not sufficiently conclusive or specific for soluble fiber per se to justify use of a health claim relating the intake of dietary soluble fiber to a reduced risk of heart disease. A major limitation in designing and evaluating research studies has been the need for better defined measures of dietary soluble fiber and standardized descriptions for source, type, and amount of dietary soluble fiber. Commonly used analytical methodologies do not detect many of the characteristics that may vary among fibers and that may be related to biological function (e.g., particle size, chemical composition, water-holding capacity). Other components associated with soluble fiber in foods (e.g., tocotrienols) may also have some cholesterol-lowering capabilities. The inability to detect many of the differences among fibers, fiber components, and other substances in foods which contain soluble fiber, and the general lack of conclusions as to the mechanism(s) of action of soluble fibers raise questions about the ability of commonly used analytical measures of dietary fiber to adequately predict biological actions of specific fibers. For these reasons, FDA is not authorizing use of a health claim relating dietary fiber to a decreased risk of CHD.

FDA's decision is consistent with recent conclusions reached about the state of the scientific evidence by the National Heart, Lung, and Blood Institute of the National Institutes of Health (Ref. 155) and recommendations in the Institute of Medicine's report "Nutrition Labeling: Issues and Directions for the 1990s" (Ref. 81). This report notes that there has been great interest in the specific effects of dietary fiber on several chronic diseases. According to the report, the strongest argument for an increased consumption of dietary fiber is the important contribution it makes to normal bowel function. Clear scientific associations of fiber intake with the incidence of cancer, heart disease, and diabetes mellitus have not been made. The report indicates that one reason for this may be the difficulty in designing appropriate experiments to test specifically for the effect of dietary fiber. Foods high in dietary fiber are also generally low in calories and total and saturated fatty acids and devoid of cholesterol; thus, determination of a specific fiber effect in a feeding study is difficult. Moreover, according to the report, foods have a variety of fiber components and each may have different actions. Chemically and physiologically, cellulose, lignin, hemicellulose, pectin, and alginate (all relatively purified fiber types) behave differently. Wheat bran, oat bran, and rice bran (all heterogeneous mixtures of fibers) are not similar in composition. It is also very difficult to analyze dietary fiber chemically, and thus it is hard to correlate the role of specific fiber components to health effects (Refs. 48 and 81). Therefore, FDA is not authorizing the use on the labels and labeling of foods of health claims relating to an association between the ingestion of dietary fiber (particularly soluble fiber) and a reduction in the risk of heart disease. In reaching this decision, the agency considered all comments received in response to its proposed rule (56 FR 60582), and reviewed the scientific literature that became publicly available after the proposal's publication and data submitted with comments.

V. Decision to Allow a Health Claim on Foods Relating Diets Low in Saturated Fat and Cholesterol and High in Fruits, Vegetables, and Grain Products, Foods That Contain Fiber, Particularly Soluble Fiber, to a Reduced Risk of CHD

FDA has reviewed the numerous authoritative documents, including Federal government reports, as well as recent research on dietary fiber and CHD risk. In addition, the agency considered all comments received in response to its proposed rule. The agency has concluded that the publicly available scientific evidence supports an association between diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products, foods that are low in saturated fat and cholesterol and are good sources of dietary fiber, to reduced risk of heart disease.

FDA agrees with the comments that show that dietary patterns that are low in saturated fat and cholesterol and high in fruits, vegetables (including legumes), and grain products are associated with a decreased risk of CHD. Although the specific roles of the numerous potentially protective substances in such plant foods are not yet understood, populations with diets rich in these foods experience many health advantages, including lower rates of heart disease. Currently, there is not scientific agreement as to whether the observed protective effects against heart disease are due to a combination of nutrient components of the foods, including soluble fiber, to other components of soluble fiber-rich diets (for example, potassium and magnesium), to displacement of saturated fat and cholesterol from the diet, or to non-nutritive substances in these foods.

Thus, the conclusion that diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products, foods low in saturated fat and cholesterol and containing soluble fiber, are associated with a reduced risk of heart disease is consistent with the available scientific evidence. The fact that these foods contain dietary fiber, particularly soluble fiber, can serve, therefore, as a useful marker for identifying those fruits, vegetables, and grain products which, when added to diets low in saturated fat and cholesterol, may help in reducing blood LDL-cholesterol levels. As discussed in the final rule on general requirements for health claims, published elsewhere in this issue of the **Federal Register**, statements about good nutrition that do not expressly or by implication refer to a substance are considered dietary guidance and not health claims. In this rule, FDA is authorizing the inclusion of a reference to dietary fiber (a substance) in a statement about the value of fruit, vegetables, and grain products in reducing the risk of heart disease. Thus, the health claim permitted under this regulation to be used on labels and labeling of certain foods associates diets low in saturated fat and cholesterol and high in vegetables, fruit, and grain products, that contain soluble fiber with a reduced risk of heart disease.

VI. Rationale and Description of the Final Regulation

A. Relationship and Significance Statements

In new § 101.77(a), the summary of the relationship between diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain soluble fiber and reduced heart disease risk is consistent with the conclusions reached in the review of the scientific evidence. Although the specific roles of dietary soluble fiber, or

of specific soluble fibers and fiber components, and the multiple nutrients and other substances contained in these foods, are not yet fully understood, many studies have shown that diets high in soluble-fiber-containing foods are associated with lower blood LDL-cholesterol levels and with reduced risk of heart disease. These diets are generally low in saturated fat, cholesterol and total fat, nutrients known to have a detrimental effect on blood LDL-cholesterol levels, and therefore, on risk of heart disease. Dietary soluble fiber can be used as a marker to identify the types of foods which correlate with reduced heart disease risk, and whose addition to diets low in saturated fat and cholesterol is considered to be useful in lowering blood LDL-cholesterol (Ref. 66). The relationship statement in § 101.77(a) also includes other information about heart disease, such as risk factors, as in other authorized health claims.

New § 101.77(b), on the significance of the relationship between consumption of diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain soluble fiber and reduced risk of heart disease, includes the information that U.S. diets tend to be high in saturated fat and cholesterol and low in fiber-containing fruits, vegetables, and grain products. A discussion of current dietary guidelines on recommended servings of fruits, vegetables, and grain products is also provided.

B. Nature of the Claim

In new § 101.77(c)(2)(i), FDA is authorizing a health claim relating diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain soluble fiber to reduced risk of heart disease. In new § 101.77(c)(2)(i)(A), the agency is requiring, consistent with other authorized claims, that the relationship be qualified with the terms "may" or "might." These terms are used to indicate that not all persons can necessarily expect to benefit from these dietary changes.

In new § 101.77(c)(2)(i)(B), the agency, consistent with other authorized claims, is requiring that the claim use the specific terms "heart disease" or "coronary heart disease" to define the type of disease dealt with by this claim. These disease terms reflect terms commonly used in dietary guidance materials, and are also reflective of the scientific evidence which links these dietary factors to heart disease risk via the intermediate mechanism of reducing blood LDL-cholesterol levels, rather than to the broader category of cardiovascular disease.

In new § 101.76(c)(2)(i)(C), the agency is requiring that the claim discuss only those fruits, vegetables, and grain products that contain dietary fiber, rather than all fruits, vegetables, and grain products. Diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, are correlated with reduced heart disease risk. Thus, a claim discussing those fruits, vegetables, and grain products that contain the marker nutrient, but does not attribute a protective effect to soluble fiber, is consistent with current scientific knowledge.

New § 101.77(c)(2)(i)(D) specifies the terms that can be used to describe the fiber component of the fruits, vegetables, and grain products that bear a health claim. Consistent with the state of the scientific evidence, this paragraph permits a choice among a number of terms, but does not allow terms for specific types of fiber to be used, e.g., those connoting the origin of the fiber. The term "soluble fiber" may be used in combination with a more general term for fiber. This permits reference to soluble fiber, which is a useful marker nutrient for foods associated with reduced risk of heart disease. However, the present scientific evidence does not permit a determination of whether it is the soluble fiber or other components in these foods or displacement of fat that provides the protective effect. Given these uncertainties about the specific role of soluble fiber, it would be misleading to place undue emphasis on soluble fiber standing alone.

New § 101.77(c)(2)(i)(F) requires that health claims specify that development of heart disease depends on many factors. This requirement is intended to prevent consumers from being misled that fruits, vegetables, and grain product intake is the only factor connected with heart disease risk.

In new § 101.77(c)(2)(i)(E), FDA is prohibiting, consistent with other authorized health claims, more specific use of dietary terms than is warranted by the current state of the scientific evidence. New § 101.77(c)(2)(i)(G) is also consistent with other authorized health claims, and prohibits any attribution of degree of risk for heart disease and fiber-containing fruits, vegetables, and grains. These requirements also standardize use of terms, thus minimizing consumer confusion as they compare food labels across products, or as they compare a health claim to the nutrition information panel.

C. Nature of the Food

New § 101.77(c)(2)(ii)(A) requires that the food bearing the health claim be or contain a fruit, vegetable, or grain product. Because the claim relates to diets high in these foods, it would not make sense for it to appear on the labeling of another type of food. A health claim that appears on a food that meets all the requirements in § 101.77(c)(2)(ii), but contains only a trivial amount of fruit, vegetable, or grain product, could be considered misleading and might misbrand the food under section 403(a) of the act.

FDA, consistent with the requirements for the health claim on dietary saturated fat and cholesterol and heart disease (published elsewhere in this issue of the **Federal Register**), is requiring in new § 101.77(c)(2)(ii)(B) that foods bearing the health claim meet requirements for "low saturated fat," "low cholesterol," and "low total" fat, or alternatively, belong to a class of products that is "low in saturated fat," "low in cholesterol," and "low in total fat." Low saturated fat and cholesterol diets are associated with reduced heart disease risk. Low or negligible total fat is also one of the characterizing features of diets rich in fiber-containing fruits, vegetables, and grain products. Because the effects of saturated fat and cholesterol are not readily separated from the effects of other nutritive components of fruits, vegetables, and grain products, and because the scientific evidence linking diets low in saturated fat and cholesterol to reduced risk of heart disease is strong, saturated fat and cholesterol are specified as qualifying nutrients. Total fat is also specified as a qualifying nutrient because a low content of total fat is characteristic of dietary patterns which relate to lower heart disease risk, and because it facilitates the ability of consumers to achieve diets low in saturated fat and cholesterol. (See final rule on "Dietary Saturated Fat and Cholesterol and Coronary Heart Disease," published elsewhere in this issue of the **Federal Register**).

In new § 101.77(c)(2)(ii)(C), FDA is requiring that fruits, vegetables, and grain products bearing the authorized health claim contain at least 0.6 g of dietary soluble fiber per reference amount commonly consumed. Because soluble fiber is a qualifying nutrient, FDA, in new § 101.77(c)(2)(ii)(D), is requiring declaration of soluble fiber content consistent with requirements in § 101.9(c)(6)(i)(A). The qualifying value of 0.6 g of soluble fiber is based on several considerations. First, an exper. panel convened by LSRO (Ref. 39)

recommended total dietary fiber intakes of 20 to 30 g daily for adults (see final rule on daily reference values published elsewhere in this issue of the **Federal Register**). It further recommended that approximately 25 percent (or about 6 g) of this be soluble fiber. This level of soluble fiber represents the same ratio of soluble to insoluble fiber normally found in foods and for which there is a long history of use, and therefore was considered by the panel to be safe. Since current U.S. dietary fiber intakes, including soluble fiber intakes, are estimated to be approximately half of the recommended levels, Americans would need to double their intakes to meet the current dietary guidelines. A total daily intake of 6 g of soluble fiber from fruits, vegetables, and grains is consistent with current dietary guidelines for the general population.

The qualifying criterion of 0.6 g per reference amount customarily consumed is also consistent with the definition of a "good source" of a nutrient (i.e., 10 percent of the daily reference value (DRV)) in the final rule on general requirements for nutrient content claims published elsewhere in this issue of the **Federal Register**. Although there is no DRV for soluble fiber, the requirement that a nutrient be present at 10 percent of a reference standard has been set as a qualifying level in other regulations authorizing health claims. (See the final rules on antioxidant vitamins and cancer and on fiber cancer published elsewhere in this issue of the **Federal Register**.) The 10 percent level is deemed useful and appropriate, because very few foods could naturally meet the requirement for a "high" source of soluble fiber. The current dietary guidance recommendations of five or more servings of fruits and vegetables and six or more servings of grain products daily, if followed, would likely result in intakes of soluble fiber close to or exceeding the recommended daily intake of 6 g. Thus, use of a qualifying criterion consistent with that used to define a "good" source for nutrients which have DRV's provides for an amount that allows a number of fruits, vegetables, and grain products to qualify, and is consistent with current dietary guidelines for general dietary patterns. Without this alternate level, very few fruits, vegetables, and grain products would qualify for the health claim, which would be contrary to the available scientific evidence and to the purpose of health claims.

Section 101.77(c)(2)(ii)(C) also requires that foods qualify as a good source of soluble fiber based on their natural level of soluble fiber. This means that foods which require fortification with soluble fiber, in order to meet the qualifying criteria for the health claim, cannot bear the claim. This requirement is consistent with the scientific basis for the claim, that is, that intakes of fruits, vegetables, and grains in their native form correlate with reduced heart disease risk. Because there are not sufficient data that specifically identify dietary soluble fiber, or particular components of soluble fiber, as the cause of a reduction in heart disease risk, and because this nutrient is being used as a marker for the substance or substances in fruits, vegetables, and grain products that provide the observed protective effect, it is the native composition of the foods that identifies their usefulness.

D. Optional Information

Under new § 101.77(d), similarly to other authorized health claims, health claims may identify additional risk factors for heart disease. The regulation specifies the factors that may be listed; all are risk factors about which there is general scientific agreement. This additional information can provide a context that is useful for an understanding of the relationship of the diet to the disease, but manufacturers are cautioned that it should not be presented in a way that is misleading to the consumer. A health claim may also indicate that reductions in saturated fat and cholesterol intake and consumption of fruits, vegetables, and grain products are part of a total dietary pattern that is consistent with the latest "Nutrition and Your Health: Dietary Guidelines for Americans," published jointly by the U.S. Department of Agriculture and the U.S. Department of Health and Human Services. Consistent with other health claim regulations, the claim may also include information on the prevalence of heart disease in the United States. In order to ensure that this information is valid, the agency is requiring that it come from one of three specified authoritative sources. Finally, because consumers frequently know their cholesterol levels or can determine their levels through readily available facilities in shopping malls and health clinics, the agency, similarly to other authorized health claims, is requiring that when information in the claim allows consumers to "self-diagnose" their own risk level, that additionally, the claim indicate the need for medical guidance if a consumer falls within a risk category.

Similarly to the requirements in § 101.73 on "Dietary Saturated Fat and Cholesterol and Coronary Heart Disease," the claim may indicate that the relationship between diets low in saturated fat and cholesterol and high in fruits, vegetables, and grains that contain fiber, particularly soluble fiber, is through the intermediate link of "blood cholesterol" or "blood total- and LDL-cholesterol." Such information is useful to consumers, but could add unnecessarily to the length and complexity of the required health claim. For these reasons, this provision is optional rather than mandatory.

E. Model Health Claims

In new § 101.77(e), FDA is providing model health claims to illustrate the requirements of new § 101.77. FDA is not prescribing specific language for claims, but certain elements are required, and these models include the required elements.

VII. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's

discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

IX. References

The following references have been placed in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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155. Lenfant, C., Letter to David Kessler, October 29, 1992.

List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. New § 101.71 is added to subpart E to read as follows:

§ 101.71 Health claims: claims not authorized.

* * * * *

(b) Dietary fiber and cardiovascular disease.

3. New § 101.77 is added to subpart E to read as follows:

§ 101.77 Health claims: fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease.

(a) *Relationship between diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease.* (1) Cardiovascular disease means diseases of the heart and circulatory system. Coronary heart disease is the most common and serious form of cardiovascular disease and refers to diseases of the heart muscle and supporting blood vessels. High blood total- and low density lipoprotein (LDL)- cholesterol levels are major modifiable risk factors in the development of coronary heart disease. High coronary heart disease rates occur among people with high blood cholesterol levels of 240 milligrams per deciliter (mg/dL) (6.21 (mmol/L)) or above and LDL-cholesterol levels of 160 mg/dL (4.13 mmol/L) or above. Borderline high risk blood cholesterol levels range from 200 to 239 mg/dL (5.17 to 6.18 mmol/L) and 130 to 159 mg/dL (3.36 to 4.11 mmol/L) of LDL-cholesterol. Dietary lipids (fats) include fatty acids and cholesterol. Total fat, commonly referred to as fat, is composed of saturated fat (fatty acids containing no double bonds), and monounsaturated and polyunsaturated fat (fatty acids containing one or more double bonds).

(2) The scientific evidence establishes that diets high in saturated fat and cholesterol are associated with increased levels of blood total- and LDL-cholesterol and, thus, with increased risk of coronary heart disease. Diets low in saturated fat and cholesterol are associated with decreased levels of blood total- and LDL-cholesterol, and thus, with decreased risk of developing coronary heart disease.

(3) Populations with relatively low blood cholesterol levels tend to have dietary patterns that are not only low in total fat, especially saturated fat and cholesterol, but are also relatively high in fruits, vegetables, and grain products. Although the specific roles of these plant foods are not yet fully understood, many studies have shown that diets high in plant foods are associated with reduced risk of coronary heart disease. These studies correlate diets rich in fruits, vegetables, and grain products and nutrients from these diets, such as some types of fiber, with reduced coronary heart disease risk. Persons consuming these diets frequently have high intakes of dietary fiber, particularly soluble fibers. Currently, there is not scientific agreement as to whether a particular type of soluble fiber is beneficial, or whether the observed protective effects of fruits, vegetables, and grain products against heart disease are due to other components, or a combination of components, in these diets, including, but not necessarily limited to, some types of soluble fiber, other fiber components, other characteristics of the complex carbohydrate content of these foods, other nutrients in these foods, or displacement of saturated fat and cholesterol from the diet.

(b) *Significance of the relationship between diets low in saturated fat and cholesterol, and high in fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease.* (1) Coronary heart disease is a major public health concern in the United States, primarily because it accounts for more deaths than any other disease or group of diseases. Early management of risk factors for coronary heart disease is a major public health goal that can assist in reducing risk of coronary heart disease. There is a continuum of mortality risk from coronary heart disease that increases with increasing levels of blood LDL-cholesterol. Individuals with high blood LDL-cholesterol are at greatest risk. A larger number of individuals with more moderately elevated cholesterol also have increased risk of coronary events; such individuals comprise a substantial proportion of the adult U.S. population. The scientific evidence indicates that reducing saturated fat and cholesterol intakes lowers blood LDL-cholesterol and risk of heart disease in most individuals, including persons with blood cholesterol levels in the normal range. Additionally, consuming diets high in fruits, vegetables, and grain products, foods that contain soluble fiber, may be a useful adjunct to a low saturated fat and low cholesterol diet.

(2) Other risk factors for coronary heart disease include a family history of heart disease, high blood pressure, diabetes, cigarette smoking, obesity (body weight 30 percent greater than ideal body weight), and lack of regular physical exercise.

(3) Intakes of saturated fat exceed recommended levels in many people in the United States. Intakes of cholesterol are, on average, at or above recommended levels. Intakes of fiber-containing fruits, vegetables, and grain products are about half of recommended intake levels. One of the major public health recommendations relative to coronary heart disease risk is to consume less than 10 percent of calories from saturated fat, and an average of 30 percent or less of total calories from all fat. Recommended daily cholesterol intakes are 300 mg or less per day. Recommended total dietary fiber intakes are about 25 grams (g) daily, of which about 25 percent (about 6 g) should be soluble fiber.

(4) Current dietary guidance recommendations encourage decreased consumption of dietary fat, especially saturated fat and cholesterol, and increased consumption of fiber-rich foods to help lower blood LDL-cholesterol levels. Results of numerous studies have shown that fiber-containing fruits, vegetables, and grain products can help lower blood LDL-cholesterol.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met.

(2) Specific requirements. (i) *Nature of the claim.* A health claim associating diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, with reduced risk of heart disease may be made on the label or labeling of a food described in paragraph (c)(2)(ii) of this section, provided that:

(A) The claim states that diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber "may" or "might" reduce the risk of heart disease;

(B) In specifying the disease, the claim uses the following terms: "heart disease" or "coronary heart disease;"

(C) The claim is limited to those fruits, vegetables, and grains that contain fiber;

(D) In specifying the dietary fiber, the claim uses the term "fiber," "dietary fiber," "some types of dietary fiber," "some dietary fibers," or "some fibers;" the term "soluble fiber" may be used in addition to these terms;

(E) In specifying the fat component, the claims uses the terms "saturated fat" and "cholesterol;" and

(F) The claim indicates that development of heart disease depends on many factors; and

(G) The claim does not attribute any degree of risk reduction for coronary heart disease to diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber.

(ii) *Nature of the food.* (A) The food shall be or shall contain a fruit, vegetable, or grain product.

(B) The food shall meet the nutrient content requirements of § 101.62 for a "low saturated fat," "low cholesterol," and "low fat" food.

(C) The food contains, without fortification, at least 0.6 g of soluble fiber per reference amount customarily consumed;

(D) The content of soluble fiber shall be declared in the nutrition information panel, consistent with § 101.9(c)(6)(i)(A).

(d) *Optional information.* (1) The claim may identify one or more of the following risk factors for heart disease about which there is general scientific agreement: A family history of coronary heart disease, elevated blood-, total- and LDL-cholesterol, excess body weight, high blood pressure, cigarette smoking, diabetes, and physical inactivity.

(2) The claim may indicate that the relationship of diets low in saturated fat and cholesterol, and high in fruits, vegetables, and grain products that contain fiber to heart disease is through the intermediate link of "blood cholesterol" or "blood total- and LDL-cholesterol."

(3) The claim may include information from paragraphs (a) and (b) of this section, which summarize the relationship between diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber and coronary heart disease, and the significance of the relationship.

(4) In specifying the nutrients, the claim may include the term "total fat" in addition to the terms "saturated fat" and "cholesterol."

(5) The claim may indicate that it is consistent with "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office (GPO).

(6) The claim may state that individuals with elevated blood total- and LDL-cholesterol should consult their physicians for medical advice and treatment. If the claim defines high or

normal blood total- and LDL-cholesterol levels, then the claim shall state that individuals with high blood cholesterol should consult their physicians for medical advice and treatment.

(7) The claim may include information on the number of people in the United States who have heart disease. The sources of this information shall be identified, and it shall be current information from the National Center for Health Statistics, the National Institutes of Health, or "Nutrition and Your Health: Dietary Guidelines for Americans," USDA and DHHS, GPO.

(e) *Model health claims.* The following model health claims may be used in food labeling to characterize the relationship between diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain soluble fiber:

(1) Diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain some types of dietary fiber, particularly soluble fiber, may reduce the risk of heart disease, a disease associated with many factors.

(2) Development of heart disease depends on many factors. Eating a diet low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber may lower blood cholesterol levels and reduce your risk of heart disease.

Dated: November 6, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

Note: The following table will not appear in the annual Code of Federal Regulations.

BILLING CODE 4160-01-F

Dietary Fiber and Cardiovascular Disease

Study	Study Design	Subjects	Methods	Results	Comments
Anderson et al., 1991 (Ref. 92).	Intervention, parallel, placebo-controlled, randomly assigned to treatment groups after 8 weeks of diet therapy on American Heart Association (AHA) Step 1 diet and stratification by gender and cholesterol level. Purpose of study: to compare hypocholesterolemic effects of two bulk laxatives relative to psyllium and placebo.	163 mild to moderately hypercholesterolemic males and females enrolled in study, 117 completed 8-week diet therapy, and 105 completed the study protocol. Subjects, ages 30 to 70 years, were free living. (total serum cholesterol (TC) 200 to 300 mg/dL and body weight within 130% of ideal.	Subjects consumed AHA Step 1 diet for an 8-week adaptation period followed by an 8-week parallel treatment period. Four doses of test product were taken each day, including one before each meal. Diet monitored with 3-day food records at 4-week intervals. Step 1 diet: Energy from fat--30 to 33%; protein--17 to 18%; carbohydrate (CHO)--46 to 51%; Cholesterol--<300 mg/day. Bulk laxatives tested: g/day psyllium powder (PSY) 10.2 methylcellulose powder (MC) 6 or 10.2 calcium polycarbophil tablets (CP) 4 cellulose placebo (PLA) 4	Average Diet During Test Period PSY / MC / CP / PLA Energy, Cal: 1755 / 1742 / 1833 / 1768 Fat, % of Cal: 30 / 33 / 32 / 31 Protein, % Cal: 17.6 / 18 / 17.5 / 16.7 CHO, %: 49.8 / 46.1 / 47.4 / 50.9 Fiber, g Total: 14.5 / 14.2 / 13 / 15.1 Soluble: 4.6 / 4.4 / 4 / 4.7 CHOL, mg: 225 / 219 / 213 / 190 Baseline Diet phase: TC ↓4.5%; LDL ↓4.7%; HDL ↓2.9%; TG ↓5.8% The difference in TC between the PSY group and the placebo is not significant (↓4.3% difference). Lipids Values--Diet + Fiber Comparison to baseline PSY / MC / CP / PLA TC, %: ↓8.2* / ↓5.3* / ↑2 / ↓3.9 LDL, %: ↓13.4* / ↓7.8* / ↑4.1 / ↓4.6 HDL, %: ↓2.2 / ↓4.8* / ↑4.8 / ↑0.1 LDL/HDL: ↓10.8* / ↓3.8 / ↓1.2 / ↓4 TG, %: ↑12.4 / ↑8.2 / ↓10.9* / ↓7.3 * Significant from baseline.	No weight change by more than 0.5% from baseline. Weights at baseline and final were not given. Compliance reported as good for all test groups.* Side effects reported were mostly gastrointestinal. Choice of cellulose as a placebo is questionable. Cellulose may actually have a cholesterol lowering effect. *No data on saturated fat

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Bremer, J. M. et al., 1991 (Ref. 91).	Intervention, randomized, single-blind, cross-over, placebo controlled.	12 hyperlipidemic men and women (TC 220 to 340 mg/dL), free living.	Subjects were stabilized on phase II AHA diet for 3 months prior to study. Base diet: fat 25 to 30% total energy; saturated fat <8%; polyunsaturated fatty acid (PUFA) 5 to 10%; monounsaturated fat >10%; cholesterol <250 mg/d; fiber >20 g/1,000 Calories. Two-week run-in with the addition of bread to the diet prior to test. Subjects randomized to oat or wheat group for 4 weeks, followed by 2-week washout, then cross-over to other diet. Bread added to diet in place of other CHO foods. Men consumed 10 to 12 slices bread/day; women consumed 6 slices. Dietary assessment by food records and bread charts. Oat bread / Wheat bread Total fiber, g%: 5.2 / 6.1 Insoluble Fiber, g%: 4.0 / 5.2 Soluble Fiber, g%: 1.2 / 0.9 Oat bran intake: 34.2 to 68.4 g/day Total dietary fiber intake: Oat period 32.2 g, Wheat period 34.1 g	At beginning of first study period, there was no significant difference between TC, LDL, and HDL between groups. At end of 4 weeks, no significant difference between lipid parameters. TC, mg/dL Week 0 / Week 4 / % change Oat bran: 286 / 274 / -4.1 Wheat bran: 297 / 286 / -3.9 LDL % change from baseline Oat bran: -5.4 Wheat bran: -6.8 HDL % change from baseline Oat bran: +10.3 Wheat bran: +8.7 Mean body weights did not change during the oat period but decreased significantly during the wheat period.	There was no measure of dietary soluble fiber. Subjects increased consumption of PUFA and decreased intake of saturated fat (all NS) during test period. Investigators accounted for ↑ in fat consumption as due to use of PUFA margarine with bread. Oat bran bread was no better than wheat bran bread on lowering serum CHOL when subjects were on AHA diet. Small sample size.
Leadbetter J. et al., 1991 (Ref. 83).	Intervention, randomized, not blinded.	40 men and women, ages 25 to 64 (TC 250 to 348 mg/dL), free-living.	A four-by-four Latin square design; Subjects added 0, 30, 60, and 90 g/day oat bran to their usual diet for 1 month intervals. No washout between periods. Oat bran provided in weighed sachets and detailed advice and recipes were provided. Five-day food records were kept prior to study and single-day records were kept during study periods. Beta-glucan content of oat bran was 3.7 to 4.2%.	Base diets (excluding oat bran): 0 g/d / 30 g/d / 60 g/d / 90 g/d Cal.: 1854 / 1947 / 2017 / 2017 % Fat: 36.6 / 34.7 / 33.5 / 34.8 % CHO: 45.3 / 48.2 / 50.2 / 48.6 % Sat Fat: 13.5 / 13.0 / 13.4 / 14.0 Fiber, g: 27 / 23 / 26 / 24 Starch, g: 64 / 86 / 93 / 99 Results: No S effect of OB at any dose on TC or LDL; no dose-related trend and no correlation between bran dose and change in CHOL conc. Oat Bran Intake, g/day 0 / 30 / 60 / 90 TC, mg/dL: 278 / 264 / 279 / 273 LDL, mmol/L: 4.77 / 4.65 / 4.85 / 4.58 HDL, mmol/L: 1.56 / 1.48 / 1.49 / 1.42	Authors state that OB used in this study may be lower in SF content than the OB used in studies showing ↓ CH with OB supplementation. No dietary or body weight data.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Resnicow, K. et al., 1991 (Ref. 96).	Health survey, not controlled.	31 Seventh Day Adventist, ages 5 to 46 years (9 children 5 to 17 yrs; 27 adults 19 to 46 yrs); mean serum CH 131.5 mg/dL; free living.	Subjects chosen had not consumed food of animal origin (including meat, poultry, fish, eggs, milk or other dairy products) for at least 6 mo prior to study. Lipid levels were reported separately for children. There were no blood lipid values for omnivore controls, so derived these values from Lipid Research Clinics Population Studies Data Book for basis of comparing vegans and omnivore controls. Current food intake measured using a quantitative food frequency questionnaire based on weekly consumption and typical portion sizes. Fiber intake for vegans: 45 g/day, controls: 20.	Results for adults only: vegans observed / expected / % differ.* mean values, mg/dL TC 139 / 182 / -23 LDL 81 / 116 / -30 HDL 54 / 50 / +8 *Statistical significantly not reported. Vegans had s lower daily intake of energy; % energy from fat (31% versus 38%), total fat, satuarted fat, Monounsaturated fatty acid, and CHOL; and protein; also s higher intake of fiber.	There are multiple confounding factors not addressed in this survey. Exercise patters, lifestyles, and body weight are just a few examples. Soluble and insoluble fiber were not assessed. Foods consumed in greater frequency by vegans: almonds, cashews, and their nut butters, dried fruits, citrus fruits, soy milk and greens. These foods contributed almost 40% of daily energy (only 7% for controls).

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Spiller, G. A. et al., 1991 (Ref. 87).	Intervention, randomized, cross-over.	13 male and females, 62 ± 3.0 years, TC 204 to 276 mg/dL, free living.	Three-day food record kept during baseline period and during 3rd week of treatment. Each treatment dose was preweighed in pouches; 3-week supply given to subjects at start of each test period. Both fiber were mixed with water or other fluid and consumed before each meal. Subjects remained on regular diets. Test periods: 21 days then cross-over to other fiber for 21 days. Blood lipid values made on days 14 and 21 during treatment period and on days 14 and 16 after treatment stopped. Fiber sources: guar gum: 15 g/day providing 11 g/d dietary fiber and 10 g/d SF; oat fiber source: 77 g/d providing 11 g/d dietary fiber and 5 g/d SF, 3.3 g β-glucan.	TC / LDL / HDL (mg/dL) Baseline: 244 / 152 / 62 Guar at day 14: 217 / 124 / 63 day 21: 219* / 126* / 63 oat bran at day 14: 235 / 142 / 62 day 21: 236* / 143* / 62 * Significant from baseline. Guar: 11% ↓ TC Oats: 6% ↓ TC	Study needs a control group. Changes in TC for both treatment groups took place within 14 days with no significant changes taking place between days 14 and 21. Limitations of study: Short test period. No washout between test periods. Baseline diets and dietary intake during treatment periods not reported; total dietary soluble fiber was not reported. Small sample size. No dietary data. No weight changes. Both guar and oat fibers consumed before meals--not typical dietary intake.
Cara, L. et. al., 1991 (Ref. 84).	Intervention.	10 men and women (8 women), 35 to 68 years, TC 254 to 367 mg/dL, 6 had mild to severe hypertriglyceridemia, free living.	Subjects consumed regular diet for one week as baseline period, followed by 4 weeks on 30 g wheat germ (2.9 g dietary fiber), then 4 weeks on regular diet with no supplementation. Base diet monitored by 7-day food recall; 3-day food recall during last week of test period. Base diet: pro. 14.4% energy; fat 35.9%, refined CHO 8.7%, complex CHO 41%, dietary fiber 13.6 g/d, alcohol 6 g/d.	Baseline / Wheat Germ / Follow up TC, mg/dL: 302 / 276* / 284 LDL, mg/dL: 191 / 189 / 195 HDL, mg/dL: 41.5 / 47 / 50 * Significant from baseline TC after final 4 weeks with no wheat germ not significantly different from baseline.	No control. Small sample size, no reporting of dietary soluble fiber and saturated fat in diet during baseline and treatment periods. Authors speculate that the protein content of wheat germ (high in vegetable protein) could account for the results observed. No saturated fat data.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Kawatra, A. et al., 1991 (Ref. 88).	Intervention.	20 overweight men and women (bodyweight 10% higher than Standard Weight for Height of Life Insurance Company India), TC 172.5 to 277.5 mg/dL, free living.	Subjects added 15 g guar gum to normal diet for 6 weeks. 10 g of guar was consumed in form of salted biscuits and 5 g was mixed with flavored drink 10 to 15 minutes before main meal. 1/5 of normal diet was collected for 3-days prior to start of test period and during the last week of the test period and analyzed for nutrient composition.	Baseline / Final / % change TC, mg/dL: 212 / 176 / ↓16.7* LDL, mg/dL: 144 / 105 / ↓26.5* HDL, mg/dL: 54.8 / 55.4 / ↑1.5 TC/HDL: 3.9 / 3.2 / ↓13.7%* * significant.	Total dietary fiber, dietary soluble fiber and saturated fat were not reported. No body weight data.
Tinker, L. F. et al., 1991 (Ref. 89).	Intervention, randomized, cross-over, subjects acted as own controls.	41 men, ages 29 to 79, TC 201 to 290, free living. 6 had history of cardiovascular disease or CV surgery.	Dietary records made from self-reported food records collected every other day for 2 weeks prior to test. Food records kept during test periods. Subjects consumed either grape juice (GJ) (360 mL/day) or 12 prunes (PR) (100 g/d) for 4 weeks, followed by cross-over to other diet for additional 4 weeks. 100 g of prunes provides 6 to 7 g DF, of which approximately 60% is pectin.	Base diet / GJ diet / PR diet Energy: 2522 / 2572 / 2579 Pro, %: 16 / 15 / 14 Fat, %: 33 / 30 / 30 CHO, %: 47 / 51 / 51 alcohol, %: 4 / 4 / 5 CHOL, mg: 276 / 255 / 277 DF, g: 21 / 18 / 24 TC, mg/dL: 226 / 230 / 226 LDL, mmol: 3.89 / 4.09 / 3.92 HDL, mmol: 1.30 / 1.27 / 1.26 There was no difference in TC levels between baseline diet & prune diet. Percent of energy from CHO on GJ and PR diets increased, % fat and Pro decreased. Fiber intake increased on PR diet, decreased on GJ diet.	Authors compared results of prune diet to grape juice noting that plasma cholesterol tended to be lower at the end of the prune period, although not statistically significant.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Karlander, S. et al., 1991 (Ref 85).	Intervention, controlled, randomized, cross-over.	13 men and women with NIDDM, mean TC 275 mg/dL, free living. 5 were on chronic treatment with beta-blockers and diuretics because of hypertension; 8 were only on diet treatment with sulfonylurea (SU).	Study was divided into three 6-week periods: a run-in period and 2 study periods. Run in period: subjects given routine dietary counseling aimed at optimizing body weight and glucose control. Subjects then randomized to start fiber-rich diet or continue with regular diet (control). After first test period, subjects switched to other diet. Medications were left unchanged. Diet history and weights were taken every 3rd week. Dietary advice: energy reduction for obese patients--CHO 55% energy, fat 30%, Pro 15%. Fiber: beet fiber--20 g Fibrex/day (16 G DF) divided into thirds and taken with each meal. Diet history showed base diets: 44% energy as CHO, 40% fat, 16% Pro, mean DF in control diet and SU-tx patients was 18 g/day. TDF during test period was 34 g/day.	During run-in period SU tx group had 8 loss in body mass index; no other weight loss occurred with either group during the test periods. Diet group / SU group TC, mg/dL fiber 278 / 247* control 275 / 275 *Significant difference from SU control group.	Cholesterol lowering (10%) only in patients treated with SU. Authors state that hypocholesterolemic effect of this magnitude appears to be common during fiber treatment of NIDDM. Authors also note that another study noted a similar effect of guar in insulin-treated, but not SU-treated patients with NIDDM. They conclude that this suggests that a hypocholesterolemic effect of fiber in NIDDM patients is not linked to the type of treatment but may be explained by patient selection. Beet fiber had no effect on serum triglycerides or in glucose control in this study. No body weight data.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Israelsson, B. et al., undated (Ref. 86).	Intervention, placebo controlled, double blind, cross-over.	27 women, 55 to 56 years, TC 263 to 297 mg/dL, free living, selected from health screening program concerned with cardiovascular disease risk factors and the effects of high alcohol consumption.	One month run-in period on a moderate cholesterol, low fat diet with increased ratio of PUFA/SFA; followed by randomized assignment to intervention or placebo group for 1 month, then cross-over. Placebo (bread crumbs or bread crumbs with bread) 30 g/day (3.5% fiber). Beet fiber (crumbs packed in 5 g portions or as bread with 3 g fiber/slice) 30 g/day. Beet fiber, Fibrex: SF 20%, IF 55%, TDF 75%. Diets provided between 1415 to 1494 Cal, 17 to 19.7% Pro, 27.6 to 26.9% fat. Total fiber 11.7 to 14.7 g/day (low fiber periods) and 33 to 34 g/day (high fiber periods).	Compared to placebo, beet fiber reduced serum cholesterol $ after 2 weeks. After 4 weeks, the difference was not significant. MEAN DIFFERENCE AFTER INTERVENTION (Fiber minus Placebo) mg/dL TC / LDL / HDL After 2 weeks w/ fiber: -10.0* / -8.5 / -3.1 After 4 weeks: -7.7 / -11.6* / +4.3 * Significant.	Subjects made changes to their diet after the run-in period by significantly decreasing their intake of alcohol. No report on the intake of dietary fat, especially the amounts of saturated and polyunsaturated fat consumed during test periods. Soluble fiber intake from diets not reported. Subjects on fiber consumed $ higher energy from fat; placebo subjects consumed $ more CHO. Limitations of study: short duration of study. No body weight data.
Kirsten, R. et al., 1989 (Ref. 97).	Intervention, controlled.	13 men and women (7 with type IIa and 6 with type IIb hyperlipidemia), mean age 57.2 yrs, mean TC 286 mg/dL, free living.	Study was divided into three phases: a 30-day pretreatment observation phase, 60 days of treatment, and 60 days of post-treatment observation. During test period subjects consumed 4 g of guar with water before each main meal (total of 12 g guar/day). Subjects instructed to avoid cholesterol-rich foods during the study.	PreTx / Tx TC, mg/dL: 286 / 251* LDL, mg/dL: 213 / 186* HDL, mg/dL: 48 / 44 *Significant compared to baseline Total cholesterol, LDL and HDL all returned to baseline 60 days after cessation of treatment.	Sample size was small. Dietary intakes were not reported. No control group.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Jenkins, et al., unpublished (Ref. 94).	Intervention, randomized, cross-over controlled feeding.	11 normal subjects (6 men, 5 postmenopausal women) with mildly increased blood cholesterol. (mean = 242 mg/dL) (3 Type IIa, 7 Type IIb, 1 Type IV), free living.	After a 2-month treatment with the AHA Step 2 diet, Ss randomized to a high soluble fiber diet (SF) or a high insoluble fiber (IF) diet for first test period. Test period 1 to 16 weeks; 2-month washout on Step 2 diet only; cross-over to test period 2 to 16 weeks. Step 2 diet: <20% kilocalories total fat, 20% Pro, 60% CHO, <50 mg cholesterol. The SF diet provided fiber from beans, peas, lentils, barley, oat bran, and psyllium enriched cereal. Ss received foods from the clinic, but lived at home. SF diet provided 16 g SF/d and 37.5 g/d IF. IF diet provided 12.0 g SF/d and 42.1 g/d IF.	Both diets (SF and IF) reduced total and LDL cholesterol. SF diet reduced total cholesterol by 6.3% and LDL cholesterol by 8.6% compared to the IF diet. Insoluble Fiber Diet Baseline / After 16 Weeks TC, mg/dL 242 / 226 LDL, mg/dL 163 / 152 Soluble Fiber Diet TC, mg/dL 257 / 211* LDL, mg/dL 172 / 139* *Significantly lower compared to IF diet.	Well controlled study. The "soluble" and "insoluble" fiber diets differed by less than 4 g of SF, on average. The authors speculate that either current analytical methods may actually underestimate SF, or that IF may have some hypolipidemic effect from certain components such as lignin. They also note that some SF have no hypolipidemic effect (acacia, agar). Authors encourage consumption of fiber sources known to lower TC.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Jenkins et al., unpublished (Ref. 93).	Intervention, controlled feeding study with randomized, cross-over design.	12 hyperlipidemic subjects (3 men, 9 postmenopausal women), ages 38 to 70, mean TC--272 mg/dL, mean LDL--192 mg/dL.	Subjects consumed a Step 2 basal diet (see study above) for 2 months then randomized to receive either psyllium or wheat bran cereal. Test period 1 to 4 weeks; 2-week washout on Step 2 diet; Test period 2 to 4 weeks. Patients received their food from the clinic, but lived at home during the study. The psyllium cereal diet provided 16.2 g/d of SF, while the wheat bran cereal diet provided 9.5 g/d SF. Subjects in the psyllium group ate 9.35 g of psyllium/day.	The psyllium cereal diet significantly reduced TC and LDL cholesterol, while the wheat bran diet did not. PSY diet: Week 0 4 mg/dL Total CHOL 275 249* LDL 199 173* Control diet: Total CH 268 257 LDL 186 182 *Significant $p < 0.05$. In individuals with increased cholesterol and triglycerides in this study (Type IIb), the psyllium cereal diet did not reduce serum LDL cholesterol, while it was effective in Type IIa (elevated cholesterol without elevated triglycerides).	Small sample size. Well controlled study. Psyllium containing cereal was shown to significantly reduce serum total and LDL cholesterol. The effect was independent of a low fat diet. No significant difference between groups for TC/HDL, LDL/HDL, apo B/A1. Preliminary results also suggest that psyllium cereals may not effectively lower LDL cholesterol in individuals with concomitantly elevated triglycerides (Type IIb). Subjects ate 9.35 g of psyllium per day (>3 ounces of cereal).

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Anderson, unpublished (Ref. 95).	Intervention, randomized, double blind, parallel.	44 men and women, mild to moderate hypercholesterolemic (TC 200 to 300 mg/dL), free living.	Subjects (Ss) were followed for 7 weeks. Week 1 was baseline period when subjects consumed their usual diets. Then Ss randomized to receive psyllium (PSY) cereal or wheat bran cereal and instructed on Step 1 diet and asked to adhere to it for 6 weeks. Step 1 diet: 55% total energy as CHO; 15% as protein; 30% as fat, less than 10% as saturated fat, and less than 300 mg cholesterol/day. Ss returned to clinic after 2, 4, 5, and 6 weeks on cereal. 3-day diet records were kept during week 3 of test period. Ss consumed 4 ounces of cereal (2 ounces in morning and 2 in evening). PSY cereal provided 11.6 g PSY, 24 g TDF, 12 g SF. Wheat cereal provided 20 g TDF and negligible SF.	PSY group TC significantly ↓ (8%) 251 to 230 mg/dL compared to baseline and significantly lower than wheat group. LDL ↓ significantly (13%) in PSY group compared to baseline. No significant changes in wheat group.	Average consumption of psyllium cereal was 3.7 ounces/day.
Earll et al. unpublished (Ref. 90).	Intervention.	7 men and women, hyperlipidemic (TC 261 to 346 mg/dL), free living, ages 32 to 71, treated by physician for (average) 2.4 years for hyperlipidemia.	Each subject served as own control. Ss were asked to take 24 g of fiber/day for 6 weeks and 48 g/day for 6 more weeks. At week 20 (8 weeks after test period ended), Ss had another blood lipid test. Ss instructed by dietitian on how to incorporate fiber into their diet and how to keep diet records. Diet records were kept for 3 days at the start, after 6 weeks, and again after 12 weeks. Corn fiber (milled and ground) provided 89% dietary fiber and less than 2% SF. Ss mixed the fiber with water. No indication when fiber was consumed during the day.	Mean fiber consumption for first 6 weeks was 22.7 g/day; for second 6 weeks--41 g/day. Two Ss stated that they could not consume 6 packets per day for 6 weeks so continued with 3 packets/day. Total cholesterol was significantly reduced on an average from 298 to 253 mg/dL, although much smaller changes were observed in two Ss and one subject had an increase in TC. TC returned to baseline after the 8-week followup period when there was no intervention. There was no significant effect on HDL. LDL was not reported.	Total dietary fiber, total SF, dietary saturated fat before, during, and after test period were not reported. Small number of subjects in this study. The serum cholesterol for all Ss except 1 remained above 200 mg with fiber intervention. No control group. No body weight data.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Wolever et al., unpublished (Ref. 101).	Intervention, randomized, controlled, cross-over.	42 subjects (21 men, mean age 55 years; 21 women, mean age 58 years), 14 Ss were on lipid lowering drugs, 3 had type 2 diabetes.	Subjects were tested for two 2-week periods separated by a 2-week washout period. The base diet was an AHA Step 2 diet. During test period Ss asked to consume 2 servings of breakfast cereal daily: one in morning and one in evening. The test and control cereals were matched for energy and fed at a dose of 60 g/day. Psyllium (PSY) cereal provided 6.7 g/d of psyllium.	After 2 weeks on PSY: Baseline / Test TC, mg/dL 261 / 244* LDL, mg/dL 183 / 168* HDL, mm/L 1.14 / 1.10* * Significantly different from baseline.	Subjects were consuming Step 2 diet which restricts fat to less than 20% of calories. Subjects consuming lipid lowering drugs had decreased TC of 6.1% and LDL of 4.7%, not statistically significant from diet alone group. The short test period of 2 weeks of this study limits the usefulness of the results.
Wolever et al., unpublished (Ref. 102).	Clinical trial to evaluate the effectiveness of psyllium taken in foods versus psyllium taken between meals.	18 subjects (9 men and 9 women), mean age 54 years; 2 Ss were on lipid lowering drugs.	Study design with three 2-week test period separated by 2-week washout periods. Ss all consumed AHA Step 2 diet prior to study. Three treatment periods: Ss provided with cereal were asked to consume one with breakfast and one with dinner; Ss asked to consume PSY cereal between meals; Ss asked to consume control breakfast cereal. PSY cereal provided 6.7 g TDF per day from psyllium and 23.1 g/d TDF from the cereal. The control cereal provided 23.2 g/d TDF.	PSY with meals: Control / PSY TC, mg/dL 259 / 237* LDL, mg/dL 185 / 164* PSY between meals: Control / PSY TC, mg/dL 259 / 251 LDL, mg/dL 185 / 174 * Significantly different from control.	The 2 week period of this study limits the usefulness of the results.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Spencer and Gee, unpublished (Ref. 109).	Intervention, cross-over, blinded, placebo used.	31 male, serum cholesterol between 200 to 270 mg/dL.	A 6-week test period. Test subjects consumed 20 ounces of a fiber-supplemented juice per day to the regular diet, which supplied 10 g of DF (70% soluble fiber, predominantly from gum arabic) Placebo group received 20 ounces per day of nonsupplemented apple juice. Ss were asked to maintain normal eating and lifestyle habits.	With both ordered groups totaled, there is a significant decrease in serum total cholesterol and LDL-cholesterol during the period of consumption of fiber-enriched juice.	The cholesterol intake was significantly higher in the juice only group. In the group, ordered plain juice, then fiber-enriched juice, there is no change in total serum cholesterol followed by a significant decrease while on fiber-enriched juice. In the group which was given fiber-enriched juice first, there is a significant decrease while on the fiber-enriched juice, followed by no increase while on plain juice. The authors attribute this to a carryover effect of the fiber, but this is difficult to say.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Neal and Balm, 1990 (Ref. 98).	Intervention, parallel, open-label, clinical trial.	59 subjects with total cholesterol between 215 and 396 mg/dL.	29 subjects were assigned to dietary intervention only; 30 subjects were assigned to dietary and psyllium intervention. During the first 7 weeks, all subjects were to adapt to the AHA phase I diet. The subjects who were in the diet plus psyllium group were instructed to take psyllium in the form of Metamucil immediately after breakfast, and immediately after the evening meal for a 13-week period.	Dietary response period: During the first 7 weeks, men had significant lowering in their total serum cholesterol; women experienced very little change. After the treatment period, the PSY group had 5.5% additional decrease (significant) in TC compared to diet only group after the treatment period. Although there was a 5.1%↓ in LDL in PSY group compared to control, this decrease was not significant. Total Cholesterol (mg/dL): Control: After diet 263, Final 261, Avg Individual % Change -1.6 PSY: After diet 266, Final 247, Avg Individual % Change -7.1* LDL Cholesterol (mg/dL): Control: After diet 182, Final 176, Avg Individual % Change -3.5 PSY: After diet 190, Final 172, Avg Individual % Change -8.6* *Significant from post diet.	Although the compliance to the diet was checked, the breakdown of nutrients and amount of total soluble finer, total fat and saturated fat were not reported for each group. During the 7 weeks pretreatment period, results showed the women's TC did not respond to the AHA diet. Small weight loss in both groups.
Uusitupa et al., 1989 (Ref. 100).	Randomized, double-blind parallel group.	39 patients with NIDDM, mean age 58.6--men and 61.4 years--women, mean TC 253 mg/dL; all 39 subjects were on drug treatment for diabetes, 15 were on antihypertensives, 7 Ss were on drug treatment for coronary heart disease, and 6 Ss were on drug treatment for both hypertension and coronary heart disease, free-living.	Ss were randomly assigned to test or control groups. Group A: Received 5 g guar gum three times per day before meals. Group B: received 5 g wheat flour three times per day before meals. After 3 months, group B switched to guar gum for the remaining 10 months of the study, and group A continued on guar. Ss advised to lower fat calories to 35% and increase carbohydrates to 50% of calories.	Serum total cholesterol (mg/dL) A: run-in 253, 3 mo 220, 12 mo 237 B: run-in 253, 3 mo 242, 12 mo 233 There is a significant difference between the guar gum group and the control at 3 months.	Significant weight loss occurred, but in both the control and treatment groups to a similar degree. Authors question compliance of Ss during months 4 to 12 because serum cholesterol increased in both groups. Group B showed highest serum cholesterol at month 11 (242 mg/dL). Diets during the test period were not reported. Total soluble fiber, total fat, and saturated fat were not reported.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
O'Connor et al., in press B302 (Ref. 103).	Multicenter (7), double-blind, randomized, parallel group, placebo controlled trial.	Males and females (169 randomized, 135 completed study), between the ages of 18 and 70 years with a diagnosis of mild to moderate primary hypercholesterolemia.	Step one diet for 9 weeks; 15-week test period. Five Fiber Supplement (FFS) packet consists of 7.5 g SF (guar and pectin) and 2.5 g of IF. Placebo packet consists to 5.2 g of IF, no soluble fiber. During Week 1 of supplementation, Ss took 1 packet FFS per day, before dinner. During Week 2, they alternated days between one packet per day before dinner, and two packets per day, one before breakfast and one before dinner. During weeks 3 to 15, Ss took two packets of FFS per day, one before breakfast and one before dinner. Ss assigned to the two packet (26.4 g) group received FFS for all doses during Week 1 through Week 15. Ss who were assigned to the placebo group received placebo treatment for all doses during weeks 1 to 15.	Percent change in fiber from baseline minus % change in placebo from baseline: Week / TC / LDL-C 3 / -9.0 / -12.7 6 / -7.8 / -10.3 9 / -8.7 / -11.8 12 / -6.2 / -10.3 15 / -6.8 / -10.2 All values are significant.	Tightly-controlled trial. Dietary factors well-controlled; all major nutrients kept constant except for fiber.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
O'Connor et al., in press B301 (Ref. 103).	Multicenter (4) double-blind, randomized, parallel group, placebo controlled trial.	Males and females (161 randomized, 127 completed study), between the ages of 18 and 70 years with a diagnosis of mild to moderate primary hypercholesterolemia.	Step 1 diet for 9 weeks; 15-week test period. Five Fiber Supplement consists of 7.5 g SF (guar and pectin) and 2.5 g of IF. Placebo consists to 5.2 g of IF, no soluble fiber. During Week 1 of supplementation, subjects took one packet of treatment per day, before dinner. During Week 2, they alternated days between one packet of treatment per day before dinner, and two packets of treatment per day, one before breakfast and one before dinner. During weeks 3 to 15, Ss took two packets of treatment per day, one before breakfast and one before dinner. Ss who were assigned to the one packet (13.2 g) of Five Fiber Supplement group received active treatment with the dose before dinner each day. The dose before breakfast during Week 2 (as required) and during Week 3 through Week 15 was placebo. Ss who were assigned to the two packet (26.4 g) group received active treatment for all doses during Week 1 through Week 15. Ss who were assigned to the placebo group received placebo treatment for all doses during weeks 1 to 15.	Percent change from baseline in "Relative Efficacy" over time (relative to placebo). Week / 1 Packet Supplement LDL-C / 2 Packets Supplement LDL-C 3 / -7.6 / -12.0 6 / -9.3 / -13.8 9 / -4.5 / -7.5 12 / -4.2 / -8.6 15 / -5.9 / -7.9 All values are significant for the two-packet group. Week / TC / TC 3 / -5.2* / -6.9* 6 / -5.0* / -8.8* 9 / -2.4 / -4.3* 12 / -2.2 / -4.7* 15 / -3.6* / -5.3* * Significant difference.	Well-controlled, free-living, trial. Dietary factors well-controlled. All major nutrients kept constant except for fiber. A dose-response was not statistically demonstrated between placebo, one-packet dosage and two-packet dosage.
O'Connor et al., in press (Study B301 extension) (Ref. 103).	An open-label study of the safety and efficacy of Five Fiber Supplement administered twice a day in conjunction with a low fat diet for 36 weeks.	Patients who completed 15 weeks of treatment with either one packet of Five Fiber Supplement per day, two packets of Five Fiber Supplement per day or placebo were eligible to continue therapy with two packets of Five Fiber Supplement per day for an additional 36-week period. 102 entered and 59 completed the 36 additional weeks.	During this open-label extension, patients were continued on their Step 1 Diet. During the first week of the extension, patients took one packet of treatment per day (before dinner). Thereafter, during weeks 17 to 51, patients took two packets of treatment per day (one before breakfast and one before dinner).	During the 36-week extension of the trial, total Cholesterol was maintained at 5.3% (Significant) and LDL-cholesterol at 8.4% (Significant) lower than baseline.	This extension to the above study was not blinded by definition. The study was well-controlled for dietary factors and other major confounders.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Whyte et al., 1992 (Ref. 104).	Intervention, randomized with cross-over.	23 men, mean age 45 years, mild hypercholesterolemia (TC 209 to 259 mg/dL), free living.	Subjects were randomly assigned to either the wheat cereal group or the oat cereal group after a 3-week baseline diet. During baseline period, all Ss consumed wheat cereal. Preweighed packages of cereal were provided: 54 g of wheat bran per day; 123 g oat bran per day. Base diet was typical Australian diet with approximately 30 to 34% of calories as fat. Ss instructed on how to keep dietary records, measure and restrict fiber (so all Ss would have approximately same total fiber intake of less than 30 g/d. Each fiber cereal (2 servings/day) was consumed for 4 weeks followed by cross-over to other fiber cereal for an additional 4 weeks. Oat cereal: 10.3 g/d SF Wheat cereal: 3.4 g/d SF All diets: TDF approximately 27 g/d. Oat diets provided 71 g/d starch; wheat diets provided 42 g/d starch.	Data analysis showed no effect of treatment order. mg/dL: TC — Baseline 226, Oat 218*, Wheat 226; LDL — Baseline 159, Oat 150*, Wheat 159 * Significantly compared to both baseline and wheat period.	Consumption of total fat and saturated fat during both test periods was about the same (35.5 g fat/1,000 kilocalories and 12.7 to 13 g saturated fat/1000 kilocalories). Short test period No dietary cholesterol intake data.
Niemi et al., 1988 (Ref. 99).	Double-blind, cross-over trial with placebo.	22 subjects: 16 women, 6 men; with poorly controlled type 2 diabetes. Ages 40 to 76. Mean serum cholesterol 235 mg/dL and 255 mg/dL. 19 subjects on medication.	The study consisted of two 12-week treatment periods separated by 4-week washout period. Eleven patients, selected at random, started with microcrystalline cellulose during the first 12-week treatment phase followed by treatment with guar gum in the second 12-week period. In the other 11 subjects, the sequence was reversed. Both types of fiber were taken with meals three times daily. The initial dose was 5 g/day, which was increased up to 15 g/day during the 2-week period at the beginning of each treatment phase.	The pooled data show that serum cholesterol was significantly lower after 12 weeks on guar gum, but no signficant change was found after cellulose. Serum cholesterol (mg/dL) Time: Start — Cellulose 235, Guar 255; 12 weeks — Cellulose 240, Guar 220* *significant from start.	Although patients were advised to keep to their normal diet, no measurements of diet (total soluble fiber, total fat and saturated fat, etc.) were discussed to verify this. Only the pooled data was reported. It would be helpful to examine the response of each group separately. Is cellulose an appropriate control?

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Cerda et al., 1988 (Ref. 105).	Intervention, double-blind, cross-over with placebo.	27 subjects: 9 men, 18 women, ages 27 to 69 years. Mean serum cholesterol 275 mg/dL (range of 208 to 420 mg/dL), free living.	A 16-week study: 4-week baseline, 4 weeks on placebo or pectin, 4-week washout, then cross-over to 4 week on placebo or pectin tablets. Ss consumed normal diets but consumed 27 tablets (9 at each main meal) daily during test periods. Dietary records were kept during weeks 1, 7, and 16. Each Ss served as own control. Grapefruit Pectin: 15 g/day Placebo (flour): 15 g/day.	Baseline / Pectin / Placebo (mg/dL) TC 275 / 254* / 275 LDL 195 / 174 / 191 HDL 41.6 / 41.1 / 41.5 *Significant from baseline and placebo.	Authors reported good compliance to tablet consumption. The subjects dietary intake of calories, total fat, saturated fat, cholesterol, and soluble fiber were not reported. Short test period. No body weight data.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Haskell et al., 1992 (Ref. 106).	Intervention, randomized, double-blind, placebo-controlled trials.	Total cholesterol range for all studies: 200 to 280 mg/dL Study (S) 1: 58 men and women, mean age 57 yrs. S 2: 40 men and women, mean age 56.4 yrs S 3: 16 men and women, mean age 52.5 yrs S 4: 49 men and women, mean age 56.3 yrs. All free living subjects.	After baseline period Ss randomly assigned to one of 4 studies: S 1: 12-week test. Evaluated CH-lowering properties of mixed SF with 56% from acacia gum. Fiber product: powder mixture of acacia gum (9.7 g), psyllium (4.9 g) and guar gum (2.6 g) for a total of 17.2 g/day divided into 3 servings/day. All placebos consisted of 15 g of fructose. S 2: 4-week test. 15 g/day acacia gum powder divided into 3 servings/day. S 3: 8-week cross-over using guar as control. Test fiber mixture: pectin (3.9 g), psyllium (6.3 g), guar (3.3 g), and locust bean gum (1.5 g) for total of 15 g/day SF given in 3 servings per day; guar control: 10 g guar and 1 g pectin for total of 11 g/day given in 3 servings/day. S 4: 4 weeks. A dose-response study with SF test mixture used in S 3. Mixtures tested: 1 svg/d, 2 svg/d, 3 svg/d pectin, g: 1.3, 2.6, 3.9 psyllium, g: 2.1, 4.2, 6.3 guar, g: 1.1, 2.2, 3.3 locust bean, g: 0.5, 1, 1.5 Total g/day: 5, 10, 15	S 1: There were no statistically significant changes from baseline to 6 or 12 weeks within or between groups. S 2: Baseline / 4 weeks (mg/dL) / % change* TC placebo 264 269 ↑1.9 acacia 266 265 ↓0.4 LDL placebo 200 206 ↑3.3 acacia 194 195 0.0 HDL placebo 55 52 ↓5.4 acacia 60 58 ↓3.9 * not statistically significant from baseline. S 3: Baseline / 4 weeks / % change TC guar 249 225* ↓9.7 fiber mix. 249 230* ↓8.3 LDL guar 184 163* ↓13.6 fiber mix. 184 166* ↓12.4 HDL guar 54 50** ↓6.5 fiber mix. 54 51** ↓5.9 * Significant from baseline p<0.01 ** Significant from baseline p<0.05. S 4: Baseline / 4 weeks / % change TC placebo 261 262 0.3 5 g/d 255 242 ↓5.2 10 g/d 259 247 ↓4.9 15 g/d 275 242* ↓12.2 LDL placebo 184 186 0.8 5 g/d 186 176 ↓5.6 10 g/d 187 174 ↓6.8 15 g/d 211 179* ↓14.9 HDL placebo 67 62 ↓6.4 5 g/d 57 54 ↓4.1 10 g/d 61 62 ↑1.9 15 g/d 53 48 ↓9.4 * Significant from placebo.	Subjects' diets were not reported. Short test periods.

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Study	Study Design	Subjects	Methods	Results	Comments
Morvi et al., 1989 (Ref. 107).	Purpose of study was to evaluate hypothesis that legumes may be a dietary risk factor for cholesterol gallstone formation in Chileans. Nonblinded cross-over intervention study.	20 young Chilean men, ages 18 to 22 years, mean TC 162 mg/dL.	Subjects received a control diet for 25 to 30 days. Food preparation and intakes were controlled by nutritionists. Diets eaten for 6 days a week; Ss were allowed free food intake on Sunday. Test period was 30 to 35 days on a legume diet: beans 4 days, peas 2 days, lentils 1 day. Ss received 120 g dry legumes each day. Control and test diets were matched for calories, protein, fat, fiber and cholesterol intakes. Control Diet / Legume Diet Energy, Cal 3219 / 3219 % of Calories Protein 14 / 14 Carbohydrate 54 / 53 Fat 32 / 33 Cholesterol, mg 300 / 302 Total Fiber, g 12.4 / 12.5	Serum cholesterol (mg/dL) Control diet 162 Legume diet 143 Difference is significant (p<.001).	Short test period. Authors reference a study that indicates that epidemiological studies have demonstrated increased prevalence of gallstones in men ingesting a diet that lowers serum cholesterol. No saturated fat intake data. No body weight data, low baseline serum cholesterol.
Unpublished study submitted with comments (Ref. 108).	Double-blind double cross-over intervention.	23 healthy men, Age > 18 years, TC > 240 (exact ages and total cholesterol not reported), free living.	Baseline period: 4 weeks Step I diet. Subjects randomly assigned to either psyllium-wheat bran-psyllium (n=12) or wheat bran-psyllium-wheat bran (n=11) for 8, 5 and 5 weeks respectively on each regimen (18 weeks total). Subjects were provided with boxes of cereal and instructed to eat 2 ounces of the study cereal in the morning and one ounce in the evening. The psyllium cereal had a total of 5 g of soluble fiber and 7.4 g of total dietary fiber per ounce. The wheat bran cereal had 1 g of soluble fiber and 5 g of total dietary fiber per ounce. Relative percentages of protein, fat, sugar and starch in the two products were reported to be similar.	Effect of Psyllium versus Wheat Bran Cereal (in mg/dL) PSY / WHEAT-BRAN / Difference TC 225 / 235 / 4.3% * LDL 148 / 157 / 6.1% * HDL 46 / 45 / - * significantly different p<.0001.	It is difficult to evaluate the results of the study because the authors do not report the initial cholesterol values of either group, instead relying on differences between the groups' average cholesterol values. It is important to review the effect of the diet order, to observe any changes in going from one test product to the other, and note any temporal trends in rising or falling of cholesterol levels on each diet. No dietary data

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Anderson et al., 1984 (Ref. 110).	Metabolic ward, study for 21 days with random allocation to groups.	10 male subjects age 46 to 66 with initial serum cholesterol > 260 mg/dL.	All subjects received the control diet for 7 days, and then were placed on a test diet for 21 days. Control diets provided 19% of energy as protein, 43% as CHO, 38% as fat 20 g plant fiber, and 6 g soluble fiber per day. The oat-bran diet provided 100 g of oat bran per day served as a bowl of hot cereal and five oat bran muffins per day. This supplied approximately 48 g total plant fiber and 18 g soluble fiber per day. The bean diet containing 100 g of dried beans per day provided the same amount of total plant fiber and soluble fiber as did the oat-barn diet. After controlled trial ended, subjects were given high-fiber maintenance diets to follow for an additional 24 weeks; four of the subjects were followed for a total of 99 weeks.	Mean serum cholesterol values of oat and bean groups: (values in mg/dl). Week / TC / LDL / HDL 1 / 294 / 216 / 37.2 4 / 226 / 167 / 29.8 7 / 233 / 169 / 31.4 10 / 234 / 164 / 33.9 16 / 232 / 164 / 33.9 24 / 218 / 164 / 35.2 *Note: All values are significantly lower when compared to week 1. After 99 weeks of followup (free-living on high-fiber maintenance diets), serum chol values were 26% (p<.001) below initial values at 24 week and 23% lower (p<.003) at 99 weeks.	Small sample size. Significant weight loss during test period; no significant weight loss during control period. Short period. No control.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Fukagawa et al., 1990 (Ref. 114).	Metabolic ward study; clinical trial, nonblinded, no placebo. Young men only ate their meals on the metabolic ward. The older group were admitted to the ward.	Six healthy male students, age 18 to 24 (TC 200 mg/dL) and six healthy older men and women, age 67 to 86 (TC 238 mg/dL).	The subjects were placed on a high fiber diet for a period of 21 to 28 days after consuming their usual ad libitum diet. High fiber diet: 68% of energy from CHOs, fat intake of 14%, protein of 18%; 33 g per 100 kilocalories of fiber. Plant fiber was provided by whole grain or grain cereals and breads(40%), vegetables such as beans, corn, or peas (20%), other vegetables (31%), and fruits (9%). Soluble fiber/day Reg. Diet / High Fiber younger group 3.5 g / 23.6 g older group 3.7 g / 17.1 g Ad libitum diet assessed by dietary recall.	Serum cholesterol in young and old subjects before and after 4 weeks of a high fiber diet: Before / After (mg/dL) Both (n=12) 219 / 170 ↓22%* Young (n=6) 200 / 147 ↓26%* Old (n=6) 238 / 193 ↓45%* *All "after" values are significantly lower than corresponding "before" values.	Small sample size. There was no control group, fat was not controlled. The ad libitum diet was significantly higher in fat (37 to 42% versus 14% of calories), saturated fat (15 to 17% versus 3% of calories), and cholesterol (720 to 755 versus 90 to 134 mg/d) than the test diet. Ad libitum diet relied on dietary history alone. It should be noted that the objective of this study was to examine the effects of a high fiber diet on insulin sensitivity; the cholesterol findings were secondary. No body weight data.
Turnbull and Leeds, 1987 (Ref. 111).	Clinical study, randomly allocated, cross-over.	9 men, 8 women, age 23 to 59, initial serum cholesterol level of at least 232 mg/dL, free living.	Subjects were placed on a one-month run-in period when they followed a low-fat diet (≤ 35% of calories from fat). Subjects were then randomly allocated to 1 month of an oat diet (50 g oats each day at breakfast and 100 g oats as biscuits or a wheat diet (37 g wheat biscuits each day at breakfast and 100 g wheat as biscuits. At the end of the month, subjects switched diets. Oat products provided 5.4 g SF/day. Wheat products provided 3.1 g SF/day.	Values for cholesterol before and after intervention: Initial / Final / Sig Change? (mg/dL) Oat period Total chol 232 / 220 / Y LDL-chol 167 / 143 / Y HDL-chol 46 / 54 / NS Wheat period Total chol 228 / 232 / NS LDL-chol 159 / 163 / NS HDL-chol 50 / 50 / NS	Fat intake is higher during oat period (this does not invalidate cholesterol-lowering effect of oats). No saturated fat or cholesterol intake data.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Walsh et al., 198[illegible] (Ref. 117).	Clinical trial, double-blind, randomly-assigned, with placebo.	20 women, (ages not given), obese (20% or more over ideal weight), mean serum cholesterol 198 mg/dL.	The trail was of 8-week duration. The glucomannan group (GM) took two capsules of a supplement containing 500 mg of purified glucomannan, three times per day, with 8 ounces of water, 1 hour before each meal. The placebo group (PG) took two capsules containing 500 mg starch under the same conditions. All patients were instructed not to deviate from their previously-established eating and exercise patterns.	Changes in weight and cholesterol Weight Change (lbs) / Chol Change (mg/dl) Week 4 / 8 / 4 / 8 GM -4.9* -5.5* -20.9* -21.7* PG 0.4 1.5 5.9 4.7 Difference between groups. 7.0 lbs 26.2 * Significant difference between groups.	Because weight loss and cholesterol-lowering are closely correlated, it is not possible to conclude that the cholesterol-lowering effect is an independent result of glucomannan supplementation.
Anderson et al., 1992 (Ref. 118).	Intervention, randomized, double-blind, parallel design.	44 men and women, ages 25 to 70, total cholesterol 199 to 300 mg/dL, 80 to 130% of desirable body weight, free living.	One-week baseline period--Ss consumed usual diet then randomized to receive psyllium-flake or wheat-bran-flake cereal (control) for 6 weeks. Ss also instructed on step 1 diet and asked to adhere to this diet for 6 weeks. Wheat cereal: 28.4 g serving with 5 g total DF, negligible SF. PSY cereal: 28.4 g serving with 6 g total DF, 2.9 g PSY, 3 g SF. Ss were instructed to consume one serving of cereal the first day and add 28.4 g additional daily until a maximum of 114 g/day was reached. 114 g of PSY cereal would provide 24 g total DF, 11.6 g PSY, 12 g SF. Ss completed 3-day diet record during week 5 of treatment period.	Base Diets Wheat bran / PSY Baseline / Final / Baseline / Final Energy (Cal) 1786 1899 1821 1723 Fat (% energy) 30.7 24.3 32.2 22.9 SF, g 5.6 5.9 6.1 15.1* *Significant difference from wheat group. Serum cholesterol, mg/dL TC 254 254 252 230+ LDL 174 174 170.5 149+ +Significant difference from baseline. Change in PSY group significantly different from change in wheat group.	Authors reported slight but significant decreases in body weight in both groups across time. However, there was no significant difference in weight loss between groups.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Braaten et al., unpublished (Ref. 119).	Intervention, randomized.	21 men and women, ages 43 to 64, hypercholesterolemic (mean serum cholesterol 255 mg/dL), free living.	Subjects consumed usual diets with the fat content adjusted to be at least 20% and preferably more than 25% of their daily caloric content. Three-day food dairy was used to record their diets before and during each treatment period. Instant soluble oat gum (3.6 g, 80% β-glucan) or placebo (maltodextrin) was mixed with noncarbonated diet fruit drink (250 mL) and consumed during each of the two main meals of the day for each 4-week period. There was a 2-week stabilization period prior to treatment, a 3-week washout period between treatments, and a 3-week washout period for the group on oat gum.	Dietary fat intake ranged from 30% to 31% of energy, total caloric intake was 2161 calories (stabilization period), 2069 calories (gum period), 1988 calories (washout), and 2077 calories (placebo period). Total Cholesterol Initial / Final mg/dL Placebo 255 255 Oat gum 262 238* *significantly different from baseline and placebo. LDL-Cholesterol mg/dL Placebo 174 176 Oat gum 190 154 During washout following oat gum treatment serum cholesterol increased from 238 to 258 mg/dL.	Total dietary soluble fiber, saturated fat and cholesterol intakes was not reported. Body weights before and after treatment were not reported. During final washout following oat period, serum cholesterol returned toward pretreatment levels further supporting a true effect of oat gum. Short test period.
Bridges, S. et al., 1992 (Ref. 120).	Clinical study, metabolic ward.	20 men, ages 38 to 73, mean serum cholesterol range of 252 mg/dL (wheat group) to 305 mg/dL (oat group).	Subjects received a base diet for 7 days followed by 3 weeks of oat bran or wheat bran supplementation. The base diet was a typical American diet composed of 43% energy from carbohydrate, 16% protein, 41% fat, and 450 mg cholesterol. Treatment = Tx; Pretreatment = Pretx Total dietary fiber = TDF Fiber Intake on Diets Wheat Bran: Pretx / Tx Oat Bran: Pretx / Tx TDF, g: 18 / 34 / 19 / 34 SF, g: 5.6 / 7.8 / 6.0 / 13.4 Oat bran and wheat bran were served as cereal or muffins.	Wheat Bran / Oat Bran mg/dL Total CHOL Pretx 252 305 Tx 242 267* LDL-CHOL Pretx 130 167 Tx 123 146* *Significantly different from pretx period.	Control period of 7 days is inadequate. Pretreatment serum cholesterol was calculated from data presented. Serum cholesterol and LDL-cholesterol between groups is not well matched; oat group had much higher serum- and LDL-cholesterol than wheat group. Both groups experienced slight but significant weight loss. Not randomized; short test period.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Kashtan et al., 1992 (Ref. 121).	Intervention, randomized, metabolically controlled, parallel, double-blind.	84 subjects in two groups: group 1 to 42 men and women, mean age 61.3, with history of previous polypectomy; and group 2 to 42 men and women, mean age 51.2, with normal colon and colonic examination. Mean serum cholesterol of group 1: 207 mg/dL; group 2: 227 mg/dL.	Subjects were randomly assigned to either the oat bran group or the wheat bran (control) group. Subjects consumed the bran products twice a day for 2 weeks. All food was prepared and delivered to the subjects. Energy content of diet was one of four amounts: 1,600, 2,000, 2,400, and 2,800 calories Ss were fed the amount closest to their requirements based on the Lipid Research Clinics tables. Base diet: 37% fat, 16% protein, 47% carbohydrate; total dietary fiber--24 to 25 g/day. Oat bran supplement: 88.4 g/day: 11 to 17 g fiber; estimated 5 to 8 g SF Wheat bran cream of wheat: 73 g/day: 11 to 17 g fiber/day.	Before / After / Change (mg/dL) Total CHOL Wheat bran 207 / 198** / -0.25 Oat bran 227* / 203** / -0.63* LDL-CHOL Wheat bran 129 / 125** / -0.11 Oat bran 150* / 131** / -0.48* *Significantly different from wheat bran. **Significantly different from baseline.	Soluble fiber consumption was not reported. Short term study--14 days.
Ranhotra et al., 1989 (Ref. 122).	Intervention, self-controlled.	17 men, ages 37 to 60 years, hypercholesterolemic (mean serum cholesterol 224 mg/dL), free living. One subject had a history of heart attack and one subject was a type II diabetic.	A 6-week control period followed by a 6-week test period. Ss consumed their usual diet during the control period but maintained daily records of intake for first 4 weeks. Ss were provided a list of cereal-based and other foods identified as sources of SF and asked to consume these with their daily diets. Additional SF supplement of processed rice bran (30 g) and oat bran (30 g) was provided.	Nutrient Intake: Control / Test Energy, Cal. 2378±431 / 2331±419 Fat, % energy 35.3±4.7 / 33.9±4.9 Saturated Fat, % 10±1.7 / 9±1.9 Total fiber, g 15.0±5.8 / 28.3±4.7 Soluble fiber, g 5.0±1.6 / 9.4±1.5 Ss individual data were reported. Six of the 17 Ss experienced lowered serum cholesterol of 1 to 17% compared to control values.	Statistical analysis not performed by authors. Results are too inconsistent in direction and magnitude to support an effect of SF on serum cholesterol. Some subjects failed to consume the supplement daily. Intake of both soluble and dietary fiber varied greatly among the participants.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Chang et al., 1992 (Ref. 123).	Intervention, randomized, controlled, cross-over.	9 men and women (2 women, 7 men); ages 45 to 67 years, with ileostomies. Mean serum cholesterol--231 mg/dL.	The goal of this study was to elucidate the cholesterol-lowering mechanisms of oat bran and to compare the sterol excretion pattern on a basic diet (wheat flour bread, low fiber diet (LFD)) to oat bran (oat bran bread, high fiber diet (HFD)). Subjects were randomly assigned to two groups (LFD or HFD) and each group followed for 3 weeks followed by cross-over to the other diet. Ss consumed the bread products with their own food which was modified to be low fiber. Wheat flour bread: 6.9 g dietary fiber; oat bran bread: 29 g dietary fiber.	Serum Cholesterol mg/dL All Ss (n=9) LFD 214 HFD 194.5* Ss with low daily bile acid excretion (n=5) LFD 234 HFD 207* Ss with high daily bile acid excretion (n=4) LFD 189 HFD 179 *significantly different from LFD.	Total dietary soluble fiber intake and intake of fat, saturated fat, and cholesterol were not reported. All subjects had ileostomies. Conclusions about fiber mechanisms in lowering serum lipids may not apply to the general population. Short test period.
Marlett et al., 1992 (Ref. 124).	Intervention, metabolically controlled, single isotope used to determine bile acid kinetics.	9 men, ages 29 to 50 years, normocholesterolemic (estimated range of 131 to 244 mg/dL).	A 2-month study: period 1: low fiber control period and period 2: high fiber period with oat bran. Base diets: energy--2,700, 3,000, 3,300, and 3,600 Cal/day with 35% fat, 15% protein, and 50% carbohydrate. Foods were consumed in a metabolic unit except an evening snack which could be taken home. Oat bran--100 g, provided 16.1% dietary fiber, of which 30% was β-glucan, and 46% was soluble fiber. Wheat gluten--an amount comparable to protein provided by oat bran was included in foods in the low fiber diet.	Low Fiber Period / High Fiber Period Mean dietary fiber intake: D.F., g/day 16 / 33.9 S.F., g/day 4.0 / 10.3 Serum Cholesterol mg/dL Prestudy 177 / Low Fiber 152* / High Fiber 138** *significantly lower than prestudy value. **significantly lower than low fiber period. Total daily fecal bile acid excretion more than doubled when oat bran was incorporated into the metabolic diet: Total B.A., micromoles/day 476.4 / 1026.2	There were no changes in body weights. Small sample size.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 91N-0100]

RIN 0905-AB67

Food Labeling: Health Claims and Label Statements; Folic Acid and Neural Tube Defects

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing its decision not to authorize a health claim for folic acid and neural tube defects at this time. However, consistent with the recently announced recommendations of the U.S. Public Health Service (PHS) that all women of childbearing age in the United States consume 0.4 milligram (mg) (400 micrograms (µg)) of folic acid daily to reduce their risk of having a pregnancy affected with spina bifida or other neural tube defects, FDA plans to work expeditiously to authorize a claim, if appropriate. At that time the PHS identified several issues that remain outstanding, including the appropriate level of folic acid in food and safety concerns regarding increased intakes of folic acid. Given the significance of neural tube defects and the PHS recommendation, the agency is continuing to address the issues about folic acid. FDA recently convened an advisory committee to consider the outstanding concerns (57 FR 52781, November 5, 1992). The advisory committee provided recommendations to the agency on the following issues: (1) What is the target population for a folic acid neural tube defect health claim? (2) How does the information available on the effective level of intake affect options for implementation? (3) What safety concerns for the target population and for persons in the general population must be addressed? and (4) If a claim is authorized, what is the most appropriate method for presenting it to the target population? The advisory committee's recommendations are currently under FDA review.

EFFECTIVE DATE: May 8, 1993.

FOR FURTHER INFORMATION CONTACT: Jeanne I. Rader, Center for Food Safety and Applied Nutrition (HFF-268), 8301 Muirkirk Rd., Laurel, MD 20708, 301-344-5832.

SUPPLEMENTARY INFORMATION:

I. Background

A. Procedural Status

In the **Federal Register** of November 27, 1991 (56 FR 60610), FDA proposed not to authorize the use on the label and labeling of foods, including dietary supplements, of health claims relating to an association between folic acid and the reduction in risk of neural tube birth defects. The agency issued this proposal in response to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101-535). The agency tentatively found that the available scientific evidence showed that daily periconceptional use of 4 mg (4,000 µg) of folic acid, an amount that exceeds the level of 0.4 mg (400 µg) per (/) day permitted under the current food additive regulation (21 CFR 172.345), was needed for reduction in risk of neural tube birth defects in women at high risk of this complication because of a previously affected pregnancy. The agency also tentatively concluded at that time that there was not significant scientific agreement that periconceptional supplementation with doses of folic acid lower than 4 mg/day would significantly reduce the risk of neural tube defects in women of childbearing age in the general U.S. population, who are at much lower risk of an occurrence of this complication.

In September 1992, following an open meeting sponsored by the Centers for Disease Control (CDC) in Atlanta, GA (57 FR 29323) and based on additional reviews of existing data and on new scientific data, the PHS recommended that all women of childbearing age in the United States consume 0.4 mg (400 µg) of folic acid daily to reduce their risk of having a pregnancy affected with spina bifida or other neural tube defects (Ref. 1). In discussing this recommendation, the PHS raised several issues that directly bear on FDA's responsibilities under the Food, Drug, and Cosmetic Act (the act) and the agency's pending rulemaking on whether to authorize a health claim regarding folic acid and neural tube defects. These issues include: (1) Identifying the population at risk, (2) considerations of appropriate level of intake with respect to options for implementation, (3) magnitude of benefit, (4) safety considerations, and (5) identifying the best approach for implementing the recommendation.

The 1990 amendments, in section 3(b)(1)(A)(x), direct FDA to consider whether to grant a health claim for dietary supplements on the effects of folic acid on neural tube defects. Section 3(b)(1)(A)(x) of the 1990 amendments directs the agency to make this judgment based on the standard that FDA is to establish for determining the reliability of health claims for dietary supplements of vitamins, minerals, herbs, and other nutritional substances under section 403(r)(5)(D) of the act (21 U.S.C. 343(r)(5)(D)). In its November 27, 1991 proposal, FDA proposed to adopt the standard that the 1990 amendments provide for conventional foods, which is set forth in section 403(r)(3)(B)(i) of the act, as the standard for dietary supplements. Given this fact, and the fact that folic acid is found in numerous conventional foods as well as in dietary supplements, FDA broadened its inquiry to a determination as to whether it should grant a health claim on folic acid and neural tube defects on any foods.

On October 6, 1992, Congress passed the Dietary Supplement Act of 1992 (the DS Act) which prohibits implementation of the 1990 amendments with respect to dietary supplements of vitamins, minerals, herbs, or other similar nutritional supplements before December 15, 1993. Under the DS Act, FDA may grant health claims for foods, including dietary supplements, using the significant scientific agreement standard specified in section 403(r)(3)(B)(i) of the act. Given this fact and given the breadth of FDA's November 27, 1991 proposal, which included conventional foods as well as dietary supplements, FDA has decided to move forward to determine whether it can authorize a health claim under section 403(r)(3)(B)(i) of the act for folic acid and neural tube defects by resolving the outstanding issues identified in the PHS recommendation (Ref. 1) and in comments to the November 1991 proposal.

With its recommendation, PHS made comments that identified several possible approaches for the delivery of folic acid in the dosage recommended to the general population: (a) Improvement of dietary habits, (b) fortification of the U.S. food supply; and (c) use of dietary supplements. PHS stated that FDA, in deciding whether to authorize a health claim, will have to determine which approaches will best achieve the goal of increasing folic acid intake, while ensuring that potential risks created by overfortification of food with folic acid, and overconsumption of this substance, do not occur.

FDA recognizes that fortification of a wide variety of foods could occur following authorization of a health claim, and that such fortification could lead to a significant increase in the

intake of folic acid by women in their childbearing years as well as by other portions of the general population. Such an increase would bring with it certain risks. The most widely recognized adverse effect of high intakes of folic acid is the potential for progressive neurologic damage resulting from undiagnosed or masked vitamin B_{12} deficiency. This potential risk was recognized by PHS, which stated that because the effects of higher intakes of folic acid are not well known but include complicating the diagnosis of vitamin B_{12} deficiency, care should be taken to keep total folate consumption at less than 1 mg (1,000 µg)/day, except under the supervision of a physician (Ref. 1).

FDA's current food additive regulation for folic acid (21 CFR 172.345) does not include limits on the fortification of specific commodities, and thus, a wide variety of foods could be fortified with folic acid to provide up to 400 µg/day from each source. Such fortification could lead to individual intakes in the range of 3 to 5 mg (3,000 to 5,000 µg) or more of folic acid per day. Thus, there is a significant question as to whether a health claim relating intake of folic acid and reduced risk of neural tube defects, if approved, could be implemented safely.

The requirement that substances eligible for health claims be safe and lawful is included in the final rule for health claims on foods (see General Requirements for Health Claims for Foods, published elsewhere in this **Federal Register**). Sections of the Federal Food, Drug, and Cosmetic Act (the act) enacted by the 1990 amendments cannot be implemented independently of the remaining portions of the act. The act must be considered as a whole, and FDA's responsibility for ensuring the safety of foods is explicitly provided for in other sections of the act (see sections 201(s), 402(a)(1) and (a)(2), and 409, as well as 403(r)(3)(A)(ii) of the act (21 U.S.C. 321, 342(a)(1) and (a)(2), 348, 343(r)(3)(A)(ii))).

The process by which FDA fulfills its responsibilities under the act will require rulemaking. While this process is underway, and before FDA can issue final regulations on fortification of food with folic acid and permissible health claims on foods that contain folic acid, further food fortification with folic acid would be inappropriate; and no health claims should be made (Ref. 1). FDA notes that the PHS recommendation clearly stated that there were risks attendant on overconsumption of folic acid.

B. Neural Tube Defects: Public Health Aspects

As discussed in the proposal (56 FR 60610), several specific malformations of the central nervous system are referred to as "neural tube defects" because the brain and spinal cord develop within the neural tube. The neural tube forms between the 18th and 20th days of pregnancy and closes between the 24th and 27th days. Anencephalus and spina bifida are serious birth defects and account for about 90 percent of neural tube defects. The majority of children with spina bifida survive and have substantial physical disabilities. Most anencephalic infants are stillborn or die shortly after birth. The minimum number of neural tube defect births in the United States is 2,500. This is an underestimate of neural tube defect pregnancies, however, because it does not include neural tube defect pregnancies identified by prenatal diagnosis and electively terminated. Recent data from state-based birth defects surveillance systems show decreasing trends for spina bifida from 1983 to 1990. The combined state rate is 4.6 cases of spina bifida per 10,000 live births (0.046 percent) (Ref. 2).

The multifactorial nature of neural tube birth defects is well recognized (56 FR 60610 at 60611). The single greatest risk factor currently recognized is having a previous neural tube defect-affected pregnancy. Prevalence rates of neural tube defects at birth have been reported to vary with a wide range of factors, including: Genetics, geography, socioeconomic status, maternal birth cohort, month of conception, race, nutrition, and maternal health including maternal age and reproductive history. Certain geographic areas may have, for unknown reasons, considerably higher rates than other areas. For example, a cluster of anencephalic deliveries occurred in the Brownsville, TX area between 1989 and 1991. Investigations of potential causes, including environmental contamination and other factors, are ongoing in this area (Ref. 3).

Maternal health (e.g., febrile illness) and maternal use of certain drugs (e.g., the anticonvulsant drug valproic acid) also contribute to risk of neural tube birth defects. There is an increased incidence of malformations, including neural tube defects, among infants of diabetic mothers. Carriership for an inborn error of homocysteine metabolism has been proposed as a risk factor for having an infant with a neural tube defect (Ref. 4). Poor maternal nutrition, which is among a number of factors associated with poverty, may increase the risk for neural tube defects. A recent case-control study of the cluster of anencephalic deliveries in the Brownsville, TX area found that women with less than a high school education were more than twice as likely to have an infant with a neural tube defect as were women who had finished high school (Ref. 3). This observation correlates with poverty as a known risk factor for neural tube birth defects (Ref. 3).

C. Folic Acid: Regulatory History

1. Drug regulation

The agency evaluated the use of folic acid as a drug in the **Federal Register** of April 9, 1971 (36 FR 6843) in response to reports received from the National Academy of Sciences on the therapeutic uses of folic acid. The agency concluded that folic acid administered orally or parenterally is effective for the treatment of megaloblastic anemias of tropical and nontropical sprue, those of nutritional origin, and those that may occur during pregnancy, infancy, and childhood. The agency found that administration of folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B_{12} is deficient because such treatment may mask the symptoms of vitamin B_{12} deficiency.

In the presence of excess folic acid and inadequate vitamin B_{12}, the anemia of vitamin B_{12} deficiency may not develop, but severe and irreversible nerve damage may continue. Because the anemia of vitamin B_{12} deficiency is frequently the earliest clinical symptom, failure of patients to present with this symptom may unduly delay the diagnosis of vitamin B_{12} deficiency and allow neurologic damage to progress without treatment. The interaction between the functions of folic acid and vitamin B_{12} has been recognized for many years and is the basis for the precautionary statement on preparations of folic acid for therapeutic use.

In the **Federal Register** of April 9, 1971 (36 FR 6843), the agency announced the conditions under which it would approve new drug applications for folic acid preparations. The labeling conditions included the following precaution: "Folic acid especially in doses above 1.0 mg daily may obscure pernicious anemia, in that hematologic remission may occur while neurological manifestations remain progressive."

Based upon the available data and information, in the **Federal Register** of October 17, 1980 (45 FR 69043 at 69044), FDA amended the "Precautions" statement to be included

in the labeling of oral and parenteral preparations of folic acid for therapeutic use because the agency found that the revision more accurately stated the level at which folic acid may obscure pernicious anemia. The **Federal Register** notice stated that "While obscuration of pernicious anemia does not occur at levels of 0.1 mg for folate per day, hematologic remissions in pernicious anemia have been reported at levels as low as 0.25 mg of folate per day. The precautions section of the labeling conditions for folic acid preparations is amended to read as follows: 'Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive'."

2. Food additive regulation

Folic acid is an approved food additive subject to the limitations on use set forth in the food additive regulations (§ 172.345). The food additive regulation states that: "Folic acid (folacin) may be safely added to a food for its vitamin properties, provided the maximum intake of the food as may be consumed during a period of 1 day, or as directed for use in the case of a dietary supplement, will not result in daily ingestion of the additive in excess of 0.4 mg for foods labeled without reference to age or physiologic state; and when age or the conditions of pregnancy or lactation are specified, in excess of 0.1 mg for infants, 0.3 mg for children under 4 years of age, 0.4 mg for adults and children 4 or more years of age, and 0.8 mg for pregnant or lactating women" (21 CFR 172.345). However, this regulation provides no limits, other than 0.4 mg, on the amounts that may be provided by specific foods.

In 1981, the Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology (FASEB) reviewed evidence concerning effects of physiologic and pharmacologic doses of folic acid in patients with pernicious anemia (Ref. 5). LSRO noted that virtually all of the experimental work reviewed dealt with the administration of pteroylmonoglutamic acid (folic acid) in relatively pure forms. Responses to folic acid in food products are less well defined than responses to a pure preparation. LSRO concluded at that time that it was not possible to answer with certainty whether intakes of folic acid in foods approaching 400 µg (0.4 mg)/day could result in transient hematologic remission in patients with pernicious anemia (Ref. 5).

D. The Proposed Rule

The scientific data relating to an association between folic acid and neural tube defects that was publicly available at the time of publication of the agency's proposed rule (56 FR 60610) consisted of four clinical intervention trials in women at high risk of recurrence of these birth defects (Refs. 6 through 9), four observational studies (Refs. 10 through 13), a number of studies in which clinical parameters such as serum or red blood cell levels of folate and other vitamins were measured in women who gave birth to one or more infants with neural tube defects (Refs. 14 through 17), and studies that attempted to identify factors that may lead to neural tube defects in animal model systems (Refs. 18 through 26).

The agency developed its proposed rule on the basis of the publicly available scientific evidence. An ongoing randomized controlled trial in Hungary of multivitamin/multimineral supplementation of women at risk of an occurrence of a pregnancy complicated by a neural tube defect had been discussed at scientific meetings (Ref. 27), but the scientific data from this trial were not publicly available.

The agency proposed not to authorize the use on the labels and labeling of foods, including dietary supplements, of health claims relating to an association between ingestion of folic acid and reduction in risk of neural tube defects. The agency based its tentative decision on the available scientific evidence, which showed that daily periconceptional intake of 4 mg (4,000 µg) of folic acid was needed for reduction in risk of neural tube birth defects in women at high risk of this condition based on a previously-affected pregnancy. Among women with histories of neural tube defect-complicated pregnancies, rates for recurrence of such defects have been estimated to be as high as 2 to 10 percent compared to occurrence rates of less than 0.1 percent in the general population (Ref. 28). Thus, because of their significantly increased risk, such women have been the focus of several clinical intervention trials. The amount of folic acid found to be effective in reducing risk of recurrence was significantly in excess of usual daily intakes and exceeded the level of 0.4 mg (400 µg)/day permitted under the current food additive regulation. FDA also tentatively concluded that there was not significant scientific agreement that periconceptional supplementation with doses of folic acid lower than 4 mg (4,000µg)/day in women of childbearing age in the general U.S. population would significantly reduce the risk of occurrence of neural tube birth defects. For these reasons, FDA tentatively determined that claims on foods, including dietary supplements, relating to folic acid and reduction in risk of neural tube birth defects were not justified.

E. Recent Developments

1. New scientific data

Preliminary data from the Hungarian randomized, controlled trial of efficacy of multivitamin/multimineral supplements containing 0.8 mg (800 µg) of folic acid in preventing occurrence of neural tube defects were presented at a meeting held in May 1992 (Ref. 29). A report of preliminary results of this trial of the effects of multivitamin/multimineral supplementation in women at risk of a first occurrence of a neural tube birth defect pregnancy became publicly available in August, 1992 (Ref. 30). This trial was conducted under the auspices of the Hungarian Optimal Family Planning Program and was directed toward overall improvement in pregnancy outcomes among Hungarian women. Nonpregnant women 18 to 35 years of age without histories of infertility or previous fetal death volunteered for this program and, upon determination of eligibility, were randomized to treatment with a multivitamin/multimineral preparation containing 12 vitamins and 7 minerals or to a placebo containing 3 trace minerals only. The multivitamin/multimineral preparation contained 0.8 mg (800 µg) of folic acid. The women participated in a 3-month preparation for pregnancy and began taking their assigned treatments 1 month before a planned conception. Treatments continued through the third month of pregnancy. Six cases of neural tube defects occurred in the pregnancies of 2,052 women taking the placebo, and no cases occurred in the pregnancies of 2,104 women taking the multivitamin/mineral supplement with folic acid. Based upon the preliminary results of this study, periconceptional use of a multivitamin/multimineral supplement apparently significantly reduced the rate of occurrence of isolated neural tube defects in women in the Hungarian population. However, use of the supplement did not affect the incidences of a wide range of other birth defects that occurred in both treatment groups (Ref. 30).

Results of a case-control study of periconceptional use of folic acid-containing multivitamins and risk of occurrence of neural tube defects in

women in Boston, Philadelphia, and Toronto were also presented at the meeting held in May 1992 (Ref. 29).

In the **Federal Register** of July 1, 1992 (57 FR 29323), CDC announced an open meeting in Atlanta, GA on July 27, 1992, to discuss a recommendation that all women of child-bearing age in the United States consume 0.4 mg (400 µg) of folic acid daily to reduce their risk of having a neural tube defect-complicated pregnancy. The results of the case-control study of periconceptional use of folic acid-containing multivitamins and risk of occurrence of neural tube defects in women in Boston, Philadelphia, and Toronto were presented at this meeting, and the transcript of the meeting is publicy available (Ref. 31). In this study, 436 occurrent neural tube defect cases (live born and still born cases and therapeutic abortuses) were selected from metropolitan hospitals in Boston, Philadelphia, and Toronto (areas of moderate prevalence) from 1988 through 1991 and compared to 2,615 controls with other major malformations as to maternal periconceptional use of folic acid. Daily use of a folic acid-containing vitamin supplement in the periconceptional period was reported by mothers of 8 percent of cases and 13 percent of controls; the adjusted odds ratio was 0.6 (95 percent confidence interval (CI)= 0.4 to 0.8). This represented approximately a 40-percent reduction in prevalence. A dietary folate assessment was also conducted among the mothers who did not use folic acid-containing supplements. A significant decrease in risk was found for the group who consumed 0.311 to 0.391 mg of folate daily; the adjusted odds ratio was 0.6 (95 percent CI=0.3 to 0.9). The results of this study as presented at the CDC meeting support a relationship between decreased risk of occurrent neural tube defects and periconceptional intake of either folic acid-containing multivitamins or dietary intake of folate at levels of 0.3 to 0 4 mg/day.

2. Reopening of comment period

The period for submitting comments in response to the November 27, 1991, proposal closed on February 25, 1992. In the **Federal Register** of July 23, 1992 (57 FR 32751), however, FDA reopened the comment period to permit the submission of new scientific data and information that might become available as a result of the meeting held by the CDC on July 27, 1992, and to provide an opportunity for public comment on that scientific data and information. The agency took this action, in part, because it had been advised that the scientific evidence to be discussed at the CDC meeting was not publicly available. The 1990 amendments require that the evidence relied upon by the agency as the basis for allowing health claims relating to a nutrient-disease relationship be publicly available.

3. PHS recommendation

In *Mortality and Morbidity Weekly Reports* of September 14, 1992 (Ref. 1), the Public Health Service issued a recommendation that:

All women of childbearing age in the United States who are capable of becoming pregnant should consume 0.4 mg of folic acid per day for the purpose of reducing their risk of having a pregnancy affected with spina bifida or other NTDs. Because the effects of high intakes are not well known, but include complicating the diagnosis of vitamin B_{12} deficiency, care should be taken to keep total folate consumption at less than 1 mg per day, except under the supervision of a physician. Women who have had a prior NTD-affected pregnancy are at high risk of having a subsequent affected pregnancy. When these women are planning to become pregnant, they should consult their physicians for advice.
(Ref. 1)

PHS noted that the evidence that consumption of folic acid before conception and during early pregnancy (the periconceptional period) can reduce the number of neural tube defects has been accumulating for several years and includes published data from two randomized controlled intervention trials (Refs. 6, 7, and 18), two nonrandomized intervention trials (Refs. 8, 9, and 33), and four observational studies (Refs. 10 through 13). Based on a synthesis of information from these studies, including those which used multivitamins containing folic acid at a daily dose level greater than 0 4 mg, it was inferred that folic acid alone at levels of 0 4 mg per day will reduce the risk of neural tube defects (Ref. 1).

In the discussion accompanying its recommendation, the PHS (Ref. 1) identified several issues that require further attention:

(1) Effective intake: The PHS (Ref. 1) recommended that all women of childbearing age should consume 0.4 mg of folic acid daily to reduce their risk of neural tube defect pregnancies. The PHS (Ref. 1) noted that because supplements containing folic acid at the 0 4 mg (400 µg) level are widely available, this dosage has been the focus of the available observational research studies. PHS also noted that "it is possible that lower doses of folic acid may reduce the risk of neural tube defects, but further research would be needed to learn the minimum effective dose" (Ref. 1).

(2) Multivitamins: The PHS recommendation for the use of folic acid alone was, by necessity, derived by inference from results of the available studies. The Medical Research Council intervention trial included a group of women who used folic acid at a dose of 4 mg per day (plus calcium and iron) and who could be compared with a control group taking calcium and iron only (Ref. 6). Thus, the specificity of folic acid as an etiologic agent in reducing recurrences by 72 percent was established for the study population at this high dose. In contrast, all four observational studies and two of the other three intervention trials measured the use of folic acid-containing multivitamins. Folic acid content and content of other nutrients in these preparations varied, or in some cases, could not be identified (Ref. 1). The preparations used in studies that obtained this information contained (at least) vitamin A, vitamin D, thiamin, riboflavin, pyridoxine, vitamin C, and niacin in addition to folic acid.

Thus, the possibility that nutrients other than folic acid, particularly at intakes of folic acid less than 4 mg daily, could contribute to the protective effect warrants further discussion.

(3) "Folate-preventable" fraction of neural tube defects in the U.S. population: The PHS recommendation recognized that protective effects against occurrence of neural tube defects found in observational studies of multivitamins containing low doses of folic acid have ranged from none to substantial (Ref. 1). Based on the information available, the PHS suggested that a reasonable estimate of the expected reduction in neural tube defects in women in the general U.S. population was 50 percent (Ref. 1).

This issue warrants further discussion because estimates of the magnitude of the preventable fraction and the variation in risks among subgroups of women of child-bearing age may affect decisions as to the best method of implementation.

(4) Safety considerations: The PHS recommendation advised women that care should be taken that folate consumption not exceed 1 mg (1,000 µg)/day except under the supervision of a physician because the effects of higher intakes are not well known (Ref. 1). One of the adverse effects noted was the effect of high intakes on the making a diagnosis of vitamin B_{12} deficiency.

The agency recognizes the risk that increased intakes of folic acid will complicate the diagnosis of the anemia of vitamin B_{12} deficiency and thereby allow the neurological damage caused by this vitamin deficiency to progress

untreated. Several other safety considerations are identified below These issues also warrant further discussion as the questions of whether and how to provide for a health claim are evaluated.

II. Comments on the Proposed Rule

A Introduction

The agency received approximately 150 comments in response to its proposed decision on health claims for folic acid and neural tube defects. Comments were received from: Consumers, consumer advocacy groups, national professional organizations of nutrition educators, national professional organizations of dietitians, organizations of Federal, state, and local regulatory officials, state and territorial public health nutrition directors, manufacturers and suppliers of vitamins to the conventional food industry and dietary supplement industry, trade associations of nutritional supplement manufacturers, practicing physicians and dietitians, and a foreign government A number of comments were received that were more appropriately answered in other dockets, and these were forwarded to the appropriate docket for response.

FDA has considered all of the comments on folic acid and neural tube defects that it received The agency reviewed all of the documents, including letters, press releases, scientific articles and data supporting those articles, review articles, and recommendations that were included in the comments A summary of the comments that the agency received and the agency's responses follow:

B Comments

1 Several comments suggested that health claims should be allowed if potential benefits exceed risks, and that FDA should have used a risk/benefit analysis in determining the validity of health claims Other comments stated that supplementation with folic acid is essentially risk-free

FDA disagrees with this comment. Section 403(r)(3)(B)(i) of the act requires that a decision to authorize a health claim be based on the totality of the publicly available scientific evidence and on significant agreement among experts qualified by training and experience to evaluate such evidence that the evidence supports a claim The concept of "no risk" as a justification for a health claim is inconsistent with the requirements of the 1990 amendments. Moreover, there are safety concerns associated with increased intakes of folic acid. These concerns are discussed below.

2. Several comments asked whether studies must be carried out in the United States for health claims. These comments noted that for the calcium/osteoporosis claim, much of the data related to peak bone mass was derived from studies in rural Yugoslavia and found to be "generalizable" to the U.S. population, but for folic acid and neural tube defects, data from non-U.S. populations studies seemed not to be acceptable to FDA. The comment also stated that in rejecting the folic acid/neural tube defect claim, FDA relied heavily on the argument that much of the data was from non-U.S. studies.

In the proposed rule on general requirements for health claims (56 FR 60610 at 60549), FDA stated that consistent results from different types of well-conducted human studies, by different investigators, in different populations would contribute to the totality of scientific evidence from which a valid health claim may be developed. In its November 27, 1991, proposal on folic acid and neural tube defects (56 FR 60610), FDA stated that it was unable to directly apply results from some studies done outside of the United States because these studies were conducted on populations at significantly higher risk than the U.S. population, they lacked adequate control groups, or they were multiply confounded.

FDA participated in the development of the recently published PHS recommendation (Ref. 1). This recommendation relied heavily upon data from other countries and was developed by combining the results from several types of studies carried out in the United Kingdom, Hungary, Cuba, Western Australia, and the United States. Thus, the folic acid rulemaking does not evidence an unwillingness on the part of FDA to consider studies on non-U.S. populations. However, the characteristics of the population at issue may affect the relevance of the study to the FDA's rulemaking.

3. Comments received from state and national professional organizations, an organization of Federal, state, and local regulatory officials, and U.S. state attorneys general were supportive of FDA's proposed rule denying a health claim for folic acid and neural tube defects. One comment stated that the preponderance of scientific literature does not strongly support such a relationship. Another comment recommended that statements regarding the relationship between folic acid and neural tube defects be postponed until further studies have been completed. One comment stated that when the confounding variables relating to the causation of neural tube defects are also considered, the wholesale claim that folic acid supplementation will reduce neural tube defects becomes even more unfounded. Another comment cited the irreversible neurological damage that can result from excess intake of folic acid by persons with undiagnosed pernicious anemia and noted that maternal hyperthermia (for example, from use of hot tubs during the first month following conception) was a recognized risk factor for neural tube defects.

Several comments stated that FDA should allow a health claim that "Folic acid intakes, at about the U.S. RDA level of 400 μg/day, have been associated with significantly lowered risk of severe birth defects, including spina bifida." A consumer advocacy group recommended that a claim for folic acid and neural tube defects be permitted only on supplements containing free folic acid because there is evidence that neural tube defects will be reduced by such supplements. The comment noted further that there is additional evidence that the incidence of neural tube defects may be reduced by food sources of folate, although there is currently no consensus on this point.

These comments raise several important issues. The agency agrees that neural tube defects are multifactorial in nature. A history of neural tube defects is the single greatest risk factor currently recognized. However, the well-conducted Medical Research Council trial (Ref. 6) demonstrated a specific relationship between intake of high doses of folic acid and reduction in risk of recurrence of some neural tube defects in women at increased risk of this complication because of a prior affected pregnancy. The effect of lower doses of folic acid on neural tube defects is less clear. However, based upon a synthesis of information from several studies (including a major study that became available after FDA published its proposal in November, 1991) (Ref. 31), all of which recorded use of multivitamins containing varying levels of folic acid, PHS has recommended that all women of childbearing age consume 0.4 mg (400 μg) of folic acid per day for the purpose of reducing their risk of neural tube defect-complicated pregnancy (Ref. 1).

With regard to the issue of effectiveness of nonsupplement food sources of folate in reducing the incidence of neural tube defects, the agency notes that the vast majority of women do not experience an occurrence of a pregnancy complicated by a neural

tube defect, and the available evidence does not provide clear evidence of the optimum folate intake to prevent this complication. Although the lowest effective dose is not known, the PHS concluded that 0.4 mg (400 µg)/day is an effective dose Dietary folate insufficiency per se does not seem to be causative in neural tube defects. The vast majority of women appear not to be predisposed to have a folate-related neural tube defect pregnancy. Data from the observational study of Milunsky et al., 1989 (Ref. 13) suggested that women whose diets contained more than 100 µg of folic acid had a lower risk of a neural tube defect pregnancy than did women whose diets contained less than 100 µg folate per day. Laurence (1983) (Ref. 32) observed that when dietary counseling to improve overall diets was provided to women at risk of a recurrence of a neural tube defect, and when such improved diets were consumed, risk reduction approached 50 percent. Similarly, a case-control study conducted in Western Australia suggested that diets containing increased amounts of folic acid, vitamin C, beta-carotene, and fiber (nutrients associated with fruits and vegetables), were protective against occurrence of neural tube defects (Ref. 11). Therefore, the agency believes, that with respect to options for implementation, the scientific data provide a basis for further discussion of the appropriate intake and source.

4. Several comments stated that FDA, in developing its proposed rule regarding folic acid and neural tube defects, rejected conclusions of the LSRO report (Ref. 33). Several comments quoted from conclusions of the LSRO report to support a health claim and stated that the conclusions of the LSRO report contributed to the significant scientific agreement that existed regarding the validity of a health claim respecting folic acid and neural tube defects.

The agency contracted with the Life Sciences Research Office of the Federation of American Societies for Experimental Biology (LSRO/FASEB; FDA Contract No. 223–88–2124, Task Order No. 9) to independently evaluate the scientific literature respecting folic acid and neural tube defects. At the time of publication of FDA's proposal in November, 1991, FDA had available a draft copy of the LSRO report "Evaluation of Publicly Available Scientific Evidence Regarding Certain Nutrient-Disease Relationships: 1. Folic Acid and Neural Tube Defects" (Ref. 33). In its proposal (56 FR 60610), FDA noted several concerns with the LSRO report, including its failure to focus on the specific relationship of folic acid to neural tube defects in studies where multiple nutrients were given, or where specific nutrient effects could not be isolated; its failure to differentiate between risk of occurrence and risk of recurrence of neural tube defects; and its failure to differentiate between daily doses of 4 mg (4,000 µg) versus 400 µg in terms of effectiveness in reducing the risk of neural tube defects.

LSRO/FASEB submitted its final report as a comment in February 1992 (Ref. 34). The agency's concerns with the draft report were not addressed in the final LSRO report. Therefore, because the final LSRO/FASEB report did not differ from the draft report available to the agency before publication of its proposal, no change in FDA's tentative conclusion is warranted.

The agency notes, however, that there are significant areas in which the agency's proposed rule and the LSRO/FASEB report (Refs. 33 and 34) are in agreement. For example, the agency is in agreement with the report on the following topics: (1) That 4 mg of folic acid has been demonstrated to have a protective effect against development of neural tube defects, (2) that there is no evidence that the effect of folic acid is long-lasting as a protectant or potential protectant against neural tube defects, (3) that in addition to maternal and fetal nutrition, other individual, dietary, nutrition, and health factors also contribute to the risk of neural tube defects, (4) that there are significant gaps in our knowledge of the etiology of neural tube defects and of how folic acid either alone or in conjunction with other vitamins may protect against neural tube defects, and (5) that it is currently unknown whether neural tube defects are caused by a gene-dependent or drug-induced vitamin dependency requiring a higher than physiological intake of folic acid or other micronutrient.

5. Several comments stated that following publication of the results of the Medical Research Council's trial in July 1991 (Ref. 6), significant scientific agreement emerged concerning the importance of folic acid for the prevention of neural tube birth defects.

FDA agrees that the Medical Research Council's randomized double-blind multicenter trial (Ref. 6) clearly found a significant reduction in recurrence rate of neural tube defects in women supplemented periconceptionally with 4 mg folic acid/day. No protective effects of vitamins other than folic acid were observed. The Medical Research Council's study established a specific role for folic acid in reduction in risk of recurrence in a significant proportion of women at high risk of this complication because of a history of neural tube defect pregnancies. This study did not investigate the efficacy of doses of folic acid lower than 4 mg (4,000 µg) per day. Based on a synthesis of available studies, however, including preliminary results of the Hungarian intervention trial, the PHS has inferred that a lower intake of folic acid will reduce the risk of occurrence of neural tube defects. However, a number of concerns have arisen with respect to the effects of a folic acid health claim that must be resolved before such a claim can be authorized.

6. A number of comments identified options for implementing a health claim, suggested means by which the folate status of the population can be improved, recommended daily doses of folic acid lower than 400 µg, identified safety concerns, or expressed concerns about the current food additive regulation on folic acid. Because these comments largely address the issues raised as needing resolution in the discussion accompanying the PHS recommendation (Ref. 1), FDA believes that it is useful to summarize these comments. However, given the ongoing nature of this rulemaking process, responses to these comments are not possible now but are likely to emerge as the process proceeds.

1. Proposed criteria for health claims and use of the food additive regulation

Several comments stated that the agency should establish criteria for foods or supplements making folic acid claims and proposed such criteria. For example, a comment suggested that requiring foods and supplements to contain more than 20 percent of the reference daily intake would be inappropriate because the widespread fortification of foods might lead to excessive folacin intakes. The comment further suggested that the agency monitor folacin intakes closely after health claims for folic acid appear in the marketplace to determine whether the public is ingesting levels that greatly exceed or fall short of the recommended daily intake of 400 µg. The comment recommended that if the agency found that excess intakes of folic acid posed a risk, it could restrict either the number of foods or supplements to which the vitamin could be added or the maximum levels allowed in foods or supplements, according to the food additive regulation for folic acid. Alternatively, the comment suggested that FDA could lower the minimum folic acid content of foods or

supplements that are allowed to make health claims

FDA intends to review the question of the appropriate level of folic acid in food However, the agency notes that the nature of the rulemaking process, particularly the formal rulemaking process applicable to food additives, does not provide the flexibility or responsiveness envisioned by the comment

Another comment stated that the agency should require full and nondeceptive health claims concerning neural tube defects and folic acid so that consumers are not misled into believing that folic acid might prevent all neural tube defects or reduce the risk of nonneural tube defect birth defects. The comment emphasized that the agency should ensure that claims on folic acid-containing supplements provide full and nondeceptive information. The comment stated that a nondeceptive claim would state that: (a) Folic acid reduces the risk of only neural tube birth defects; (b) scientists estimate that folic acid intakes may prevent only half of neural tube defects; (c) consuming more than 400 µg (0.4 mg) of folic acid daily will not necessarily provide additional protection against birth defects; and (d) scientists have not fully evaluated the safety of doses higher than 800 µg (0 8 mg).

The act requires that claims on foods must be truthful and not misleading. The failure to disclose material facts would render a claim misleading under section 403(a) of the act. The agency agrees that, based on the results of the Medical Research Council trial (Ref. 6), the association between folic acid intake and birth defects is specifically related to neural tube defects. This trial also found that folic acid, while significantly reducing the risk of neural tube defects in women at high risk of recurrence of this complication, did not significantly alter the incidences of a wide variety of other birth defects in the population studied. Therefore, in deciding whether to authorize a health claim, the agency will consider whether such a claim should specifically state that the only types of birth defects for which an association with folic acid has been identified are neural tube defects, such as anencephaly, spina bifida, and anencephalocoele.

2. Effective intake

One comment stated that better information on the lowest effective level of folic acid is desirable in order to provide as strong a basis as possible for a food fortification program. Another comment noted that the available data suggest that the recommended level of 400 µg of folic acid/day is probably considerably higher than is actually needed to achieve protection. Several comments suggested that a daily dose of 0.2 mg folate (200 µg) was probably adequate for reduction in risk of neural tube defects, and that data from older as well as more recent studies support such a conclusion. Several comments stated that the consideration of efficacy of lower doses is important because there are uncertainties as to whether daily supplements of folic acid plus iron can reduce zinc absorption and result in intrauterine growth retardation in pregnant women.

The question of effective intake was highlighted by PHS This issue was addressed by the advisory committee that FDA convened. Although PHS acknowledged that there may be a lower dose that is effective, it concluded that all women who could become pregnant should ingest 0.4 mg of folic acid daily to reduce their risk of having a pregnancy affected with a neural tube defect (Ref. 1).

3. Specific safety issues

Another comment observed that widespread fortification of the food supply could result from authorization of a health claim as products added folate in order to claim that they were useful in reducing the risk of neural tube defects. The comment noted that following such fortification, the usual intake of folic acid by the U.S. population would rise from about 250 µg/day/person to about 3 to 4 mg (3,000 to 4,000 µg)/day/person, and that the safety of such an outcome is by no means clear. The comment identified large segments of the population with low vitamin B_{12} status and mentioned the potential for development of neurological deficits in such persons as a result of a food supply highly fortified with folic acid. The comment urged the agency to delay action until a full public airing permits a review of all of the implications of each approach to policy in this and related areas. One comment stated that the proposed intake of 0.4 mg (400 µg) should be evaluated in subjects with low zinc status because findings from the United States, Sweden, and Britain suggest that low zinc status is much more common in pregnancy than has been previously suspected, and that zinc deficiency is a known cause of neural tube defects in animal model systems. The comment cited several references that reported that folate can interfere with the utilization of dietary zinc.

These issues were considered by the advisory committee that FDA convened and by the agency in reaching a final decision in this matter

4. Options for implementation

One comment noted that while the quickest and easiest approach to increasing the folate intake of women of reproductive age is to encourage the consumption of folic acid supplements, compliance with such a program would be poor. The comment noted that many adolescent women refuse to use birth control even when provided free of charge and choose not to protect themselves against life-threatening diseases, such as acquired immunodeficiency syndrome (AIDS). Several comments observed that because of the higher rates of neural tube defects among women from lower socioeconomic status groups, alternatives to a "one-a-day" pill method of implementation should be considered. Several comments recommended that fortification of a staple food would likely reach greater numbers of women than would programs utilizing the pill approach. One comment stated that food fortification would require careful documentation of population distributions of consumption of the designated foodstuffs by age, gender, and socioeconomic status. Several comments also included references dealing with the folate status of specific subgroups of the U.S. population and suggested that fortification of staple foods in the food supply would be an appropriate method of improving folate status. The comment noted groups within the population identified in surveys or in clinical studies as at potential risk of folate deficiency include children, adolescents, adults (including pregnant women), and the elderly who could also benefit from folate fortification. Comments also identified other segments of the population at risk of low folate status as those who use alcohol, oral contraceptives, antifolates, and specific nonsteroidal anti-inflammatory drugs.

Again, the comments parallel concerns that were raised by PHS. They will be fully addressed by the agency in deciding, if a health claim is authorized, what is the most effective method of presenting the claim to the U.S. public.

III. Review of the Recent Scientific Literature

In addition to its evaluation of all comments received in response to its proposed rule regarding folic acid and neural tube defects, FDA, using the same criteria identified in the proposal (56 FR 60610 at 60614), also reviewed the scientific literature, including

human studies and studies in animal model systems, that has become publicly available since publication of its proposed rule relative to the relationship between folic acid and neural tube defects.

A. Human Studies

1. Laurence (1991) (Ref. 35) reported the results of an uncontrolled folic acid supplementation trial in women who had a previous pregnancy complicated by a neural tube defect. Women in Cardiff, United Kingdom, at recurrent risk of a neural tube defect pregnancy and who declined to participate in the Medical Research Council trial (Ref. 6) were advised to take a supplement containing 4 mg folic acid and minerals for not less than 1 month before conception and continuing until 12 weeks of gestation. Laurence (1991) (Ref. 35) reported that there were two (2) recurrences of neural tube defects among 234 pregnancies (recurrence risk of 8.5 per 1,000) in the supplemented women. The estimated risk for recurrence among untreated women (none were included in the trial) was about 30 per 1,000. Laurence (1991) (Ref. 35) estimated that the folic acid plus minerals supplementation reduced the risk of recurrence of neural tube defects by more than two-thirds. The author noted that although this was an uncontrolled trial, folic acid should be offered to all high risk women planning further pregnancies.

2. Measurement of maternal or fetal blood levels of specific vitamins is one method used to test the hypothesis that folic acid status is directly related to risk of neural tube defects. Several investigations have tested this hypothesis by determining whether occurrence of neural tube defects is associated with decreased maternal levels of vitamins (Refs. 14 through 17). A recently reported study, Holzgreve et al. (1991) (Ref. 36), found no differences in serum and erythrocyte folate in blood samples from fetuses with neural tube defects (n=17) or fetuses without such defects (n=45). Samples were obtained at 16 to 22 weeks of gestational age. The folate level of women pregnant with a neural tube defect-affected fetus was normal, and nutritional status did not differ between the two groups. The authors noted that their findings of no correlation between neural tube defects and fetal blood folate values do not necessarily contradict the Medical Research Council study (Ref. 6) but show that an easy explanation for the protective effect of folate observed in the British study cannot as yet be provided. The authors also stated that further research is needed to define the role of micronutrients in the development of neural tube defects.

3. The results of the Medical Research Council trial (Ref. 15) demonstrated that women at very high risk of having a recurrence of a neural tube defect-complicated pregnancy could significantly reduce their risk by taking a high level of folic acid periconceptionally. Other investigators have attempted to determine how these results might apply to a general population of women at much lower risk of occurrence of neural tube defects. Mills et al. (1992) (Ref. 37) measured levels of folate, vitamin B_{12}, and retinol in maternal serum samples drawn early in 89 pregnancies resulting in neural tube defect offspring and in 178 control pregnancies. Samples were obtained within 8 weeks of neural tube closure. The results of this population-based study in Finland, a low prevalence area for neural tube defects, demonstrated no relationship between maternal serum folate, vitamin B_{12}, and retinol during pregnancy and the risk of neural tube defects.

B. Animal Studies

Studies with animal model systems are one of several lines of evidence that are used to establish associations between various nutrients or toxicants and birth defects. The relationship between folate deficiency and the incidence of neural tube defects in experimental animal model systems is not clear. A variety of protocols have been used to study the relationship between nutritional status and risk of neural tube defects (56 FR 60610). The anticonvulsant drug valproic acid is suspected of causing neural tube defects in humans. The mechanism for such effects is unknown but has been postulated to involve induction of a deficiency of folic acid. Hansen and Grafton (1991) (Ref. 38) examined this possibility by culturing rat embryos concurrently in valproic acid and folinic acid, a folic acid derivative. The authors reported a dose-related increase in the number of open neural tubes in rat embryos cultured in valproic acid. When various concentrations of folinic acid were added in combination with a teratogenic dose of valproic acid, there was no decrease in the incidence of open neural tubes. The results of this study suggested that valproic acid-induced open neural tubes in this experimental animal model system are not the result of a deficiency of folic acid.

However, Wegner and Nau (1991) (Ref. 39) also studied the protective effects of folinic acid against valproic acid-induced neural tube defects in the mouse and reported a different result. These authors observed significant diurnal variations in folate metabolism in mouse embryos between days 8.5 and 9.5 of gestation. They measured significant time dependent protective effects against valproic acid-induced teratogenesis such that folinic acid reduced neural tube defects when provided at one time period but not when provided at another time period. Such findings indicate the extreme sensitivity of developing embryonic tissue to external factors and are of importance in considering interactions of drugs with folate metabolism as a possible mechanism of teratogenesis (Ref. 39).

Other investigations have sought to determine whether mice deficient only in folic acid produce embryos with neural tube defects. For example, Heid et al., 1992 (Ref. 40) used folate-free amino acid-based diets for producing well-defined dietary concentrations of folic acid for rats and mice. Heid et al (Ref. 40) reported that when Swiss-Webster mice were fed inadequate dietary folic acid, fewer and smaller embryos (that developed normally) were produced during pregnancy. Their studies indicated that folate deficiency alone is insufficient to produce neural tube defects in Swiss-Webster mice.

C. Authoritative Statements

1. Institute of Medicine, National Academy of Sciences

In 1990, the Institute of Medicine of the National Academy of Sciences published its report, "Nutrition During Pregnancy" (Ref. 28). The Institute of Medicine updated this report in 1992 (Refs. 41 and 42) to reflect new data (primarily the results of the Medical Research Council trial; Ref. 6) that had become available since the first publication of the report. Data from the Hungarian randomized intervention trial were not publicly available at the time the report was updated. The report noted that a previous history of a neural tube defect should alert health care providers to the need for preventive measures before a subsequent pregnancy. The report recommended that women with a history of neural tube defect-complicated pregnancy follow the CDC recommendations (Refs. 41 and 42) for high-dose folic acid supplementation (preconceptionally and throughout the first trimester, under a physician's supervision) to reduce their risk of recurrent neural tube defects (Refs. 41 and 42). The report noted that questions remain concerning the etiology of neural tube defects, the most appropriate dosage, and the

appropriate role of nutrition in preventing first occurrences.

2. World Health Organization

That there is still considerable uncertainty as to how best to reduce the risk of neural tube defects is shown by information in a recently published "World Health Organization (WHO) Drug Information Bulletin" (Ref. 43). The bulletin notes that an expert advisory committee has now been set up in the United Kingdom to consider how best to ensure that all women likely to become pregnant receive supplementary folic acid (Ref. 44). The WHO Bulletin states "Unfortunately the available data provide no indication of how long supplementation needs to be continued to obtain the maximum effect, or of whether the same protective effect can be obtained with lower doses. These are matters of some importance because it may be impracticable to supply a supplement of 4 mg daily from dietary sources alone. Some empiricism will be required to arrive at a recommendation. Short of conducting a further trial with different dosage regimens, formal demonstration of a dose-effect relationship will remain outstanding" (Ref. 43). FDA notes that data from the Hungarian intervention trial were not publicly available at the time this statement was prepared.

D. Conclusions from the Recent Scientific Literature

The recent scientific literature, including studies in humans and animals, is consistent with PHS recommendation and raises a number of issues that PHS noted as needing resolution.

IV. Actions on Folic Acid

A. Determination That No Claim Can be Authorized at This Time

Section 403(r)(3)(B)(i) of the act states that FDA is to grant a health claim when there is significant scientific agreement that the scientific data relating a nutrient to a disease or health condition supports such a claim. The recent PHS recommendation (Ref. 1) evidences that such agreement exists. However, the Food, Drug and Cosmetic Act must be read as a whole.

Sections 403(r)(3)(A)(ii), 402(a), and 409 of the act express the proposition that the use of a substance in food must be safe. As the PHS recommendation states (Ref. 1), there are significant questions that persist about the use of folic acid in food. Questions raised in the PHS recommendation (see section I.E.3. of this document) include the safety of high intakes by both the target population as well as by other segments of the population who may unintentionally be exposed to high intakes if overfortification of the food supply were to occur as a result of the PHS recommendation. There are, additionally, several other unresolved scientific questions that will require discussion before a claim is authorized.

Based on these concerns, FDA concludes that under section 403(r)(3) of the act, it cannot authorize a health claim on folic acid and neural tube defects. FDA is concerned that the possibility exists that folic acid itself could be a substance that increases the risk of a disease or a health-related condition in persons in the general population (see section 403(r)(3)(A)(ii) of the act). Therefore, FDA concludes that it cannot authorize a health claim on folic acid until the questions regarding the safety of the use of this nutrient as well as the other concerns raised by PHS are satisfactorily resolved. However, the agency is undertaking efforts to address and resolve these concerns. The remainder of this document outlines how the agency will do so.

B. Issues

1. Estimation of range of increased intakes

FDA expects that there would likely be a significant increase in consumption of folic acid by women in their childbearing years, and by the general population, if a health claim were to be authorized because manufacturers would add folic acid to their products in order to claim that these products are useful in reducing the risk of birth defects. Intakes of multiple doses of free folic acid in the form of supplements and from its increased presence in the food supply could rapidly result in intakes of more than 3 mg (3,000 μg)/day by persons in the target population as well as by persons in the general population (see Table, Estimate A). Considerably higher amounts of folic acid (approximately 7 mg (7,000 μg)/day) could be consumed by subgroups of the population (e.g., teen-age and young adult males, heavy users of supplements) (see Table, Estimate B).

a. *Differences in bioavailability between free folic acid and food folates.* It is well-recognized that the bioavailability of free folic acid (the form included in dietary supplements and in fortified foods) is several-fold greater than that of naturally occurring food folates. Estimates of the increased bioavailability ("potency") of free folic acid relative to food folates range from at least 2-fold to 4-fold or greater (Ref. 45). The pronounced differences in bioavailability between free folic acid and food folates must be factored into considerations of appropriate dose as well as considerations of potential safety issues.

b. *History of use.* Because the National Research Council recommended daily allowances have been set below 500 μg of food folates ("folacin") (except those for pregnant women) since 1968 (Refs. 46, 47, and 48), and because the food additive regulation has limited the amount of free folic acid added to fortified foods and supplements to 400 μg/day (except supplements for pregnant or lactating women), there is no history of long-term use by persons in the general U.S. population, including pregnant women, of daily intakes of free folic acid in excess of about 1 mg (1,000 μg). Therefore, potential safety concerns must be addressed.

2. Specific safety issues and estimates of magnitude

If a wide variety of food sources were fortified with 400 μg folic acid/serving, as would likely occur following authorization of a health claim, intakes of folic acid could easily reach 3 mg (3,000μg)/day or higher. FDA's concerns regarding large increases in folic acid fortification, and the large increases in intake that would result, are summarized below.

a. *Vitamin B_{12}*-related issues. (i) Issue: As mentioned above, in the presence of excess folic acid and inadequate vitamin B_{12}, the anemia of vitamin B_{12} deficiency may not develop but severe and irreversible nerve damage may continue. This interaction between the functions of folic acid and vitamin B_{12} has been recognized for many years and is the basis for the precautionary statement on oral and parenteral preparations of folic acid for therapeutic use in treating folate-deficiency anemias. The agency is reviewing the literature upon which this concern is based.

In 1945, folic acid was introduced as a possibly specific substance for the treatment of pernicious anemia. A large number of reports based on small numbers of cases studied for short periods of time followed the introduction of this new therapy (Ref. 49). It was soon recognized that the two manifestations of pernicious anemia (the hematologic disturbances and the neurologic disturbances) responded differently to therapy with folic acid. Reports began to appear in the literature calling attention to the deleterious and sometimes "explosively" harmful effects of folic acid on the neurologic

manifestations of the disease (Refs. 50 through 53).

There is ample evidence that most patients with pernicious anemia respond hematologically to folic acid (Refs. 54 through 59). Doses of 1 to 5 mg folic acid can reverse the hematologic abnormalities of the deficiency (Refs. 60 through 64). Hematologic improvement in pernicious anemia has also been noted at doses of folic acid lower than 1 mg (e.g., 200 to 500 µg) (Refs. 58, 59, 65 through 67, and 100), but the responses have been less predictable than those to doses of 1 to 5 mg. For example, Chosy et al. (1962) (Ref. 66) reported that daily injections of 400 µg of folic acid caused hematologic responses in some patients with pernicious anemia. Some investigators have not been convinced that amounts of folic acid within the range of 200 to 500 µg/day would mask pernicious anemia (Refs. 65, 68, and 101), while others have reported suboptimal responses to 500 µg of folic acid in patients with pernicious anemia (Refs. 58 and 59).

On the basis of the degree of reticulocyte response, 200 µg folic acid has been used to differentiate between the megaloblastic anemias caused by folate deficiency and vitamin B_{12} deficiency (Ref. 69). Chanarin (1969) (Ref. 69) cautioned that this use should not be interpreted to mean that long-term administration of 200 µg of folic acid could not mask pernicious anemia in some otherwise untreated patients. Herbert (1975) (Ref. 70) and Herbert et al. (1980) (Ref. 71) recommended that 100 µg folic acid be administered orally in therapeutic trials. This dosage has been shown to provide a maximal hematologic response in patients with folate deficiency but not in those with vitamin B_{12} deficiency (Ref. 72). This finding is in agreement with the statement of Chanarin (1969) (Ref. 69) that doses of folic acid greater than 200 µg/day might produce hematologic responses in some patients with pernicious anemia.

Pernicious anemia is not an insignificant or rare condition in the United States (see section IV.B.2.a.ii. of this document), nor is its diagnosis always straightforward. For example, Lindenbaum et al. (1990) (Ref. 73) has reported that while serum cobalamin levels have been generally considered to be essentially 100 percent sensitive in the detection of clinical disorders caused by cobalamin deficiency, there is a significant minority of patients with cobalamin deficiency whose serum cobalamin levels are normal. In such individuals, measurements of serum metabolite concentrations of methylmalonic acid and total homocysteine may be necessary to facilitate the diagnosis of vitamin B_{12} deficiency (Ref. 73).

In summary, the available evidence indicates that some patients with pernicious anemia will respond to folate therapy in doses less than 500 µg/day. Other individuals with pernicious anemia will not exhibit hematologic remission at such doses but will respond to doses of 1 mg of folic acid and higher. It is not possible to answer with certainty whether intakes of folic acid in foods approaching 400 µg/day could result in transient hematologic remission in patients with pernicious anemia. The agency believes that this issue warrants further discussion.

(ii) Estimates of magnitude: Vitamin B_{12} deficiency anemias are not uncommon in the U.S. population. Information from the National Center for Health Statistics indicates that there were 740,000 patient visits to physicians' offices with a diagnosis of pernicious anemia during the 2-year interval 1989 to 1990 (Ref. 74). Approximately 524,000 of these visits were by women (Ref. 74). An additional 16,000 patient visits during this interval involved a diagnosis of other vitamin B_{12} deficiencies (for example, those associated with consumption of vegetarian diets).

National Center for Health Statistics records from the National Hospital Discharge survey for 1990 identified 31,000 discharges that included a diagnosis of pernicious anemia and an additional 7,000 discharges that included a diagnosis of other vitamin B_{12} deficiency anemia (Ref. 75).

It is recognized that among African-Americans, particularly African-American women, pernicious anemia is not confined to the elderly, as it generally is among whites (Refs. 76 through 78). Thus, a large subgroup of young African-American women in the general population may be especially vulnerable to adverse effects of significantly increased intakes of folic acid.

Although the number of "visits" recorded in the ambulatory care surveys mentioned above include multiple visits by some patients, the data show that pernicious anemia is not an insignificant or rare condition in the U.S. population. There is currently no way to determine how many persons in the general U.S. population have undiagnosed vitamin B_{12} deficiency. A large number of people have subnormal levels of serum vitamin B_{12} without having any classical manifestations of vitamin B_{12} deficiency (Refs. 79 and 80). Ten to twenty percent of elderly persons, more than 25 percent of demented patients, 15 to 20 percent of AIDS patients, and 15 to 20 percent of patients with malignant diseases have low serum vitamin B_{12} levels. In addition, 5 to 10 percent of all patients, regardless of age or clinical status, are found to have low serum B_{12} levels. Metabolic and subtle neurologic dysfunction are demonstrable in a significant fraction of such cases (Ref. 79). Very little is known about whether folate supplementation has any effect on such persons, who are more numerous in the population than are patients with pernicious anemia (Ref. 79). This issue requires consideration in assessing the potential impact of increased intakes of folic acid.

b. *Risks to pregnant women.* In "Nutrition During Pregnancy," the Institute of Medicine (IOM) stated that the safety of large doses of folic acid during pregnancy has not been systematically determined (Ref. 28). The IOM noted that large doses of folic acid may inhibit the absorption of other nutrients by competitive interaction and can also obscure the diagnosis of onset or relapse of pernicious anemia which is extremely rare in women of childbearing age. The IOM recommended modest supplementation for some segments of the U.S. population at risk of folate inadequacy. Such subpopulations include some pregnant women who lack the knowledge or financial resources to purchase adequate food, abusers of alcohol, cigarettes, or drugs, those with malabsorption syndromes, pregnant adolescents, and women bearing more than one fetus. Based upon data available at the time, the IOM recommended 300 µg folate daily during pregnancy for such subpopulations (Ref. 28).

(i) Issue. A potential risk of increased folic acid supplementation involves effects of high blood levels of free folic acid on the embryo during early gestation. The Medical Research Council study that treated women at high risk of a recurrence of a neural tube defect pregnancy with 4 mg folic acid daily did not have the power to ascertain the safety of such high level supplementation in the population studied. This concern was stated by the study's author (Ref. 6). The agency noted above that there is no history of long-term use in the United States of folic acid at levels at or above about 1 mg/day.

(ii) Estimate of magnitude. About 4 million pregnancies occur in the United States each year. The concern regarding the lack of safety data for high doses of folic acid in pregnant women has been

discussed in the scientific literature since the report of the successful Medical Research Council trial (Ref. 6). For example, Leeming et al. (1991) (Ref. 81) stated that while 4 mg of folic acid until 12 weeks of pregnancy may reduce the incidence of neural tube defects in women at high risk of recurrence, there may also be damaging effects. These authors suggested that substantial amounts of unmetabolized folic acid appear in the plasma after a single high dose and suggested that high circulating levels of folic acid may damage developing neural tissue during early embryonic development. They further noted that high levels of folic acid are not normally found in the circulation. Scott et al. (1991) (Ref. 82) also suggested the seriousness of risk during early embryonic development. They stated that while the fully developed brain may be protected from neurotoxic effects of high circulating levels of folic acid, no information is available as to whether developing neural tissue is similarly protected.

c. *Persons with epilepsy* (i) Issue. The possibility has been raised that folic acid supplements in high doses may reverse the effectiveness of anticonvulsant medication (Ref. 83). Folic acid and certain anticonvulsants compete with each other for receptors on brain cells. A potential concern is whether high intakes of folic acid exacerbate seizures in persons with uncontrolled or with drug-controlled epilepsy.

(ii) Estimates of magnitude. There are an estimated 200,000 persons in the United States whose epilepsy is not controlled. Most studies on the effects of folic acid in persons with drug controlled epilepsy have involved institutionalized individuals and responses to increased intakes have been variable.

d. *Persons taking drugs that interfere with folate metabolism.* (i) Issue. Folate antagonists such as Methotrexate are used in the treatment of various cancers, including leukemias (Ref. 84). In addition, low doses of Methotrexate are currently used in the treatment of psoriasis, rheumatoid arthritis, and bronchial asthma. The antifolate Trimethoprim is used to treat bacterial infections. Other therapeutic drugs that interfere with folate metabolism include: Pyrimethamine, Triamterene, sulfasalazine, colchicine, phenyltoin, and Trimetrexate (Ref. 84). Recognition of the therapeutic usefulness of these antifolate drugs for the conditions above has developed during the last 30 years.

(ii) Estimates of magnitude. The drugs mentioned above are used in the treatment of: Psoriasis, rheumatoid arthritis, bronchial asthma, malaria, hypertension, Crohn's disease, gout, epilepsy, and AIDS. Taken together, many of these conditions affect significant portions of the general U.S. population.

The safety of significantly increased folate intakes by persons with these disorders, whether or not they are receiving antifolate medications, remains an open question (Ref. 85). The safety or toxicity of oral folic acid supplements in persons who are being treated with drugs known to interfere with folate metabolism requires further discussion.

It is not known whether substantially increased intakes of folic acid would impair (or reverse) the therapeutic effectiveness of these medications. It is known, for example, that "rescue" by 5-formyl-tetrahydrofolate (a biologically active reduced folate derivative that can compete with antifolate compounds and does not require the activity of the enzyme dihydrofolate reductase for conversion to an active form) is used in patients undergoing chemotherapy with the antifolate Methotrexate. Treatment with 5-formyl-tetrahydrofolate is used to reduce the toxicity of Methotrexate and to protect nonmalignant cells (for example, those in the intestinal tract) from damage by the chemotherapeutic agent.

3. Identifying and targeting the population at risk

a. *The target population.* Given the absence of biological markers to identify women at greatest risk of a neural tube defect pregnancy, a very large population of women must be reached in attempts to reduce the risk of neural tube defects. There are about 70 million women of reproductive age in the United States, of whom about 2,500 annually will have a pregnancy complicated by a neural tube birth defect. As noted above, this number is an underestimate of the number of neural tube defect pregnancies that occur. The safety issues show the importance of the method of implementation chosen to reach the target population. Fortification of the food supply, for example, would expose more than 250 million people to increased folic acid intakes to reach the approximately 4 million women who become pregnant each year. Use of supplements, while potentially capable of targeting some of the population at risk, would not likely reach those of lower socioeconomic status or noncompliers who might also be at increased risk.

b. *Estimation of the "folic acid-preventable" fraction of neural tube defects.* The folic acid-protective effects against risk of neural tube defects found in studies of folic acid at levels lower than 1 mg/day have ranged from none to substantial (Ref. 1). In general, observational studies in areas of moderate prevalence (2–5 neural tube defects/1,000 births) have found protective effects, while a study in two areas of lower prevalence (less than 1 neural tube defect/1,000 births) found no protective effect. While such considerations should not negate an appropriate recommendation for women of child-bearing age, the magnitude of the preventable fraction may influence decisions on how best to implement the PHS recommendation and thus whether and how to provide for a health claim.

4. How does the available information on effective levels of intake affect options for implementation

The neural tube forms and closes during the first month after conception before most women are aware of their pregnancy. For this reason, and since more than half of the pregnancies in the United States are unplanned (Ref. 119), the PHS recommendation stated that it would be prudent for women to consume 0.4 mg of folic acid daily on a regular, continuous basis as long as they are capable of becoming pregnant (Ref. 1).

In the supplementary information accompanying its recommendation, the PHS noted that it is possible that lower intakes of folic acid may reduce the risk of neural tube defects, but that further research would be needed to learn the minimum effective level (Ref. 1). This issue is of importance not only because supplement doses lower than 0.4 mg (400 μg) have not been studied adequately, but because of the unknown contribution of dietary intake to the results reported in the available studies. Most of the studies of supplement use have not evaluated folate intake from foods. Thus, the base of dietary folate intake to which a folic acid-containing supplement was added is unknown. This complicates assessment of intake-response relationships.

Consideration of the minimum effective level of intake is also relevant because of the need for women to maintain good folate nutriture at least 1 month before conception and through the first 6 weeks of pregnancy. Given this fact and the high rate of unplanned pregnancies in the United States, women potentially must consume an effective amount of folic acid during all or most of their child-bearing years. This represents 30 years or more of chronic exposure for the target population. If the minimum effective

level is added to the conventional food supply, it represents a lifetime of exposure for the entire population.

The best available studies used daily intakes of folic acid of 0.8 mg (800 µg) or 4 mg (4,000 µg). These levels are outside of the range of folate provided by usual U.S. diets (100 to 500 µg/day). For example, the well-conducted Medical Research Council trial demonstrated that 4 mg of folic acid daily during the periconceptional period was effective in women at high risk of a recurrence of a neural tube defect-affected pregnancy (Ref. 6). Preliminary data from the recently closed Hungarian trial in women at risk of occurrence of a neural tube defect pregnancy showed that periconceptional use of 800 µg folic acid in a multivitamin/multimineral preparation significantly reduced these defects (Ref. 30). Under current regulations, products with these dosages are drugs.

Based on a synthesis of information from several studies, including those that recorded use of multivitamins containing folic acid at varying doses, the PHS inferred that folic acid at levels of 0.4 mg per day will reduce the risk of neural tube defects (Ref. 1). This level is currently regulated as a food.

Whether other vitamins have an impact on the effect of folic acid when taken at low doses is not known. For example, Smithells et al. (Ref. 8) used 360 µg folic acid with other vitamins, and the Hungarian study (Refs. 27 and 30) used a dose of 800 µg folic acid with other vitamins. The study of Milunsky et al. (1989) (Ref. 13) examined folic acid as a component of multivitamins, and Mulinare et al. (1988) (Ref. 12) studied vitamin use but there was no documentation of folic acid use. All preparations associated with reductions in risk of neural tube defects, with the exception of preparations used in the Medical Research Council trial, contained (at least) vitamin A, vitamin D, thiamin, riboflavin, pyridoxine, vitamin C, and niacin in addition to folic acid. The results of Mills et al. (1989) (Ref. 10) showed no effect of folic acid from multivitamins or fortified cereals at a level of 400 µg. Information from a recent case-control study in Boston, Philadelphia, and Toronto suggested that a daily intake of 300 to 400 µg/day of folates from conventional foods offered significant protection from risk of neural tube defects (Ref. 31). The interrelation between several vitamins and folic acid may be explored by the advisory committee.

The difficulties in identifying a minimal potentially protective intake of folic acid are related in part to observations that poor folic acid status per se is not directly related to neural tube defects (that is, a dietary insufficiency of folic acid has not been consistently associated with increased risk of neural tube defects or predictive of women who would be most likely to benefit from folic acid supplementation). Neural tube birth defects are not among adverse pregnancy outcomes that have been associated with clinical folate deficiency in humans. Inconsistent results have been obtained in clinical studies carried out to determine if mild to moderate folate deficiency is associated with adverse pregnancy outcomes (Ref. 28).

For example, Yates et al. (1987) (Ref. 16) reported that although erythrocyte folate levels were lower in women who had several infants with neural tube defects, there was no association between erythrocyte folate levels and dietary folate intake. Thus, the risk for recurrence of a neural tube defect pregnancy could not be attributed to lower dietary folate intakes by mothers of affected infants (Ref. 16). Mills et al. (1992) (Ref. 37) recently measured levels of folate, vitamin B_{12}, and retinol in maternal serum samples drawn early in 89 pregnancies resulting in neural tube defect offspring and in 178 control pregnancies. Samples were obtained within 8 weeks of neural tube closure. The results of this population-based study in Finland, a low prevalence area for neural tube defects, demonstrated no relationship between maternal serum folate, vitamin B_{12}, and retinol during pregnancy and the risk of neural tube defects.

Nutrition during early pregnancy is critical for normal embryonic development. Human intervention and observational studies have focused on the periconceptional interval as a time when maternal nutritional status is particularly important, and when intervention may be of greatest value. In human embryogenesis, the neural tube forms and closes within the first month of pregnancy, often before a women realizes that she is pregnant.

5. Options for implementation

The supplementary information accompanying the PHS recommendation stated that there are three potential approaches for the delivery of folic acid to the general population in the dosage recommended. These include: (1) Improvement of dietary habits, (2) fortification of the U.S. food supply, and (3) use of dietary supplements. Each option has certain advantages and disadvantages. A careful review of these options is warranted as the agency works toward deciding whether and how to authorize a health claim.

V. Role of the Advisory Committee

Given the significance of neural tube defects and the recommendation of the PHS, FDA convened an advisory committee to help resolve the outstanding concerns on the effects of food claims describing the effects of folic acid intake on neural tube defects. The process that the agency has instituted and the concerns that need to be addressed and resolved are described below.

In addition to convening the advisory committee, the agency will conduct an indepth analysis of consumption patterns for specific foods across all age groups and both genders. The agency will consider various possibilities for fortification of foods, and such analysis will facilitate a determination of the effects of fortification of specific foods on overall intake in selected groups in the population.

The advisory committee heard testimony from experts as well as from other interested parties and provided recommendations to the agency on four broad issues:

(1) What is the target population that needs to be reached regarding the effects of folic acid on neural tube defects?

(2) How does the available information on the effective level of intake affect options for implemenation?

(3) What are the safety concerns for persons in the target population and in the general population?

(4) If a claim is to be authorized, what is the most appropriate method for presenting it to the target population?

An announcement of the meeting of the advisory committee and an opportunity to participate was provided in a **Federal Register** notice (57 FR 52781, November 5, 1992). The agency is reviewing the recommendations provided by the advisory committee.

VI. Impact Statements

A. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was

published in the **Federal Register** of November 27, 1991 (56 FR 60856). The agency requested comments on the RIA along with the food labeling proposals.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

B. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.71 is amended by adding new paragraph (c) to read as follows:

§ 101.71 Health claims: claims not authorized.

* * * * *

(c) Folic acid and neural tube defects.

Dated: December 17, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

Note: The following table will not appear in the annual Code of Federal Regulations.

BILLING CODE 4160-01-F

Table. Estimates of intakes resulting from fortification of foods with folic acid

Folate/folic acid source	Amount (µg)	Estimate of bio-availability[1] (percent)	Free folic acid equivalent (µg)
Estimate A:			
Usual diet	300	50	150
Add foods fortified to unit limit of 400 µg:			
Plus 1 supplement	400	100	400
Plus 5 servings breads and cereals	2,000	75	1,500
Plus 2 servings fruit juice	800	75	600
Plus 3 servings dairy products	1,200	75	900
Total µg/day	4,700		3,550
Estimate B:			
Usual diet	300	50	150
Add foods fortified to unit limit of 400 µg:			
Plus 2 supplements	800	100	800
Plus 10 servings breads and cereals	4,000	75	3,000
Plus 4 servings fruit juice	1,600	75	1,200
Plus 6 servings dairy products	2,400	75	1,800
Total µg/day	9,100		6,950

[1]Estimates of bioavailability used in FDA's calculation were 50 percent for food folates, 75 percent for folic acid added to foods, and 100 percent for folic acid in supplements.

[FR Doc. 92-31514 Filed 12-28-92; 8:45 am]
BILLING CODE 4160-01-C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 91N-0101]

RIN 0905-AB67

Food Labeling: Health Claims and Label Statements: Antioxidant Vitamins and Cancer

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing its decision not to authorize the use on the label or labeling of foods of health claims relating to an association between antioxidant vitamins and cancer. However, FDA is authorizing a health claim relating substances in diets low in fat and high in fruits and vegetables (foods that are low in fat and may contain dietary fiber, vitamin A, and vitamin C) to a reduced risk of cancer. This action is in response to provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) that bear on health claims, and was developed in accordance with the final rule on general requirements for health claims, published elsewhere in this issue of the **Federal Register**.

Based on the totality of the publicly available scientific evidence, including recently available evidence, the agency has concluded that there is not significant scientific agreement among qualified experts that a claim relating antioxidant vitamins to reduced risk of cancer is supported. The publicly available evidence does indicate, however, that diets rich in fruits and vegetables, which are generally low in fat and high in vitamin A (as beta-carotene), vitamin C, and dietary fiber, are associated with decreased risk of several types of cancer and there is significant scientific agreement that the evidence supports this association. The evidence is not sufficient to attribute the reduction in risk specifically to vitamin A (as beta-carotene), vitamin C, or vitamin E, alone or in combination, or to other components of these diets. In order to evaluate further the relationship between antioxidant vitamins and cancer, FDA is planning to convene an advisory committee to review the available data and recommend whether a health claim for specific antioxidant vitamins and cancer should be authorized.

EFFECTIVE DATE: May 8, 1993.

FOR FURTHER INFORMATION CONTACT: John N. Hathcock, Center for Food Safety and Applied Nutrition (HFS-465), Food and Drug Administration, 200 C St., SW., Washington, DC 20204, 301-344-6006.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 27, 1991 (56 FR 60624), FDA proposed to deny the use on food labeling of health claims relating antioxidant vitamins (specifically, vitamin C, vitamin E, and beta-carotene) to the risk of cancer. The proposed rule was issued in response to provisions of the 1990 amendments that bear on health claims and in accordance with the proposed general requirements for health claims for food (56 FR 60537). As amended by the 1990 amendments (Pub. L.101-535), the Federal Food, Drug, and Cosmetic Act (the act) provides that a food is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition unless the claim is made in accordance with section 403(r)(3) or (r)(5)(D) of the act (21 U.S.C. 343(r)(3) or 343(r)(5)(D)).

Congress enacted the health claims provisions of the 1990 amendments to help U.S. consumers maintain good health through appropriate dietary patterns and to protect consumers from unfounded health claims. Section 3(b)(1)(A) of the 1990 amendments specifically requires the agency to determine whether claims respecting 10 nutrient-disease relationships meet the requirements of section 403(r)(3) or 403(r)(5)(D) of the act. The relationship between antioxidant vitamins and cancer is one of the claims required to be evaluated. In carrying out this inquiry, FDA chose for consideration three antioxidant vitamins: vitamin C, vitamin E, and beta-carotene. Vitamins C and E were chosen because they are vitamins that function as antioxidants. FDA chose beta-carotene because it is an antioxidant, and because it is a provitamin and an important source of dietary vitamin A activity. FDA did not choose preformed vitamin A (retinol or retinoic acid) because its biological functions are not through an antioxidant role, and because vitamin A cannot function in an antioxidant fashion similar to that of beta-carotene (carotenoids) and vitamins C and E. FDA extended consideration of this topic area to all sources of antioxidant vitamins, i.e., both conventional foods and dietary supplements (56 FR 60624 at 60625).

FDA published a notice, in the **Federal Register** of March 28, 1991 (56 FR 12932), requesting scientific data and information on the 10 specific health claim topic areas identified in the 1990 amendments, including antioxidant vitamins and cancer. Relevant scientific studies and data received in response to this request were considered as part of the agency's review of the scientific literature on antioxidant vitamins and cancer in the proposed rule. Comments received in response to the notice and not specifically addressed in the proposed rule are summarized and addressed below.

In the proposed rule (56 FR 60624), FDA requested written comments on its tentative determination not to authorize a health claim for antioxidant vitamins and cancer. The agency specifically requested submission of data which directly bear on: (1) whether beta-carotene, vitamin C, and vitamin E per se, rather than some other component of food, decrease the risk of cancer in humans, and (2) the range of beta-carotene, vitamin C, and vitamin E intake that produce this effect. In addition, on January 30 and 31, 1992, FDA held public hearings on all aspects of the proposed rules published in response to the 1990 amendments (57 FR 239, January 3, 1992).

In the **Federal Register** of July 23, 1992, FDA published a notice reopening the comment period for three specific health claim topics, including antioxidant vitamins and cancer (57 FR 32751). In that document, FDA noted that the agency had received or identified several new studies on the relationship between antioxidant vitamins and cancer, which appeared to present significant new information that was not identified in the studies that FDA reviewed in its proposal. FDA listed the new studies and requested comments on them. Using the same criteria as described in the proposed rule (56 FR 60624 at 60629), these new studies are reviewed below. Comments received on the new studies are incorporated into the discussion of comments that follows.

Altogether, the agency received approximately 100 comments from consumers, consumer advocacy groups, State health departments, organizations of health professionals, the food industry, and Government agencies. A number of comments were received that were more appropriately answered in other companion food labeling documents, and these were forwarded to the appropriate docket for response.

The Dietary Supplement Act of 1992 (H.R. 6181) established a moratorium on the implementation of the 1990 amendments with respect to dietary supplements. The Dietary Supplement

Act says that FDA can grant health claims for foods, including dietary supplements, under section 403(r)(3)(B)(i) of the act. However, it may not act on such claims under section 403(r)(5)(D) of the act until it establishes a standard to implement that section of the act, which the Dietary Supplement Act says may not occur until December 1993. Section 3(b)(1)(A)(x) of the 1990 amendments directs the agency to evaluate the antioxidant vitamins and cancer claim based on the standard that FDA is establishing for determining the reliability of health claims under section 403(r)(5)(D) of the act. In the November 27, 1991, proposal on general requirements for health claims, FDA proposed to adopt the standard that the 1990 amendments provide for conventional foods, which is set forth in section 403(r)(3)(B)(i) of the act, as the standard for dietary supplements. Given this fact, and the fact that antioxidant vitamins are found in numerous conventional foods as well as in dietary supplements, FDA broadened its inquiry to a determination as to whether it should grant a health claim on antioxidant vitamins and cancer for any foods.

Because the Dietary Supplement Act provides that FDA may grant claims using the significant scientific agreement standard specified in section 403(r)(3)(B)(i) of the act, and given the breadth of FDA's November 1991 proposal on antioxidant vitamins, FDA has decided to move forward to determine whether it can authorize a claim under section 403(r)(3)(B)(i) of the act for antioxidant vitamins and cancer. However, this rule does not apply to dietary supplements. While a manufacturer of a dietary supplement can make a claim on antioxidant vitamins and cancer without rendering its product misbranded under section 403(r)(1)(B) of the act, the manufacturer should assure itself that the making of the claim will not misbrand the product under section 403(a).

II. Review of New Scientific Evidence: Beta-carotene, Vitamin C, and Vitamin E (Review of the Scientific Literature Available From 1991 Through February 1992, and Publications Submitted as Part of Comments)

A. New Studies

As noted in the **Federal Register** of July 23, 1992, results of several human studies have been reported in the scientific literature on the association between antioxidant vitamin intake and risk of cancer since the drafting of the proposed rule. Additionally, comments received in response to the proposed rule (56 FR 60624) noted some studies that FDA had overlooked in its proposal. FDA also identified some new studies through literature searches. Most of the new studies evaluated the effects of antioxidant vitamins in the larger context of diet and cancer, with some focusing primarily on the relationship of the antioxidant vitamins to fat and energy intakes. The recently available studies collectively addressed the relationship between antioxidant vitamins and a variety of types of cancer, including cancer of the breast, prostate, pancreas, uterine cervix, urinary bladder, colo-rectum, lung, and stomach.

Those studies submitted as comments which contributed to the totality of the scientific evidence on antioxidant vitamins and cancer are included in the following review. Those studies submitted as comments which were not germane to the topic or did not provide useful scientific information are addressed in the response to comments later in this final rule.

1. Overall cancer mortality rate

The relationship between vitamin C intake and total and cancer-related mortality rates in the United States was investigated through evaluation of the data from the National Health and Nutrition Examination Survey (NHANES I) (Ref. 1) (Table 1). The results indicated that higher vitamin C intakes are not significantly related to lower cancer mortality rates. The standardized mortality rate from all types of cancer collectively was a nonsignificant 0.78 for those taking supplemental vitamin C, compared with those who did not supplement with vitamin C.

2. Bladder cancer

A study of bladder cancer (Ref. 2) found that higher calculated vitamin E intake from foods was associated with slightly reduced risk of bladder cancer, after adjusting for smoking and total calories (Table 1). No association with cancer risk for the level of retinol or carotenoid intake was evident in this study. The participation rate was approximately 70 percent for the cases, the hospital-based controls, and the population-based controls. This study may have introduced bias by including prevalent cases (approximately 40 percent). Case-control studies usually select incident (newly diagnosed) cases. Prevalent cases are patients who have survived the disease for a period of time. Prevalent cases are generally not included in case control studies because the characteristics that contributed to their survival may modify potential risk factors of disease.

3. Breast cancer

In a recent study on breast cancer and foods that contain antioxidant vitamins (Ref. 3), dietary carotene and vitamin C intakes from foods were found to be associated with protection, but use of these constituents as dietary supplements had no effect on risk of breast cancer (Table 1). Patients with breast cancer tended to eat fewer than 10 fruits and vegetables per week. There was a low participation rate (56 percent of eligible cases and 46 percent of eligible controls), which may have introduced bias into the study. It is unclear why a large percentage of those identified as eligible did not participate, and this makes extrapolation of the results to the general population more difficult.

Another case-control study of breast cancer (Ref. 4) reported a marginal protective association between fruits rich in beta carotene and risk of breast cancer when premenopausal and postmenopausal women were evaluated together (Table 1). There was also a marginal protective association found for calculated preformed vitamin A (i.e., retinol) intake in postmenopausal women. When both premenopausal and postmenopausal women were analyzed together, the study found no significant association between antioxidant vitamin intake and the risk of breast cancer. There was also no evidence in this study that vegetable consumption was associated with reduced risk of breast cancer.

A case-control study in France (Ref. 5) found significantly higher intake and higher serum levels of vitamin E and higher serum vitamin E/total cholesterol ratio in breast cancer cases than in controls (Table 1). This effect remained after eliminating vitamin supplement users. Leukocyte vitamin E was elevated in cases; leukocyte vitamin C was also elevated in cases, but the elevation was not statistically significant. The report hypothesized that this effect may be the result of vitamin E-related metabolic alterations from breast cancer, rather than a cause of the disease.

Another case-control study on breast cancer (Ref. 6) found that diet was a more important risk factor for breast cancer in postmenopausal women than in premenopausal women (Table 1). After adjusting for energy intake, education, and age at menarche, the studies found that the intakes of dietary vitamin C, beta-carotene, total retinol equivalents and cellulose were positively associated with reduced risk of breast cancer in postmenopausal

women. The findings demonstrated that there was a marginally higher risk of breast cancer associated with high intake of nutrients from animal products and, after adjusting for the confounders described above, a lower risk associated with high intake of fruits and vegetables.

4. Cervical cancer

A recent case-control study of invasive cervical cancer (Ref. 7) reported that a slightly lower risk was associated with higher consumption of fruits and fruit juices (Table 1). No significant difference in risk of invasive cervical cancer was evident based on level of consumption of vegetables or legumes. There was decreased risk associated with higher intakes of vitamin C, beta-carotene, and other carotenoids. When vitamin C and beta-carotene were included in the same statistical model, the association for beta-carotene was attenuated, but the protective effect of vitamin C remained significant. This suggested that while beta-carotene and vitamin C are often present simultaneously in foods, the observed effect was more closely associated with vitamin C than beta-carotene. These results are difficult to interpret because there is generally more measurement error for beta-carotene intake than for vitamin C intake, and the strength of correlations may be affected by the size of the error variance.

A companion study in the same population (Ref. 8) focusing on serologic indicators of antioxidant vitamin intake found that intake of vitamin A (i.e., retinol), cryptoxanthin, lycopene, alpha-carotene, lutein, and vitamin E (alpha-tocopherol) did not significantly differ between cases of invasive cervical cancer and controls (Table 1). In addition, beta-carotene levels remained steady as cervical cancer progressed, arguing against an effect of disease progression on serum level. After adjusting for age, study site, reproductive history, socioeconomic status, and papilloma virus infection, higher serum beta-carotene and gamma-tocopherol levels were associated with decreasing risk of the disease. Considered together, the two studies found an association between beta-carotene intake, serum levels of beta-carotene, and decreasing risk of cervical cancer. In general, the protective effects were stronger for foods than for specific nutrients.

A clinical survey of patients with abnormal cervical cell types (cervicitis or dysplasia) in a recent study (Ref. 9) involved only 75 women and was confounded by smoking habits (Table 1). It did not have sufficient statistical power to find a significant difference in risk in relation to serum levels of antioxidant vitamins.

A case-control study of cervical intra-epithelial neoplasia in relation to dietary and serum carotenoids found ambiguous results for beta-carotene (Table 1) (Ref. 118). Protective associations were observed, however, for serum concentrations of the carotenoid lycopene and for dietary vitamin C.

5. Colorectal cancer

A study from the Balleric islands (Ref. 10) found no significant association between the risk of either colon or rectal cancer and the level of intake for vitamin A, retinol, carotene, vitamin C, or vitamin E (Table 1). There was a significant protective association for consumption of fiber from legumes and folic acid from cruciferous vegetables and reduced risk of cancer. The report stated that the findings support the recommendation for a diet high in vegetables as part of a lifestyle to reduce the risk of colorectal cancer.

6. Lung cancer

One of the new papers is a report of the results of a prospective cohort study (Ref. 11) regarding dietary intake of antioxidant vitamins and the risk of lung cancer in Finnish men (Table 1). The study found a protective effect associated with intake of foods rich in vitamins A, E, and C on the risk of lung cancer in nonsmokers. There was a strong protective association observed in this Finnish study between margarine intake and the risk of lung cancer in both smokers and nonsmokers. The report hypothesized that this finding was due to an effect of the vitamin E in margarine, although the researchers could not rule out an anticarcinogenic effect of some other constituent of margarine. Similarly, there was a lower incidence of lung cancer associated with consumption of foods that contributed 80 percent of the vitamin C in the Finnish diet (fruits, potatoes, and vegetables). The study could not separate the role of these nutrients from that of the foods which contain them in this association of reduced risk of lung cancer with diet, and could not rule out anticarcinogenic effects of other, nonnutritive constituents of fruits and vegetables, such as terpenes, flavones, and phenols. Also, behaviors possibly associated with intake of antioxidant-rich foods, such as exercise, not smoking, and decreased fat intake, may reduce cancer risk. The report concluded that studies focused on dietary patterns, intake levels, and protection against lung cancer by other constituents of antioxidant-rich foods are needed. Because the dietary estimate was based only on intake in the year preceding entry into the 20-year study, the estimate of antioxidant vitamin intake may not accurately represent the actual intake during the study duration, since changes in diet and supplement use were likely over the 20 years of the study.

Another new case-control study evaluated diet during the year preceding diagnosis and serum vitamin concentrations at diagnosis with lung cancer (Ref. 12) (Table 1). The calculated mean dietary intakes of beta-carotene were 24 percent lower for lung cancer cases than for controls, and 10 percent for other epithelial cancer cases than for controls. Serum concentrations of beta-carotene, retinol, and vitamin E were lower in the cancer patients than in the controls by 58, 30, and 31 percent, respectively, for lung cancer, and 33, 11, and 14 percent, respectively, for other epithelial cancer cases. The odds ratios for intakes of fruits and vegetables were rather irregular, and the associated trends were weaker than the trends for beta-carotene. The time period addressed in the dietary recall was the year prior to diagnosis. By comparison, cases in a 2-year period following sampling or interview are often excluded from prospective studies to help reduce the chance that the effects are a result of the cancer. Thus, the design of this study could have introduced bias related to deaths from preexisting cancer.

7. Oral and pharyngeal cancer

A population-based case-control study evaluated diet and dietary supplement use in relation to oral and pharyngeal cancer (Ref. 13) (Table 1). The results show decreased risk in association with higher consumption of fruits and vegetables and dietary supplements. In this four-State study, use of supplements was associated with being female, white, more highly educated, having a lower body mass, being a resident of California, and consuming more fruits and vegetables. Users of supplements of individual vitamin types were at lower risk after controlling for effects of tobacco, alcohol, and other risk factors. After adjustment for use of other supplements, vitamin E supplementation was the only one that remained associated with reduced risk.

8. Pancreatic cancer

A study on pancreatic cancer (Ref. 14) found a protective association between intake of dietary vitamin C and risk of pancreatic cancer after adjusting for

smoking and total calories (Table 1). Weak protective effects were also associated with vitamin A (i.e., retinol) and fiber intake and risk of cancer. Pancreatic cancer is characterized by a very rapid clinical course and deterioration of the pancreas, so dietary interviews and histopathologic confirmation are often not feasible. The Zatonski study may have introduced bias by using surrogates for assessing dietary history in 71 percent of cases. Reliance on a surrogate adds to the difficulty of recall. The spouse was sought as the surrogate in this study, because spouses generally provide reasonable dietary histories. Radiographic diagnosis of pancreatic cancer was used in 57 percent of the cancer cases. In lieu of a histologic diagnosis, the possibility of inaccurate diagnosis cannot be dismissed. This is a flaw in the study because noncases may have been included in the case group, and the signs of pancreatic cancer could have been confused with those of cancers of the upper gastrointestinal tract.

Another study on pancreatic cancer (Ref. 15) reported a statistically significant protective effect of vegetable consumption on the risk of pancreatic cancer after adjusting for smoking and total calories (Table 1). Protective effects were also demonstrated for consumption of both fresh vegetables and cooked cruciferous vegetables. This study did not separate the role of the food versus nutrients in the noted protective effects. A large percentage of dietary interviews relied on a proxy or substitute, which may have introduced errors in the estimates of food consumption. Proxies may not be aware of the complete dietary habits of the case that they represent.

9. Prostatic cancer

A study in Madrid, Spain, found no association between dietary vitamin A or C intake and the risk of prostate cancer (Ref. 16) (Table 1). However, the report noted that the customary Mediterranean diet is rich in fruits and vegetables. Any protective effect may have been pervasive at all levels of intake observed.

A case-control study of men in Utah (Ref. 17) found only a slight protective association between vitamin A intake in older men and the risk of prostate cancer (Table 1). Beta carotene had a nonsignificant protective association for prostate cancer in men aged 45 to 67 years. Dietary fat in men aged 68 to 74 years was the strongest association between a dietary risk factor and prostate cancer.

10. Skin cancer

A nested case-control study of serum micronutrients and low incidence cancer in Finland found a large decrease in risk of melanoma in association with higher serum beta-carotene concentrations (Ref. 18) (Table 1). There was a significant association, also, between higher serum alpha-tocopherol concentrations and reduced risk of melanoma. However, the small size of the study and wide confidence intervals prevent drawing strong conclusions from this study.

11. Stomach cancer

A case-control study of stomach cancer in high- and low-risk areas of Germany found a significant strong protective association between vitamin C from fruits and vegetables (RR = 2.32 for the lowest against the highest quintile of calculated intake) and risk of stomach cancer (Ref. 19) (Table 1). The results also implicated local water supply and smoked meat as possible sources of carcinogens or their precursors.

It has been suggested that vitamin C may reduce the risk for some cancers, particularly stomach cancer, through an antioxidant role in which the vitamin blocks formation in the stomach of carcinogens such as nitrosamines (Refs. 20 and 21). Most nitrosamines are mutagenic and carcinogenic in test systems, and, thus, many studies of the possible role of vitamin C in reducing the risk of cancer have focused on nitrate, nitrite, nitrosamines, and mutagenicity. Hence, several recent studies were directed toward relationships between vitamin C and formation of N-nitroso compounds, or between N-nitroso compounds and stomach cancer or precancerous pathology of the stomach. Data from such studies could prove useful in determining the specificity of vitamin C in relation to reduced risk of stomach cancer.

A case-control study in Shanghai, China, found that urinary ascorbic acid was lower and urinary nitrate higher in patients with gastric cancer than in normal controls (Ref. 22) (Table 1). The urine was not mutagenic (Ames test) in controls but the urine of subjects with dysplasia was somewhat mutagenic and that from gastric cancer patients was highly mutagenic. Normal controls had low levels of N-nitroso compounds in gastric juice, compared with the higher levels in patients with chronic atrophic gastritis, dysplasia or gastric cancer. The mutagenicity of the urine may have been related to synthesis of N-nitroso compounds in the stomach, and differences in this process may have been due to differences of ascorbic acid and nitrate. From studies of gastric cancer patients, without any other type of data, it is not clear whether the N-nitroso compounds are causal, predictive, or the result of gastric cancer.

The role of mutagenic/carcinogenic N-nitrosamides in stomach cancer was evaluated in a study with a complex, integrated design in China (Ref. 23) (Table 1). The study included: (1) Measures of mutagenicity of extract of local fish sauce before and after nitrosation, (2) determination of the carcinogenicity of these nitrosated products in the growing rat, (3) assaying the N-nitrosamides in these products, and (4) correlation of N-nitrosamides in gastric juice with the severity of precarcinogenic pathological changes in the stomachs of human subjects. In the absence of nitrosation, none of the fish sauce extracts was mutagenic. After nitrosation, all samples were mutagenic in common mutagenicity tests (Ames and sister chromatid exchange tests). The local fish sauce extracts from only two villages were mutagenic in the micronucleus test. Four weeks after treating newborn rats with fish sauce, only those treated with the sauce that was mutagenic in all three tests showed marked precancerous dysplasia. After 16 weeks, the same treatment groups had cancerous ulceration in the glandular stomach, with dysplastic glands and cells that had penetrated the mucosa and infiltrated into submucosa and muscular layers of the gastric wall. The mean concentrations of N-nitrosamides in the nitrosated fish products were more than 15 times higher in the samples from a high-risk area than in the samples from a low-risk area. The N-nitrosamide concentrations in gastric juice of human subjects had a strong positive correlation with the severity of pathological changes in the stomach.

A preliminary study in China (Ref. 24) found that N-nitroso compounds in the urine were higher in subjects with gastric dysplasia than in normal controls or subjects with chronic atrophic gastritis and/or intestinal-type metaplasia of the stomach (Table 1). The levels of N-nitroso compounds were lower in gastric juice than in the urine. With the small size and variability of this study, the N-nitroso compound levels in gastric juice could not be evaluated in relation to severity of stomach pathology.

The urinary concentrations of N-nitroso compounds and nitrate in urine of children from areas of low- and high-risk of stomach cancer in Costa Rica

have been studied (Ref. 25) (Table 1). The children were dosed with either 500 milligrams (mg) proline plus 200 mg ascorbic acid or 500 mg proline alone. (The proline was administered to assure that the quantities of N-nitrosoproline excreted were large enough to be chemically assayed in the 24-hour urine collected.) The amounts of N-nitrosoproline excreted were lower in the children from the low-risk area than from the high-risk area. In children from both areas, ascorbic acid treatment decreased the amount of N-nitroso-proline excreted. The N-nitrosoproline excretion had a highly significant positive correlation with the amount of nitrate excreted.

In a clinical trial involving English patients at high risk of stomach cancer (in this study, patients with atrophic gastritis, pernicious anemia, partial gastrectomy, or vagotomy), high doses of ascorbic acid (4 grams per day (g/day)) substantially decreased urinary N-nitroso compound excretion by all patients except those with pernicious anemia (Ref. 26) (Table 1). All patients received their normal diets, but avoided vegetable and fruit juices during the 4 weeks of the ascorbic acid treatment and 4 weeks of post-treatment observation. Serum ascorbic acid levels indicated excellent compliance with the ascorbic acid treatment.

A clinical trial of nitrosation of added L-proline by a high level of endogenous nitrate in test meals that were either low or high in endogenous ascorbic acid found that dietary levels of ascorbic acid significantly inhibit nitrosation of proline by dietary nitrate (Ref. 27) (Table 1). The results indicate that not all subjects synthesized nitrosoproline in vivo, and those who did not were the subjects who failed to show inhibition by ascorbic acid. Those who had in vivo nitrosation (13 of 19 subjects) showed strong inhibition of this process by ascorbic acid.

These results are supported by the results of a study that found lower excretion of nitrosoproline in subjects eating a lacto-vegetarian diet than in subjects eating a free-choice diet (Ref. 28). Supplementation with as little as 60 mg/day ascorbic acid decreased nitrosoproline excretion by the lacto-vegetarians, but not by those eating free choice diets. Supplementation with ascorbic acid at 300 or 3,000 mg/day decreased nitrosoproline excretion by both groups. Similarly, an earlier study found that dietary ascorbic acid (330 mg/day, principally from lemon juice) strongly decreased urinary excretion of two nitrosated products of the anthelmintic drug piperazine that are potent carcinogens in animals (Ref. 29). The inhibition of nitrosation by supplemental ascorbic acid decreases the mutagenicity of gastric juice (Ref. 30) and fecal mutagenicity (Refs. 31 and 32). Also, low concentrations of ascorbic acid in gastric juice are associated with chronic atrophic gastritis (Ref. 33) (Table 1), a condition widely considered to be premalignant (Ref. 34).

B. Conclusions From New Studies

1. Beta-carotene

Consistent with earlier studies reviewed in the proposed rule, these recent studies support findings that there is an inverse relationship between dietary intakes of green and yellow fruits and vegetables and the risk of cancer. This relationship is strongest for lung cancer. Intakes of the green and yellow fruits and vegetables have also been shown to be inversely associated with cervical cancer, but the evidence is not as consistent as with lung cancer. These studies were based on calculated intakes of nutrients from these foods. However, it is not possible to determine from these studies what substance or substances in these foods were responsible for the results. Beta-carotene may be responsible for the effect, or its presence in these foods may simply serve as a marker for some other unmeasured substances that are responsible for the protective effect of fruits and vegetables. Mechanistic studies provide a theoretical basis (singlet oxygen quenching) on which to postulate a protective antioxidant effect by beta-carotene, but the evidence from experimental animal carcinogenesis studies is less supportive. The evidence continues to be consistent with the conclusions of the major authoritative documents (e.g., "The Surgeon General's Report on Nutrition and Health" (Ref. 35) (the Surgeon General's report); the National Research Council's (NRC's) Report on Diet and Health: Implications for Reducing Chronic Disease Risk (Ref. 36) (the Diet and Health report); and the recent Life Sciences Research Office (LSRO) review (Ref. 37)) that the consumption of fruits and vegetables is inversely associated with risk of some cancers.

2. Vitamin C

Current data are compatible with the tentative conclusion in the proposed rule that consumption of fruits and vegetables rich in vitamin C may protect against some types of cancer. These data also provide additional indications of a mechanism to explain the relationship between vitamin C and reduced risk of stomach cancer. The relatively small number of studies reported since publication of the proposed rule are in agreement with earlier findings that consumption of fruits and vegetables is protective against cancer at several sites, particularly stomach cancer. The new studies, taken together with previous studies, indicate that consumption of fruits and vegetables is most consistently protective against cancers of the stomach, lung, and cervix, and less consistently protective at other sites. These data, however, are not sufficient to identify vitamin C versus other substances in these foods as being responsible for the observed protective effect.

The evidence from studies related to N-nitroso compounds is useful in identifying a mechanism, in human populations, whereby vitamin C could be responsible for decreasing the risk of some cancers, such as stomach cancer. The production of N-nitroso compounds with known carcinogenicity potential has been suggested as a cause of at least some stomach cancers in high-risk populations in China, Costa Rica, and Great Britain. The relevant data come from clinical trials showing the inhibition of nitrosation reactions in the stomachs of study populations, and epidemiological studies showing an association of N-nitroso compounds with precancerous and cancerous pathology of the stomach.

The results of the clinical trials on N-nitroso compound excretion, including new studies, indicate that levels of ascorbic acid from foods inhibit nitrosation reactions in humans by nitrite produced from dietary levels of nitrate, and that supplemental ascorbic acid within the range commonly obtained from foods (60 to 300 mg) can significantly decrease excretion of nitrosated products. Other new evidence shows that gastric juice and urinary nitrosamine concentrations are higher in normal persons in high-risk geographical areas than in normal persons living in low-risk areas, higher in persons with the more severe preneoplastic pathological changes in the stomach than in persons with less severe pathological changes, and higher in stomach cancer patients than in normal individuals. Ascorbic acid is only one determinant of endogenous nitrosation; dietary nitrate and its subsequent reduction to the nitrosating product nitrite by oral and gastric bacteria is also a strong determinant of endogenous nitrosation. Other determinants include nondietary influences such as smoking.

The carcinogenicity of N-nitroso compounds formed by endogenous nitrosation is determined by the amount of products formed and by their

chemical identities. The amounts formed are controlled by nitrate intake, nitrate reduction to nitrite, amounts of precursor amines available, and inhibition by ascorbic acid and other inhibitors of nitrosation. The identities of nitrosation products are determined by the identities of the precursor amines, available endogenously, in foods, or from other sources such as pharmaceutical products.

Although most of the several hundred nitrosamines and nitrosamides that have been tested are animal carcinogens, those used in evaluation of the potential for nitrosation in human subjects were selected because they are noncarcinogenic. Nevertheless, they provide a useful indicator of the effectiveness of vitamin C in decreasing the synthesis of carcinogenic members of the N-nitroso family of compounds. Studies of N-nitrosoproline, for example, must therefore be interpreted as indicators of nitrosation potential and associated risk of cancer, and not direct indicators of carcinogenic risk from that substance. It seems probable that the identities of precursor amines, and therefore of the N-nitroso compounds produced by endogenous nitrosation, will be different from one human population to another, depending on diet and other factors. Current scientific information is not sufficient to determine which specific mutagenic and carcinogenic N-nitroso compounds may be responsible for stomach cancer in various human populations, and it is reasonable to expect that these may vary from one population to another. Nonetheless, vitamin C is an inhibitor of the nitrosation reaction through its interaction with nitrite, regardless of the identify of the amine or amide being nitrosated and the corresponding identity of the resulting nitrosamine or nitrosamide.

The possible relationship of urinary and gastric juice N-nitroso compounds with stomach cancer is shown by the association of these compounds with precancerous pathological changes in the stomach and by the association of these pathologies with elevated risk of stomach cancer. The concentrations of N-nitroso compounds in gastric juice and urine are directly correlated with the degree of severity of the precancerous lesions in the stomach. The mutagenicity and carcinogenicity in test systems and experimental animals of N-nitroso compounds from food sources provide suggest a cause-and-effect relationship of N-nitroso compounds and stomach cancer in humans.

These effects cannot be interpreted as indicating that all stomach cancers are attributable to N-nitroso compounds or any other chemical carcinogens, or that vitamin C or other antioxidants can eliminate the risk of stomach cancer. Current data do not allow the exclusion of other mechanisms, such as general antioxidant effects, from the possible protective effects of vitamin C. Furthermore, the data from clinical trials showing inhibition of nitrosation reactions in the stomach, and epidemiological studies showing an association of N-nitroso compounds with precancerous and cancerous pathology of the stomach do not directly link vitamin C intakes with cancer risk or establish the validity of nitrosation reactions as a risk factor for stomach cancer in the U.S. population. These data provide a mechanistic basis for understanding a possible protective effect of vitamin C for stomach cancer risk. At this time, however, nitrosation has not been accepted by the general scientific community as a validated risk factor for stomach cancer. One of the unresolved questions is whether studies of this mechanism from the Chinese and other populations, which differ from the U.S. population in genetic, dietary, and environmental risk factors, adequately explain the etiology of stomach cancer in the United States.

3. Summary of vitamin C and cancer risk

Results from the newer data are similar to results of studies reviewed in the proposed rule, which showed that diets high in fruits and vegetables were associated with a reduced risk of some cancers. Additionally, the new data on the relationship of vitamin C in inhibiting nitrosation reactions in the stomach, resulting in reduced production of N-nitroso compounds with known carcinogenicity, provide a basis for a mechanism by which vitamin C may reduce the risk of some cancers such as stomach cancer in some people. However, these studies were done in populations outside the United States, so their relevance to the pathology and etiology of the types of stomach cancer in the United States is controversial. Furthermore, nitrosation has not received acceptance by many experts as a valid and quantifiable risk factor or surrogate marker for stomach cancer risk. Its validity and utility as an endpoint for evaluating the effect of nutrients on stomach cancer risk, therefore, warrants further discussion.

4. Vitamin E

The latest available information since the publication of the proposed rule is not sufficient to reach a definite conclusion about an association between vitamin E intake and the risk of cancer. Some studies provide suggestive evidence of an association of lower plasma/serum concentrations and lower dietary intake of vitamin E with increased risk of cancer. Mechanistic and animal studies provide a theoretical basis on which to expect a protective effect, but human studies are inconsistent and do not provide a convincing pattern of support for that conclusion. Even if an effect of vitamin E were assumed, it would not be clear from current data which specific chemical of the tocopherol family was responsible for the observed effect.

III. Summary of Comments and The Agency's Responses

Several comments supported the proposed rule to disallow a claim for antioxidant vitamins and cancer, without giving a rationale. Others supported the proposed rule, indicating that a cause-and-effect relationship of lowered risk has been established for fruits and vegetables, but that it is not clear that this relationship is due to the antioxidant vitamins in those foods.

The three final LSRO reports (Refs. 37 through 39) submitted as comments, which provided independent up-to-date reviews of the scientific evidence, also reached similar conclusions, except for vitamin C and stomach cancer. The LSRO report on vitamin C and cancer (Ref. 39) noted the consistency of epidemiological findings associating high intakes of vitamin C or vitamin C-rich foods with reduced risk of stomach cancer, but noted that vitamin C was either not related to other cancer sites or that study results were much less clear about such relationships. The LSRO report on Vitamin A and cancer (Ref. 37) concluded that, for foods containing beta-carotene, the associations with decreased cancer risk could not be attributed specifically to beta-carotene or to any other carotene compound. The LSRO report on vitamin E and cancer (Ref. 38) concluded that there was not a clear association of decreased cancer risk with consumption of foods high in vitamin E, and the tentative associations observed could not be attributed to vitamin E rather than to some other component. The report further stated that studies on vitamin E with animals and in vitro test systems provide a theoretical basis on which reduced risk of cancer can be hypothesized.

Many comments opposed the proposal not to allow a health claim for antioxidant vitamins and cancer. Issues raised in these comments are discussed below.

A. Scientific Standard and its Application

In the proposed rule (55 FR 60624), FDA reviewed the evidence and conclusions reached in recent authoritative documents from the Federal Government and other sources. The agency updated the evidence reached in these documents by reviewing all human studies in the literature subsequent to these documents, and by contracting with the LSRO of the Federation of American Societies for Experimental Biology (FASEB) for an independent review. The agency considered the results of animal studies to the extent that they clarified human studies or suggested possible mechanisms of action. The agency evaluated the strengths and weaknesses of individual studies and then assessed the strength of the overall combined evidence, taking into account the strength of the association, the consistency of findings, specificity of the association, evidence for a biological mechanism, and presence or absence of a dose-response relationship.

1. A number of comments discussed the types and weighing of data used by FDA in reaching its tentative position. Several comments noted that the proposed rule repeatedly suggested that epidemiological data are not enough, and that complete clarity must await the completion of clinical trials. One comment stated that clinical trials should be undertaken only when feasible and likely to yield a definitive answer, and that this is not the case for antioxidant vitamins and cancer. Other comments stated a belief that FDA favored prospective over case-control studies because they are less subject to misclassification and recall bias. One of these comments argued that there are advantages to case-control studies in cancer research and that concurrent followup (prospective cohort) studies are too expensive and time-consuming to be done often. The comment further noted that followup studies usually cannot address interactions and confounding factors because the necessary information does not exist or because too few subjects develop the cancer of interest, and that the case-control study is uniquely well-suited to the study of cancer and other diseases of long duration. A comment stated that most epidemiological studies handle the issue of nutrient intake from dietary supplements in a manner that obscures their impact, that many studies have insufficient power for specific outcomes, and that many involve inadequate or inappropriate questionnaires. Another comment stated that the 1990 amendments do not set out a drug efficacy standard, but only require that there be significant scientific agreement that a claim is supported by the scientific evidence.

FDA disagrees that the proposed rule indicated that clinical trials are specifically required to support a health claim. FDA's proposed validity standards for health claims and conformance with these standards were discussed in the proposed rule on general requirements for health claims (56 FR 60537 at 60547 through 60549). In that document, FDA noted that, while intervention (i.e., clinical) studies are generally more reliable than observational studies for determining cause-and-effect relationships, the agency recognized that there are frequently reasons why the conduct of such studies is not feasible or ethical. FDA also noted that, in evaluating proposed claims, it would take into account the overall strengths and weaknesses of the available data, and that a combination of various types of studies can frequently compensate for deficiencies in individual studies and thus provide a stronger case to prove or disprove a hypothesis. Furthermore, regardless of the type study used (e.g., case-control versus prospective), study designs are most useful when they can determine whether or not an observed effect is due to the specific food component of interest.

In the proposed rule on health claims for antioxidant vitamins and cancer (56 FR 60624 at 60629 through 60630, 60633, 60636), FDA listed additional criteria used in evaluating the scientific evidence for each of the three antioxidant vitamins and risk of cancer. FDA again indicated that it assessed the weaknesses and strengths of individual studies; and then the agency assessed the strength of the overall evidence, taking into account the strength of the associations, the consistency of the findings, the specificity of the associations, the evidence for a biological mechanism, and the presence or absence of a dose-response relationship. FDA noted that the agency's tentative conclusions reflected the strength, consistency, and preponderance of the data as reported. FDA did not speculate about what the results of specific studies might have been if they had involved different designs, greater statistical power, or more specific questionnaires.

After reviewing the conclusions of the federal government and other authoritative reports and the updated literature review, FDA concluded that the evidence is strong that consumption of fruits and vegetables that are good sources of beta-carotene and vitamin C are associated with lowered risk of cancer at a number of sites (56 FR 60624 at 60631, 60635, and 60638). However, the agency tentatively concluded that the data were not sufficient to establish that these two vitamins themselves were responsible for this association. The agency also noted that it was aware of ongoing clinical trials that, when completed, would provide valuable data about the specific effect of the antioxidant vitamins on the risk of cancer. However, the agency did not intend that this statement should be interpreted to mean that the results of these or other studies were a necessary condition for authorizing a health claim for the antioxidant vitamins and risk of cancer. Rather, the agency simply stated this information to indicate its awareness of these studies and the rapidly evolving nature of the scientific evidence relative to the topic area. While FDA discussed the relative advantages and disadvantages and generally agreed upon weighting of various types of human studies in a generic sense, the agency did not intend to convey the impression that one type of study would be rejected or that clinical studies were required. Rather, it was the overall sufficiency of the available evidence that was important.

FDA has not required a drug efficacy standard for health claims on foods under the 1990 amendments. The requirements for demonstration of drug efficacy differ substantially from the scientific standard for authorization of health claims on foods. For example, clinical trials are necessary to gain approval of a new drug; as discussed above, they are not required for authorization of a health claim on food, if other types of available data are sufficient.

2. A comment expressed concern that the agency had used a more liberal standard in evaluating health claims for calcium and osteoporosis and lipids and cancer than for antioxidant vitamins and cancer. The comment cited the proposed rule on dietary lipids and cancer (56 FR 60764 at 60765 through 60766, November 27, 1991) in which FDA quoted from the diet and health report that data from epidemiological and experimental animal studies were sufficient to support a claim that dietary fat may influence the risk of some types of cancer, although the precise determination of the quantitative relationship and nature of the association between dietary fat and the overall risk of cancer has not been determined. The comment compared the proposed rule on antioxidant vitamins and cancer (56 FR 60624 at

60632 through 60632), arguing that FDA concluded that similar data are inadequate to support a claim for antioxidant vitamins and cancer. The comment claimed that distinctions between the arguments FDA used to accept a claim on lipids and cancer and reject a claim on antioxidant vitamins and cancer are illusory at best.

FDA disagrees with the assertion that the agency applied a variable standard for authorizing various health claims. For some topics such as calcium and osteoporosis, sodium and hypertension, lipids and heart disease, and lipids and cancer, there was a long history of review by expert panels from the Federal Government, the National Academy of Sciences, and other authoritative groups. These groups concluded that the science supports these nutrient/disease relationships, and this fact provides evidence for significant scientific agreement among qualified experts about the state of the evidence. In contrast, the authoritative reviews have concluded that the publicly available data do not support a conclusion that the antioxidant vitamins reduce cancer risk. In reviewing the recent human studies which became available subsequent to publication of these authoritative reports, FDA did not find compelling evidence that these nutrients were specifically responsible for reduced risk of cancer in persons consuming diets high in fruits and vegetables. Without such data, FDA could find no basis to conclude, counter to these previous conclusions of expert panels that, based on the totality of evidence, there is significant scientific agreement that an antioxidant vitamins/cancer claim is supported.

3. Some comments stated that FDA has relied on the Surgeon General's report (Ref. 35) and the Diet and Health report (Ref. 36) without considering all recent publications. These comments noted that the earlier authoritative reviews failed to consider all of the available data, and thus some of their conclusions may have rested on incomplete data. The comment also noted that the explosion of new research on the relationship between antioxidant nutrients and cancer has produced a large number of recently published studies which escaped the LSRO reviews. The comment also identified a number of studies included in the LSRO reviews that were not included in the tables published in the proposed rulemaking. The comment suggested that, while this may or may not have influenced the decisionmaking in this case, it might provide an incomplete picture to others who read the FDA proposal.

FDA disagrees with these statements. FDA considered not only the Surgeon General's report (Ref. 35) and the Diet and Health report (Ref. 36), but also all available recent publications that were relevant to the issue, including the recent review by the LSRO (Refs. 37 through 39). FDA recognizes that the authoritative review documents may not have considered and certainly did not cite every available publication related to the subject matter under consideration. FDA believes, however, that they authoritatively considered the original research publications and critical reviews necessary to reach accurate conclusions about the state of the scientific evidence on antioxidant vitamins and cancer.

The topics in the authoritative reports were evaluated by nationally recognized experts who would be expected to be familiar with all significant findings available at the time of the reports. Furthermore, except for the LSRO reports, these reports were subject to no requirements to list, as references, all available scientific literature. Most likely, they followed the common procedure of the scientific community and listed only those studies considered most relevant to the issues under review. FDA advises that any papers which were not cited in these reports but which commenters felt were important could have been submitted as comments to the public docket. Those that were submitted were included in FDA's review of new studies, or if not appropriate for inclusion in that section, are discussed in specific comments.

FDA also acknowledges that not every paper cited in the LSRO reviews was incorporated into the proposed rule. Conclusions from the LSRO preliminary reports were considered in developing FDA's proposed rule. Those relevant studies not included by FDA in the proposed rule, but cited by LSRO, have been included as new scientific evidence in this final rule (see section II. of this document).

The additional studies cited by one comment either are not sufficiently relevant to warrant their inclusion in the review of new scientific evidence, did not meet the inclusion criteria in the proposed rule, or are old enough to have been considered for inclusion in the Surgeon General's report (Ref. 35) and the Diet and Health report (Ref. 36) or the recent reviews by the LSRO (Refs. 37 through 39). There is broadly based scientific agreement of an association between dietary patterns high in fruits and vegetables and reduced risk of cancer, as acknowledged in the proposed rule, and in the Surgeon General's report (Ref. 35) and the Diet and Health report (Ref. 36). However, studies that identify or confirm the established relationship of protective effects of fruits and vegetables on cancer risk without providing data on the unresolved question of the specificity of one or more of the antioxidant vitamins in relation to reduced risk of cancer are not helpful in supporting a health claim on antioxidant vitamins and cancer. Those studies that are newer and more nearly relevant to the issue of antioxidant vitamins and cancer, in contrast to fruits and vegetables, are summarized and cited in Table 2 (Refs. 41 through 59). One study described and listed in Table 2 (Ref. 46) is a further description of a study already reported elsewhere and considered in the proposed rule. Those listed by the comment but not included in the review of new scientific evidence in an earlier section of this document, and not cited in Table 2, were reviewed and found either to be not sufficiently relevant, to not have found significant results, or to be old enough to have been included in earlier reviews if that had been considered appropriate (Refs. 60 through 109).

4. Some comments argued that the biochemical data on the effects of antioxidant vitamins on the probable mechanisms of chemical carcinogenesis are strong evidence, and could stand alone in support of an association between antioxidant vitamins and cancer. One comment suggested that numerous studies have shown antitumorigenic effects of antioxidant vitamins in animal models, and, although not showing protective effects from every nutrient in every animal model and in every dosage regimen, quite consistently show a strong and significant protective effect. However, no data were submitted to support this assertion.

FDA disagrees with these comments. Although biochemical data can indicate the possibility of a protective effect of the antioxidant vitamins against cancer, they cannot demonstrate that the effect is one of practical importance in humans, in the context of the total daily diet, alone, support a health claim. FDA recognized in the proposed rule that animal and mechanistic data provide a strong theoretical basis on which to postulate that the antioxidant vitamins decrease the risk of cancer in humans. FDA does not agree, however, that such evidence alone are sufficient to support the conclusion that the effect is necessarily of practical importance in humans, in the context of the total daily diet.

5. Some comments stated that FDA's fragmented approach to considering the

evidence has made it difficult to see the extraordinary consistency of the data. These comments state that, although the 1990 amendments directed FDA to consider a health claim regarding "antioxidant vitamins and cancer," the agency chose to consider three antioxidants (beta-carotene, vitamin C, and vitamin E) separately. The comments stated that this approach is counter to the requirements of the 1990 amendments and is inherently incapable of revealing the consistency of the data on the antioxidant vitamins. A few comments stated that FDA should have reviewed selenium.

FDA disagrees with these comments. The term "antioxidant" defines a functional characteristic of a substance rather than its specific identity. Antioxidant nutrients include the vitamins under consideration and the mineral selenium. FDA has not considered selenium, because the 1990 amendments specified "antioxidant vitamins and cancer," and, although it is an antioxidant, selenium is not a vitamin.

FDA reasonably interpreted the language of the 1990 amendments to refer either to an independent effect of one or more of the vitamins with antioxidant characteristics (i.e., vitamins C and E, and the provitamin A, beta-carotene) or to an effect of a combination of two or more of the antioxidant vitamins. Certainly, FDA did not interpret the language of the act to mean that the only effect to be considered was that of the three antioxidant vitamins in combination. FDA recognizes that much of the data from surveys of dietary patterns and intakes of specific foods involve consumption of combinations of the antioxidant vitamins. The agency notes, however, that the composition of fruits and vegetables includes many substances other than the antioxidant vitamins, such as dietary fiber, and believes that the results of studies of fruit and vegetable intake cannot be interpreted as demonstrating that a combination of the antioxidant vitamins is responsible for the observed protective effects. FDA advises, however, that a petition in support of a health claim for a combined effect of the three antioxidant vitamins may be submitted for evaluation.

6. Some comments stated that, in the proposed rule on antioxidant vitamins and cancer, FDA made a "Type II error" by failing to identify an effect when it exists. (In contrast, a Type I error is that of mistakenly identifying an effect when it does not exist.) The comments indicated that this type of error causes important health benefits that are justified by the available evidence to be denied. These comments also stated that a benefit/risk analysis could properly be used to allow health claims because the agency had stated in the proposed rule that "FDA will use its discretion to give greater weight to those studies that are more persuasive regardless of the nature or age of the studies."

FDA agrees that both types of error are possible. In general, decreasing the probability of a Type II error will increase the probability of a Type I error, and vice versa. In the proposed rule on general requirements for health claims (56 FR 60537 at 60547), FDA noted that the standard for conventional foods in the 1990 amendments required that the agency have a "high level of comfort that the claim is valid." FDA proposed that the same standard be used for both conventional foods and dietary supplements (56 FR 60357 at 60547). FDA believes that it has properly balanced the probabilities of making the two types of error by requiring that the totality of the data support the disease/nutrient relationship. Giving more weight to studies that are most persuasive, within the broader context of the strengths and weaknesses of individual studies and the types of evidence available, is appropriate in assessing the totality of the evidence. This approach does not, however, permit selective use of studies supporting a relationship at the expense of evaluating those studies which fail to support the relationship. Moreover, FDA's cited statement in the proposal does not support use of risk/benefit analysis to evaluate a health claim. Such an analysis would be inappropriate. FDA is responsible for ensuring a safe food supply, and thus foods bearing health claims must be demonstrated to be safe and lawful. (See § 101.14(b)(3)(ii)).

7. A comment stated that, in proposing not to authorize health claims for antioxidant vitamins and cancer, FDA was inconsistent with its cosponsorship, with the American Health Foundation, of a recent international conference on antioxidants and cancer. The comment stated that the overall content of the conference was to substantiate the protective effect of antioxidant vitamins against cancer.

FDA agrees that research discussed in the conference provided further evidence of the existence of plausible and substantiated mechanisms, including inhibition of nitrosation reactions, inhibition of free radical oxidations, and support of immune responses, through which antioxidant vitamins may decrease the risk of cancer. FDA also agrees that the conference provided evidence of the association of consumption of foods that are good sources of beta-carotene and vitamin C with protection against certain cancers. The research presented at the conference was generally consistent with a protective relationship between antioxidant vitamins and cancer, but the conference organizers and participants did not directly address whether the evidence met the standards and criteria specified in the 1990 amendments.

B. Relationships Between Antioxidant Vitamins and Cancer

8. Some comments asserted that a major problem with the proposal is that all cancers are referred to together. They further stated that the 1990 amendments do not specify or define antioxidant vitamins, and this makes it impossible for a regulation to be issued.

FDA disagrees. In the proposed rule (56 FR 60624 at 60633 through 60636), FDA broke out its review of vitamin C by type of cancer. There were insufficient data on beta-carotene and vitamin E for such an organizational structure. FDA does not believe that the organization of its review biased the conclusions. However, in the scientific review for this final rule, FDA organized its review of the effect of antioxidant vitamins by type of cancer. FDA's approach was again driven by the availability of data. As explained in the proposed rule, FDA selected beta-carotene, vitamin C, and vitamin E for review because they are vitamins (or, in the case of beta-carotene, a provitamin), they have antioxidant properties, and their known biological functions are through antioxidant activities.

9. Some comments disagreed with the statement by FDA that the amount of antioxidant vitamins needed to produce an effect must be identified. A comment also objected to the agency's statement that it would need to determine whether the food supply already provides that amount of the antioxidant vitamin, arguing that this is not a valid requirement because it does not consider variations in dietary intake. This comment stated that: (1) If FDA needs to know simply that effective levels may be obtained in a normal diet, the epidemiology can tell us that, and (2) if FDA is attempting to identify a specific amount, then this quest is misguided for several reasons. The reasons given included: (1) The required level is determined in part by the level of oxidant stress, (2) most of the epidemiologic data suggest that there is not a threshold, but rather a continuous trend of decreasing risk with increasing intake, and (3) the effective level may

well differ for different cancer sites. The comment stated that: (1) Protective levels are in the range attainable in the context of the total daily diet, and (2) in contrast to FDA statements or implications in the proposed rule, the antioxidant nutrient status of the U.S. population is not ample. No definition was given, however, for "ample."

FDA agrees that, if a cause-and-effect relationship has been shown for a particular type of cancer and a specific antioxidant vitamin, epidemiological data can be relied upon to indicate effective levels. FDA disagrees that any attempt to identify precise amounts of the antioxidant vitamins needed to decrease risk of cancer is misguided. The agency acknowledges the important considerations raised by the comment, but considers the rationale incomplete. Amounts of specific vitamins must be identified to provide a regulatory basis for the qualifying criteria for a health claim. In the final rule on general requirements for health claims published elsewhere in this issue of the **Federal Register**, FDA has concluded that foods that bear a health claim must contain meaningful amounts of the targeted nutrient relative to the claimed effect (in this instance, potential for reduction in cancer risk) (§ 101.14 (21 CFR 101.14)). Any alternative approach would be misleading to the consumer.

FDA agrees, however, that, if the cause-and-effect relationship has been shown, protective levels might include the range most commonly obtained from the diet. Because protective levels of the antioxidant vitamins are not known, it seems futile to speculate as to whether protective levels, if and when identified, will be attainable within the context of the total daily diet. As is explained fully in the preamble of the final rule on the general requirements for health claims published elsewhere in this issue of the **Federal Register**, it would not be permissible for a health claim to imply that levels clearly beyond the range attainable in the context of the total daily diet would be effective in reducing the risk of a disease or health-related condition.

FDA acknowledges that its statements about the need for information on the current dietary status for the antioxidant vitamins in the proposed rule were not clear. The agency also agrees that high average intake and high intake in major population groups do not indicate that all individuals or population subgroups would have similarly high intakes. However, because of space limitations on food labels, it is not possible to provide information on the recommended nutrient intakes for major age and sex groupings or for all situations which might affect need. Rather, labels will show a reference value, and educational programs will help consumers understand the relevance of the reference value to their individual needs.

10. A comment stated that results from epidemiological studies are sufficient to show that the antioxidant vitamins per se decrease the risk of certain cancers. Some comments claimed that FDA's statement that the effects of fruits and vegetables cannot be specifically attributed to the antioxidant vitamins is not valid and is biased against dietary supplements in that the data on antioxidant vitamins and cancer are no more confounded than those on dietary fat and cancer. A comment stated that, although FDA documents note repeatedly that the evidence for fruits and vegetables is strong, FDA nevertheless rejected a health claim on the antioxidant vitamins and cancer on two grounds: (1) The association could be due to other factors associated with fruit/vegetable intake, and (2) even if the protective factor is an antioxidant, it is not clear which nutrient is effective. Several comments stated that FDA should allow a qualified claim such as "a diet high in fruits and vegetables containing antioxidant vitamins may help reduce the risk of certain cancers."

FDA agrees that the scientific evidence is strongly supportive that diets high in fruits and vegetables are associated with a reduced risk of several types of cancer. Theoretical considerations and some research findings have suggested that several common components of fruits and vegetables, or substances at low concentrations in diets containing large quantities of these plant foods, may be responsible for reduced risk of cancer, including vitamin C, beta-carotene, other carotenoids, vitamin E (alpha-tocopherol) or other tocopherols, dietary fiber, folic acid, and other substances such as the indoles in cruciferous vegetables. Fruits and vegetables may also provide a protective effect because they are generally low in fat and calories, and because they may displace higher fat foods in the total diet. In the final rule on general requirements for health claims (§ 101.14), FDA notes that labeling statements relating ingestion of general food groups (e.g., fruits and vegetables), in which a specific substance is not implied, to a disease or health-related condition will not be regulated as health claims under § 101.14, but will be subject to the requirement in section 403(a) of the act that they be truthful and not misleading.

FDA concludes that epidemiological studies of associations between food consumption and cancer, in which the antioxidant vitamins are provided almost entirely by fruits and vegetables, are not likely by themselves to establish a cause-and-effect relationship between antioxidant vitamins and cancer sufficiently to generate significant scientific agreement. It is not possible from these studies alone to identify the particular substances or combination of substances responsible for the effect. FDA recognizes that many studies have used multiple regression procedures to control for potential confounders and to attribute specificity to statistically significant relationships. However, unless all effective components are measured, it is not possible to differentiate between a measured variable which may be serving as a marker for other unmeasured components in the food and a real effect of the measured nutrient itself.

As to the concern expressed that FDA intentionally discriminated against dietary supplements, FDA disagrees. FDA, as stated in the proposed rule on general requirements for health claims (56 FR 60357), focused on the role of specific nutrients or foods as they relate to reduction in risk of a disease, regardless of source. The source of vitamin C, for example, could thus be naturally occurring vitamin C in foods, vitamin C added as a fortificant, or vitamin C obtained from dietary supplements. Consumers obtain their nutrients from a variety of sources. FDA's conclusions were driven by the nature of available evidence: for antioxidant vitamins and cancer, most of the available evidence is from studies on consumption of fruits and vegetables.

In regard to a health claim on conventional foods in which specific nutrients are named, such as "diets high in fruits and vegetables containing antioxidant vitamins may reduce the risk of cancer," FDA is persuaded by the comments that a similar claim may be useful, and that a similar claim is supported by the evidence. FDA, therefore, has decided to authorize a health claim relating low fat diets high in fruits and vegetables (which are low in fat and may contain vitamins A and C and dietary fiber) to a reduced risk of some types of cancer. Statements relating foods to cancer risk with acknowledgment of significant nutrient contributions of those foods to total diets are frequently the types of statements used in Federal Government and other dietary guidelines. The 1990 amendments clearly indicated that Congress intended that health claims on foods be a useful source of information to help Americans implement the U.S. Dietary Guidelines for Americans (Ref.

40). The authorized claim will provide such useful information.

11. One comment argued that time-release formulations of antioxidant vitamins are superior to standard formulations in their ability to decrease the risk of cancer, and that cancer clinics are using them successfully.

This comment did not provide scientific support for a conclusion that time-release formulations of the antioxidant vitamins have been shown to provide any special benefit or advantage over standard formulations. The literature submitted in support of the assertion consisted of general, nonscientific review and position statements, and was not useful in assessing the totality of the scientific evidence on the relationship between antioxidant vitamins and cancer. Moreover, FDA does not consider the issue of time-release formulation to be relevant to this rulemaking.

12. One comment submitted a copy of the entire April 1, 1992, issue of Cancer Research (Vol. 52, pp. 2091s through 2126s). Some comments submitted a review (Ref. 110) of carotenes, vitamin C, and vitamin E as protective antioxidants in human cancers.

One paper in the submitted issue of Cancer Research addressed antioxidant vitamins and cancer (Ref. 111) concluded that increased intakes of fruits, vegetables, and carotenoids, and elevated blood levels of beta-carotene are consistently associated with reduced risk of lung cancer. Nevertheless, this review concluded that, with current data, the effects of beta-carotene cannot be identified separately from those of other carotenoids, other constituents of fruits and vegetables, and associated dietary patterns.

The other review covered both animal experiments and epidemiologic research. Its overall conclusion was that antioxidant nutrients appear to play many important roles in protecting the body against cancer, but many important questions remain before dietary supplementation and/or food fortification can be recommended. In contrast, it concluded that there is a strong scientific basis for current dietary recommendations that emphasize frequent consumption of fruits and vegetables.

13. Another comment stated that the study on beneficial effects of dietary supplementation on longevity (Ref. 1) used inappropriate methods and therefore should not be used for identification of benefits from use of supplements. This comment stated that a major problem lies in the fact that cancers develop at different rates, thus requiring more time for conclusive studies.

FDA has indicated elsewhere in this document that this study did not find a significant effect of any antioxidant vitamin on cancer mortality. Thus, while the issue of the relevancy of the methods used may merit scientific review, it has no practical effect on the conclusions reached relative to health claims.

C. Safety Issues

14. Several comments disagreed with the statement by FDA in the proposed rule that high intakes of one vitamin without commensurate increases in the others may not support optimum status and functions for these nutrients. The comments stated that dietary supplements provide greater opportunity for deliberately balanced intakes of the antioxidant vitamins than do foods, and other comments asserted that FDA is wrong in stating that foods provide a better balance of antioxidant vitamins than do dietary supplements. The comments also suggested that interactions can be protective, as illustrated by data from animal experiments.

FDA agrees that dietary supplements allow the opportunity to provide a more controlled amount of nutrients than do foods. However, in the case of antioxidant vitamins and cancer, the scientific evidence from data that are customarily used in setting dietary goals and nutrition policy is not sufficient at present to identify an independent effect of these substances. Therefore, any attempt to define dosages or optimum balances among the three antioxidant vitamins is premature. The statement that foods may provide a better balance is consistent, therefore, with the limitation of current scientific evidence.

Additionally, FDA agrees with the statement that interactions can be either helpful or harmful. However, FDA's decision to propose not to authorize a health claim on antioxidant vitamins and cancer was not based on concern about toxicities or adverse interactions among nutrients, but, instead, on the insufficiency of the data available.

15. Some comments expressed concern that, if a health claim were permitted for vitamin C, the public might take supplemental doses far in excess of the Recommended Dietary Allowances, and that this could result in gastrointestinal disturbances, iron overload in some people, precipitation of calcium oxalate kidney stones, disruption of copper metabolism, and induction of postnatal bleeding in women. They also stated that dietary supplements should be required to list a warning statement regarding use of the supplement along with any health claim permitted.

FDA points out that most reports of possible adverse effects from ascorbic acid ingestion have involved dosages of 3 to 30 g per day (Ref. 112). The Surgeon General's report (Ref. 35) states that amounts of vitamin C in excess of the Recommended Dietary Allowance may cause rare adverse effects, but does not identify how far above the Recommended Dietary Allowance values adverse effects are observed. The adverse effects noted include gastrointestinal disturbances, iron overload in susceptible individuals, altered metabolism of certain drugs, precipitation of calcium oxalate kidney stones, altered absorption (both positive and negative) of several minerals, and interference with several laboratory tests. The review article cited as the source of this information (Ref. 112) concluded that, although the effects listed should be considered possible, consumption of supplemental vitamin C leads to no significant adverse health effects in humans in general, but nevertheless individuals who have a history of kidney stone formation and those who experience iron overload should exercise caution before using supplemental vitamin C.

The Diet and Health report (Ref. 36) recommends avoiding taking dietary supplements in excess of the Recommended Dietary Allowance in any one day. It states that several vitamins and minerals, if consumed in excess, can be toxic and cause numerous adverse health effects, but that there is no evidence that the public is harming itself by the use of low levels of supplements. This report did not discuss the possible adverse effects of vitamin C in detail, but instead reprinted a table from a review article in which the adult oral minimum toxic dose was estimated to be between 1 and 5 g. The NRC's "Recommended Dietary Allowances" 10th ed. (Ref. 113) stated that many persons habitually ingest 1 g. or more of ascorbic acid without developing apparent toxic manifestations, although a number of adverse effects have been reported.

Additionally, the LSRO report (Ref. 39) indicates that intakes of ascorbic acid of up to 1 g/day are well tolerated (Ref. 114). Occasionally, intakes above this may be associated with nausea and diarrhea. Ascorbic acid intakes of 4 g/day were used in a long-term intervention trial on rectal polyps without adverse effects in a population of adult men and women (Ref. 115).

FDA is not currently authorizing a health claim relating antioxidant vitamins and cancer. If such an authorization occurs in the future, these conclusions about vitamin C may be used in evaluation of its safety.

16. Some comments addressed the issue of possible iron overload as a result of high vitamin C intake. The comments stated that vitamin C added to foods can increase the amount of iron absorbed. These comments refer to a longstanding concern that persons carrying the genetic trait for idiopathic hemochromatosis, and perhaps also persons with the heterozygous trait, are at risk of earlier onset of the disease or more severe effects if the intake or bioavailability of dietary iron is increased. One comment, however, concluded that the effect, although likely to be insignificant in normal individuals, may be slightly greater in those who are heterozygous for the gene for hereditary hemochromatosis. This comment noted that an effect as great as doubling of iron stores might result, under very specific conditions of iron to ascorbic acid ratio in the food, from switching to a vitamin C-fortified food from a nonfortified food and continuing this practice for several years. Such a situation is presumably unlikely to occur frequently, making the potential impact on iron status much smaller.

FDA recognizes that the role of vitamin C in enhancing iron bioavailability under short-term test conditions is well established (Ref. 116). Studies in normal persons without the idiopathic hemochromatosis genetic trait show no increase in iron stores with chronic intakes of large amounts of supplemental ascorbic acid (Refs. 115 and 116). FDA, however, was not able to find similar studies in patients with hemochromatosis, and no such data were submitted as comments. Thus, the issue of safety of ascorbic acid intakes in enhancing iron uptake by hemochromatosis patients, and the dose-response relationship of ascorbic acid in this effect, cannot be resolved from current data.

17. A comment stated that FDA makes much of the need to determine precise intake levels of beta-carotene, vitamin C and vitamin E regarding potential benefits, but resorts to the broadest generalizations when it comes to possible detrimental actions of excessive intakes of vitamins. The comment pointed out that the amounts of vitamin C in diets recommended by the U.S. Department of Agriculture (USDA) and the National Cancer Institute exceed 200 mg, and that the situation is analogous for vitamin E.

FDA agrees that the proposed rule described the need to identify levels of antioxidant vitamins that are effective in reducing the risk of cancer, and that possibilities were discussed for adverse effects. The agency also is aware that current dietary patterns in the United States consistently result in average intake levels above current Recommended Dietary Allowances. The agency's discussions on effective intakes were presented because this issue can affect evaluations of safety. This information is also essential for determining qualifying criteria for foods bearing an authorized claim, and for deciding on the types of information needed to be included in a label statement. Estimates of current dietary intakes or intakes likely to occur if persons follow dietary guidelines are largely irrelevant to evaluating whether a nutrient/disease relationship exists.

IV. Decision Not to Authorize Health Claims Relating Antioxidant Vitamins and Cancer and to Authorize Health Claims Relating Substances in Fruits and Vegetables and Cancer

A. Scientific Evidence Regarding the Relationship between Antioxidant Vitamins and Cancer and Between Fruits and Vegetables and Cancer

FDA has reviewed numerous authoritative documents, including Federal Government reports, as well as recent research on diet and cancer risk. In addition, the agency considered all comments received in response to its proposed rule. The agency has concluded that the scientific evidence does not provide the basis for significant agreement among qualified experts that there is a relationship between antioxidant vitamins (specifically, beta-carotene, vitamin C and vitamin E) and a reduced risk of cancer. However, the publicly available scientific evidence does support an association between diets high in fruits and vegetables, which are good sources of two of the antioxidant vitamins (vitamin A as beta-carotene and vitamin C) and reduced risk of cancer.

Based on the scientific evidence in the proposed rule, the comments received, and new studies, FDA has reached the following decisions:

1. Vitamin E

Based on a review of the totality of the scientific evidence and comments received relative to the available evidence, FDA concludes that the data do not support a relationship of vitamin E to reduced risk of cancer and that there is not significant scientific agreement that vitamin E reduces the risk of cancer. Most studies on the possible protective effect of vitamin E have related plasma or serum levels of vitamin E (rather than fruit and vegetable consumption) to cancer risk. FDA recognizes that some evidence shows an association of low plasma/serum levels of vitamin E and reduced cancer risk, but finds that the inadequacies in the available data, as noted in the proposed rule (56 FR 60624), have not been adequately addressed by newer data; comments received in response to the proposed rule were not sufficiently convincing to reverse the proposed conclusion.

FDA recognizes that the animal and biochemical data provide a basis on which to hypothesize a protective effect by vitamin E (alpha-tocopherol) in humans, but the data from epidemiological studies, although providing some suggestion of an effect, are not sufficient to conclude that such effects are of importance in humans. Therefore, although vitamin E has been shown to have antioxidant effects in humans, the data are not sufficient to associate such effects with protection against cancer.

2. Beta-carotene

Based on a review of the totality of the scientific evidence and comments received relative to the available evidence, FDA concludes that data do not support the relationship of beta-carotene (provitamin A) to reduced cancer risk. FDA also concludes that there is not significant scientific agreement that beta-carotene reduces the risk of cancer. However, the available data show an association of consumption of fruits and vegetables and calculated beta-carotene intakes from these foods with reduced risk for some types of cancer. The scientific evidence is not sufficient to conclude that beta-carotene in these foods is responsible for the protective effect. Beta-carotene has been shown to protect against chemical carcinogenesis in some animal models, and the biochemical and mechanistic data provide a plausible scientific basis on which to hypothesize a protective effect in humans.

3. Vitamin C

In the proposed rule, FDA recognized that mechanistic and animal studies suggest that vitamin C may reduce the risk of cancer through the mechanism of inhibition of nitrosamine synthesis. Cancer of the stomach is the likely site of highest N-nitroso compound exposure, and is the site for which the data were the most complete. However, FDA found that the data available at the time of the proposed rule were not

sufficient to establish the relationship between inhibition of N-nitroso compound synthesis and stomach cancer in humans. FDA also recognized, in the proposed rule, that higher intakes of fruits and vegetables, higher calculated intakes of vitamin C, and increased blood levels of vitamin C are associated with lower risk of cancer of the stomach, and, more weakly, with cancers at other sites. New studies that are relevant to these issues are reviewed in previous sections of this document.

Epidemiological studies published since the review for the proposed rule further support the association of fruits and vegetables and calculated vitamin C intakes with protection against certain types of cancer, especially cancer of the stomach.

The studies showing the relationship of N-nitroso compounds (a class of compounds with known carcinogenicity) to stomach cancer provide evidence for a mechanism by which a specific vitamin C effect might occur for this and other cancers (e.g., esophageal and uterine cervical). Formation of N-nitroso carcinogens in the stomach would be expected to have the greatest effect at the site of production and greatest exposure, the stomach, and lesser effects at distal sites that require absorption and translocation of the putative carcinogen before an effect could occur. In animal test systems, preformed N-nitroso compounds are multitarget organ carcinogens. These conclusions are consistent with the conclusions of the recent LSRO review (Ref. 39).

When considered together, the different types of data are suggestive, but not conclusive, that vitamin C may be responsible for at least part of the reduction in risk of stomach cancer associated with consumption of diets high in fruits and vegetables. The evidence for specificity of vitamin C includes epidemiological associations of decreased risk with higher intakes of vitamin-C containing fruits and vegetables, clinical trials that show decreased concentrations of N-nitroso compounds after vitamin C supplements, and epidemiological associations of higher concentrations of N-nitroso compounds with higher risk of stomach cancer and precancerous pathology of the stomach. However, the N-nitroso compound data have not generally been validated as a basis for establishing a relationship between vitamin C and risk of stomach cancer in the U.S. population. At present there is not significant scientific agreement that this mechanism is an etiologic factor in stomach cancer risk in the United States, or that qualitative or quantitative changes in production and excretion of nitroso-compounds are a risk factor for stomach cancer.

In order to allow the issue of intermediate or surrogate markers (such as formation of N-nitroso compounds) for cancer risk to be more fully evaluated, FDA will be convening an advisory committee in the near future to make recommendations which can then be applied to evaluations of data for determining the scientific basis for health claims relating antioxidant vitamin intakes to cancer risk.

4. Fruits and vegetables

Dietary patterns that are low in fat and high in plant foods, including fruits and vegetables, are generally high in vitamin C and provitamin A (beta-carotene), and other nutrients such as dietary fiber, and are associated with a decreased risk of some types of cancer. The mechanisms responsible for this relationship are not known. Several factors could be important contributors to this protective effect. For example, fruits and vegetables are low in fat. FDA has reviewed the evidence supporting the relationship between low fat diets and reduced risk of cancer and has concluded that there is sufficient scientific evidence and significant scientific agreement among qualified experts to support this relationship. (See the final rule on health claims for lipids and cancer published elsewhere in this issue of the **Federal Register**). FDA is, therefore, authorizing a health claim for fat and cancer. Thus, one possible mechanism whereby fruits and vegetables may contribute to reduced cancer risk is through displacement of higher fat foods in a diet, with a net effect of reducing total fat intakes.

The subject of this final rule relates to the possible protective mechanism of vitamins with antioxidant functions in reducing cancer risk. Three antioxidant vitamins were considered: Beta-carotene, vitamin C and vitamin E. Fruits and vegetables are the major food source of beta-carotene (pro-vitamin A) and vitamin C in the U.S. diet. Vitamin E is more ubiquitously distributed, but some vegetable oils and whole grain products are significant sources. Fruits and vegetables are also good sources of dietary fiber. The possible protective role of dietary fiber in reducing cancer risk has been discussed in the final rule on health claims for dietary fiber and cancer published elsewhere in this issue of the **Federal Register**.

Finally, fruits and vegetables contain a number of nonnutritional substances (e.g., indoles, phenols, flavones, and terpenes) which have been hypothesized to be possibly protective against cancer risk through antioxidant or other functions. Fruits and vegetables also contain many carotenoid compounds in addition to beta-carotene, the carotenoid which has the greatest pro-vitamin activity. While the other carotenoids do not contribute significantly, if at all, to vitamin activity, they are antioxidants and, thus, may also provide a protective effect against cancer risk. The specific roles of these numerous, potentially protective substances in plant foods are not yet understood, and knowledge of their content in fruits and vegetables is lacking. Consequently, dietary intakes of these substances have not been estimated in human studies which show associations between fruit and vegetable intakes and cancer risk.

B. Conclusion Based on Scientific Evidence

In conclusion, while populations with diets rich in fruits and vegetables experience many health advantages, including lower rates of some types of cancers, it is not possible to specifically determine that the two antioxidant vitamins (i.e., beta-carotene and vitamin C) which are contained in fruits and vegetables are responsible for this effect, or to rule out the possibility of significant protective effects from nonmeasured components in these fruits and vegetables. Since many of these food substances (both nutritive and nonnutritive) coexist in fruits and vegetables, an observed correlation between a measured nutrient may be reflective of a "true" correlation between a coexistent, nonmeasured food substance. Currently, there is not significant scientific agreement as to whether the observed protective effects of fruit and vegetable consumption against cancer risk are due to a single or combined effect of the antioxidant vitamins and other nutrients with antioxidant functions (i.e., selenium), to other nutritive components of such foods (such as dietary fiber), to unmeasured components of such diets (for example, nonnutritive components such as carotenoids, indoles or flavonoids), or to displacement of other known risk components (such as fats and calories) within the total diet.

Thus, the conclusion that diets low in fat and high in fruits and vegetables (foods which are low in fat and are generally good sources of vitamins A and C and dietary fiber) are associated with a reduced risk of cancer, is consistent with the available scientific evidence.

Because dietary patterns which have high consumption of fruits and vegetables are not only low in fat but

can also be characterized by high intakes of dietary fiber and vitamins A and C, these nutrients can serve as useful markers for identifying the types of foods which contribute to a dietary pattern that is associated with a reduced cancer risk. Calculated intakes of vitamin C and vitamin A (often but not always identifying the fraction from beta-carotene) from diets high in fruits and vegetables have been correlated with reduced cancer risk. Although it is not known if it is the antioxidant vitamin components or some other components of these diets that provide the protective effects against cancer, these nutrients are characteristic of protective foods. Therefore, FDA is authorizing the use on labels and labeling of health claims regarding the association between diets low in fat and high in fruits and vegetables and a reduced risk of cancer with specific mention that these diets and foods are generally rich sources of vitamin A (as beta-carotene), vitamin C, and dietary fiber.

V. Rationale For Final Rule

A. Relationship and Significance sections

New § 101.78(a) is consistent with the conclusions reached in the science review that it is fruits and vegetables which relate to the reduced risk of cancer, not the antioxidant vitamins per se. Yet, because of the usefulness of vitamins A (as beta-carotene) and C and dietary fiber in identifying fruits and vegetables most likely to correlate with reduced cancer risk, these nutrients are specifically identified as being characteristic of the protective dietary pattern. Any one or a combination of these three nutrients can serve as the identifying marker. Since fruits and vegetables are also characterized by their absence of fat, and because of the identified relationship of low fat diets to reduced risk of cancer, this also is required to be a characterizing nutrient for the type of dietary pattern associated with decreased cancer risk. Other components of the relationship statement, for example, risk factors, have been indicated, similar to other authorized health claims.

In new § 101.78(b), on the significance of the relationship between consumption of diets low in fat and high in fruits and vegetables and reduced risk of cancer, the summary includes the information that U.S. diets tend to be high in fat and low in fruits and vegetables. Discussion of current dietary guidelines on recommended servings of fruits and vegetables, and dietary fiber intakes are also given. Because of the coexistence of all of these nutrients in fruits and vegetables, and because all have been associated with reduced risk of cancer, all four nutrients are indicated. Because the mechanism of the protective effect is not known and because it is not known which of these nutrients is effective, or if some combination of these nutrients is effective, the health claim is focused on fruits and vegetables as a product class and their relationship to cancer risk.

B. Nature of the Claim

In § 101.78(c)(2)(i), FDA is authorizing health claims relating substances in diets low in fat and high in fruits and vegetables to reduced risk of cancer. In new § 101.78(c)(2)(i)(A), the agency is requiring, similar to other authorized claims, that the relationship be qualified with the terms "may" or "might." These terms are used to indicate that not all persons will necessarily benefit from these dietary changes. In new § 101.78(c)(2)(i)(B), the agency, consistent with other authorized claims, is requiring that the claim not indicate that all cancers may be affected, but rather that the risk of "some types of cancer" or "some cancers" may be reduced. The relationship of dietary factors to various types of cancers appears to be variable; in many cases, the available data are inadequate to specifically identify which cancers will be affected.

In new § 101.78(c)(2)(i)(C), the agency is requiring that the claim characterize fruits and vegetables as foods that are low in fat and contribute vitamin A, vitamin C, and dietary fiber to the diet. All four nutrients must be identified as characteristic of this dietary pattern. As noted in the conclusions reached from the available scientific evidence, it is not known what substances in fruits and vegetables are responsible for their protective effect. The best documented relationship is for fat and cancer. Roles for dietary fiber and vitamins A and C have been speculated and intakes of these nutrients from fruits and vegetables are correlated with cancer risk. By requiring that all characterizing nutrients be identified as characteristic of dietary patterns rich in fruits and vegetables without specifically attributing reduced cancer risk to a single nutrient, the claim is consistent with the current scientific knowledge. The claim should also minimize consumer confusion, since its wording is similar to current dietary guidelines from the U.S. Government, including the National Cancer Institute. New § 101.78(c)(2)(i)(D) requires the claim to specify that the food bearing the claim contains at least one of the following: Dietary fiber, vitamin A, or vitamin C. This statement is required in order to identify the contribution of the labeled food to the diet in an accurate and nonmisleading manner. Only those nutrients for which the labeled food qualifies as a good source under § 101.54 may be identified in the health claim. Although the regulation does not restrict the manner in which these nutrient levels may be described, terms used must be consistent with other labeling regulations.

In new § 101.78(c)(2)(i)(E), FDA, consistent with other authorized health claims, is prohibiting the attribution of a specific reduction in risk to diets low in fat and high in fruits and vegetables. In new § 101.78(c)(2)(i)(F), (c)(2)(i)(G), (c)(2)(i)(H), and (c)(2)(i)(I), FDA is prohibiting, similar to other authorized health claims, more specific use of dietary terms than is warranted by the current state of the scientific evidence. These requirements also standardize use of these terms, thus minimizing consumer confusion as they compare food labels across products, or as they compare a health claim to the nutrition information panel. Section 101.78(c)(2)(i)(J) requires that health claims indicate that development of cancer is dependent on many factors. This requirement is intended to prevent consumers from being mislead that fruit and vegetable intake is the only factor connected with cancer risks.

C. Nature of the Food

New § 101.78(c)(2)(ii)(A) requires that the food bearing the authorized health claim be or contain a fruit or vegetable. Because the claim relates to diets high in those foods, it would not make sense for it to appear on the labeling of another type of food. A health claim that appears on a food that meets all the requirements in § 101.78(c)(2)(ii) but contains only a trivial amount of fruit or vegetables could be considered misleading and might misbrand the food under section 403(a) of the act.

FDA, consistent with the requirements for the health claim on fat and cancer (published elsewhere in this issue of the **Federal Register**), is requiring in new § 101.78(c)(2)(ii)(B) that foods bearing the authorized health claim be "low fat" foods or, alternatively, belong to a class of products that is "low in fat." Low fat diets are associated with reduced cancer risks. Low or negligible fat is also one of the characterizing nutrients for diets rich in fruits and vegetables. Since the effect of fat is not readily separated from the effect of other nutritive components of fruits and vegetables, it is required to be included as a qualifying nutrient.

In new § 101.78(c)(2)(ii)(C), FDA is requiring that fruits and vegetables bearing the health claim meet requirements for a "good source" (greater than or equal to 10 percent of the Reference Daily Intake (RDI)) for vitamin A and vitamin C, and greater than or equal to 10 percent of the Daily Reference Value (DRV) for dietary fiber. The requirement that these nutrients be present at 10 percent of the RDI or DRV is being established as a specific alternative to the 20 percent (i.e., "high") requirement for qualifying nutrients in the final rule on general requirements for health claims published elsewhere in this issue of the **Federal Register**. (See § 101.14(d)(2)(vii)). This alternate level was deemed useful to assure that most fruits and vegetables would be eligible for this health claim, because fruits and vegetables in general are the product class for which correlations with reduced cancer risk have been observed as opposed to specific fruits and vegetables. Moreover, as a product class, fruits and vegetables are significant sources of vitamins A and C and fiber in the U.S. dietary pattern. Without this alternative level very few fruits and vegetables would qualify for the health claim. This seems contrary to the available evidence and to the purpose of health claims.

This section also requires that the qualifying nutrients be based on "natural" levels in foods. This means that foods which require modification, for example, fortification with vitamins A or C or dietary fiber, in order to meet the qualifying criteria for the health claim, cannot bear the claim. This requirement is consistent with the scientific basis for the claim; that is, that fruits and vegetables in their native form correlate with reduced cancer risk. Since there are not sufficient data to specifically identify vitamins A and C and dietary fiber as causal, and because these nutrients are being used as markers for the substance(s) in fruits and vegetables that provide the observed effect, it is the native nutritional composition of the foods that identifies their usefulness. At the same time, this requirement does not prohibit fortification of qualifying foods with the characterizing nutrients, once the qualifying criteria have been met.

D. Optional Information

Under new § 101.78(d), similarly to other authorized health claims, health claims may identify additional risk factors for cancer. The regulation specifies the factors that may be listed; all are risk factors about which there is general scientific agreement. This additional information can provide a context that is useful for an understanding of the relationship of the diet to the disease, but, manufacturers are cautioned that it should not be presented in a way that is misleading to the consumer. A health claim may also indicate that reductions in fat intake and consumption of fruits and vegetables are part of a total dietary pattern that is consistent with the latest "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 40) published jointly by the USDA and the Department of Health and Human Services (DHHS). Consistent with other health claim regulations, the claim may also include information on the prevalence of cancer in the United States. In order to ensure that this information is valid, the agency is requiring that it come from one of three specified authoritative sources.

Additionally, for the health claim relating substances in diets high in fruits and vegetables to reduced risk of cancer, the agency is allowing the use of the term "beta-carotene" in addition to the term vitamin A in listing nutrients that are characteristic of the protective dietary pattern. Beta-carotene is the form of the vitamin which has antioxidant functions. Therefore, the use of this term is consistent with a possible mechanism of action. On the other hand, if, after a food meets the qualifying criteria for a health claim, the food is fortified with vitamin A (as retinyl palmitate or another form of preformed vitamin A rather than with beta-carotene), then it would be misleading to indicate that its vitamin A content is primarily beta-carotene. Thus, FDA is permitting the term beta-carotene to be used in the claim only when the vitamin A in the food bearing the claim is beta-carotene.

E. Model Health Claims

In new § 101.78(e)(1) and (e)(2), FDA is providing several model health messages to help manufacturers understand the requirements of new § 101.78 and to help them understand the type of health claim that FDA considers to be appropriate. FDA is not prescribing specific language for claims, but certain elements are required, and these models include the required elements.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's disucssion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food lableing final rules. The final RFA will be placed on file with the dockts Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitues a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

VIII. References

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List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6, of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.71 is amended by adding new paragraph (d) to read as follows:

§ 101.71 Health claims: claims not authorized.

* * * * *

(d) Antioxidant vitamins and cancer.

3. New § 101.78 is added to subpart E to read as follows:

§ 101.78 Health claims: fruits and vegetables and cancer.

(a) *Relationship between substances in diets low in fat and high in fruits and vegetables and cancer risk.* (1) Cancer is a constellation of more than 100 different diseases, each characterized by the uncontrolled growth and spread of abnormal cells. Cancer has many causes and stages in its development. Both genetic and environmental risk factors may affect the risk of cancer. Risk factors include a family history of a specific type of cancer, cigarette smoking, alcohol consumption, overweight and obesity, ultraviolet or ionizing radiation, exposure to cancer-causing chemicals, and dietary factors.

(2) Although the specific roles of the numerous potentially protective substances in plant foods are not yet understood, many studies have shown that diets high in plant foods are associated with reduced risk of some types of cancers. These studies correlate diets rich in fruits and vegetables and nutrients from these diets, such as vitamin C, vitamin A, and dietary fiber, with reduced cancer risk. Persons consuming these diets frequently have high intakes of these nutrients. Currently, there is not scientific agreement as to whether the observed protective effects of fruits and vegetables against cancer are due to a combination of the nutrient components of diets rich in fruits and vegetables, including but not necessarily limited to dietary fiber, vitamin A (as beta-carotene) and vitamin C, to displacement of fat from such diets, or to intakes of other substances in these foods which are not nutrients but may be protective against cancer risk.

(b) *Significance of the relationship between consumption of diets low in fat and high in fruits and vegetables and risk of cancer.* (1) Cancer is ranked as a leading cause of death in the United States. The overall economic costs of cancer, including direct health care costs and losses due to morbidity and mortality, are very high.

(2) U.S. diets tend to be high in fat and low in fruits and vegetables. Studies in various parts of the world indicate that populations who habitually consume a diet high in plant foods have lower risks of some cancers. These diets generally are low in fat and rich in many nutrients, including, but not limited to, dietary fiber, vitamin A (as beta-carotene), and vitamin C. Current dietary guidelines from Federal Government agencies and nationally recognized health professional organizations recommend decreased consumption of fats (less than 30 percent of calories), maintenance of desirable body weight, and increased consumption of fruits and vegetables (5 or more servings daily), particularly those fruits and vegetables which contain dietary fiber, vitamin A, and vitamin C.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met.

(2) Specific requirements. (i) *Nature of the claim.* A health claim associating substances in diets low in fat and high in fruits and vegetables with reduced risk of cancer may be made on the label or labeling of a food described in paragraph (c)(2)(ii) of this section, provided that:

(A) The claim states that diets low in fat and high in fruits and vegetables "may" or "might" reduce the risk of some cancers;

(B) In specifying the disease, the claim uses the following terms: "some types of cancer", or "some cancers".

(C) The claim characterizes fruits and vegetables as foods that are low in fat and may contain vitamin A, vitamin C, and dietary fiber;

(D) The claim characterizes the food bearing the claim as containing one or more of the following, for which the food is a good source under § 101.54: dietary fiber, vitamin A, or vitamin C;

(E) The claim does not attribute any degree of cancer risk reduction to diets low in fat and high in fruits and vegetables;

(F) In specifying the fat component of the labeled food, the claim uses the term "total fat" or "fat";

(G) The claim does not specify types of fats or fatty acids that may be related to risk of cancer;

(H) In specifying the dietary fiber component of the labeled food, the claim uses the term "fiber", "dietary fiber", or "total dietary fiber";

(I) The claim does not specify types of dietary fiber that may be related to risk of cancer; and

(J) The claim indicates that development of cancer depends on many factors.

(ii) *Nature of the food.* (A) The food shall be or shall contain a fruit or vegetable.

(B) The food shall meet the nutrient content requirements of § 101.62 for a "low fat" food.

(C) The food shall meet, without fortification, the nutrient content requirements of § 101.54 for a "good source" of at least one of the following: vitamin A, vitamin C, or dietary fiber.

(d) *Optional information.* (1) The claim may include information from paragraphs (a) and (b) of this section, which summarize the relationship between diets low in fat and high in fruits and vegetables and some types of cancer and the significance of the relationship.

(2) The claim may identify one or more of the following risk factors for development of cancer: Family history of a specific type of cancer, cigarette smoking, alcohol consumption, overweight and obesity, ultraviolet or ionizing radiation, exposure to cancer-causing chemicals, and dietary factors.

(3) The claim may use the word "beta-carotene" in parentheses after the term vitamin A, provided that the vitamin A in the food bearing the claim is beta-carotene.

(4) The claim may indicate that it is consistent with "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Agriculture (USDA) and the Department of Health and Human Services (DHHS), Government Printing Office.

(5) The claim may include information on the number of people in the United States who have cancer. The sources of this information must be identified, and it must be current information from the National Center for Health Statistics, the National Institutes of Health, or "Nutrition and Your Health: Dietary Guidelines for Americans," USDA and DHHS, Government Printing Office.

(e) *Model health claims.* The following model health claims may be used in food labeling to characterize the relationship between substances in diets low in fat and high in fruits and vegetables and cancer:

(1) Low fat diets rich in fruits and vegetables (foods that are low in fat and may contain dietary fiber, vitamin A, and vitamin C) may reduce the risk of some types of cancer, a disease associated with many factors. Broccoli is high in vitamins A and C, and it is a good source of dietary fiber.

(2) Development of cancer depends on many factors. Eating a diet low in fat and high in fruits and vegetables, foods that are low in fat and may contain vitamin A, vitamin C, and dietary fiber, may reduce your risk of some cancers. Oranges, a food low in fat, are a good source of fiber and vitamin C.

Dated: November 3, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

Note: The following tables will not appear in the annual Code of Federal Regulations.

BILLING CODE 4160-01-F

TABLE 1

Human Studies. Antioxidant Vitamins and Cancer Through March 1, 1992

Study	Study Design	Subjects	Methods	Results	Comments
Basu et al., 1991. (Ref. 9)	Clinical survey of 75 subjects attending a referral clinic in the Bronx, New York for evaluation of abnormal screening Pap smear.	30 women with no cervicitis on pap smear, 45 women with histopathologically diagnosed dysplasia.	Pap smears, papilloma virus screening, age, parity, last menstrual period, contraceptive practice and duration, number of cigarettes per day and duration in years obtained from each patient. Venous sample obtained for micronutrient analysis: ascorbic acid, beta-carotene and retinol. Ascorbic acid levels were significantly lower in smokers, regardless of cervical status or detection of human papilloma virus infection.	Analysis directed at serum antioxidant levels in smokers versus nonsmokers. After dividing smokers and nonsmokers into groups, there was no significant difference in ascorbic levels in the women with cervical dysplasia and those without. Although not noted in the paper the serum retinol level was lower in smokers with cervical dysplasia than those without and serum beta-ccarotene levels were lower in smokers with cervical dysplasia than those without.	The study group was small, and both cigarette smoking and antioxidant level are continuous variables. The results do not show a significant association between cervical dysplasia and serum antioxidants.
Benito et al., 1991. (Ref. 10)	Case--control study; colorectal cancer in Majorca, Spain.	Cases - 286 histologically confirmed colorectal cancer cases, diagnosed between July 1984 and Feb. 1988 Controls--295 population controls and 203 hospital controls. Both cases and controls had to be residents of Majorca for previous 10 years.	A food frequency questionnaire with data on 99 food items was used. Average frequency of consumption in previous year assessed. Local food consumption tables used to estimate intake. Age, sex, weight 10 years prior to interview, meals per day, education in years, occupation, and physical activity in workplace (surrogate for energy expenditure) were used in regression model.	There was no significant association between the risk of either colon or rectal cancer and level of vitamin A, retinol, carotene, vitamin C, or vitamin E intake.	Based on the significant inverse association between fiber from legumes and folic acid in cruciferous vegetable, the findings support a recommendation for diets high in vegetables, along with a healthy lifestyle including moderate intake of calories and adequate physical activity.

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Boeing and Frentzel-Beyme, 1991. (Ref. 19)	Environmental epidemiology study of stomach cancer; multicenter, hospital-based, case-control study in high- and low-risk areas for stomach cancer in Federal Republic of Germany.	An area with high stomach cancer mortality rate was compared with another area with a low rate. During the 2-year study period, 143 stomach cancer cases and 579 controls completed the interview.	Dietary information by recall was assessed for the last 5 years before onset of the disease. All interviews were coded by one person. Data were obtained on vitamin C intake, source of water supply, years of refrigerator use, and use of spruce for smoking meat at home. Risk estimates were obtained by unconditional logistic regression methods.	A low intake of vitamin C relative risk (RR) = 2.32, 95% confidence interval (CI) 1.22 to 4.43 for lowest against highest quintile), noncentralized water supply (RR = 2.17, CI 1.14 to 4.13 against central water supply), refrigerator use for less than 25 years (RR = 1.33, CI 0.82 to 2.15 against more than 30 years, and use of spruce for smoking (RR= 3.33, CI 1.56 to 71.2) against not smoking meat at home), were identified as factors possibly causally related to stomach cancer occurrence.	The results are consistent with the hypothesis that increased intake of vitamin C reduces the risk of stomach cancer by inhibiting nitrosation reactions in the stomach, or by decreasing the carcinogenicity of putative carcinogens in smoke (especially polyaromatic hydrocarbons and nitrosamines). Also, the data implicate possible sources of carcinogens or carcinogen precursors (smoked meat and local water supply) in the occurrence of stomach cancer.
Bravo et al., 1991. (16)	Case-control study, Madrid, Spain prostatic cancer	Cases-90 men with histologically diagnosed prostatic carcinoma between January 1983 and December 1987. Controls-180 male hospital patients with illnesses other than urologic disease or a primary tumor. Stratified by age and date of admission.	Standardized questionnaire covering occupation, medical, socioeconomic history, dietary factors including types and amounts of food eaten. Diet classified into five types; normal, rich in animal fat, rich in vegetable fat, deficient in vitamin A, and deficient in vitamin C. Food composition based on Madrid data. Odds ratio (OR) for diet, obesity and prostatic cancer calculated.	This study found no association between a diet deficient in vitamins A or C and the risk of prostatic cancer. The relationship between intake of vegetable fats and prostatic cancer was also not significant.	The diet of central Spain is rich in fruits and vegetables. It is possible that even the lowest quintile of intake for fruits and vegetables in Mediterranean areas are relatively high in relation to other cuisines. The results of this study may not be generalizable.
De Mesquita, et al., 1991. (Ref.15)	Case-control; Netherlands; Pancreatic (exocrine) cancer; study conducted 1984 to 1988	164 cases (surrogates interviewed for 50% males and 46% females); 480 controls (surrogates interviewed for 34% males and 26% females)	Interview using dietary questionnaire containing 116 food items; dietary assessment covered year before interview; 68% of cases were histologically confirmed; others diagnosed clinically.	Adjusted for smoking and total calories: Daily consumption of vegetables statistically significant Inverse association between intake of fresh vegetables, cooked cruciferous vegetables and pancreatic cancer.	Daily consumption of vegetables show a protective effect; large percentage of proxy interview of cases introduces bias

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Enstrom et al., 1992. (Ref. 1)	Population data base analysis, National Health and Nutrition Examination Survey (NHANES I) data and a median of 10 years of prospective followup mortality.	11,348 men and women, aged 25 to 74 years at time of NHANES I survey, wit a total of 1,809 deaths during the followup period.	Comprehensive nutritional status survey that included clinical, biochemical and dietary methods. The population was allocated into three groups: intake 50 <mg/day without supplements, intake ≥50 mg/day without supplements, and ≥50 mg/day with supplements. Followup mortality rates determined in total and for several specific causes, including cancer and heart disease.	Higher dietary intakes of ascorbic acid were associated with significant reduction total mortality rate and in the mortality from heart disease. These effects were enhances by supplements. The standardized mortality rate from cancer (total for all sites) was a nonsignificant 0.78 with supplemental ascorbic acid. In contrast with the results for total mortality and heart disease mortality, the results with cancer mortality were not significant because the standardized mortality rate was not a low and because the cohort size was decreased (heart disease produced approximately 40 percent of the total mortality, whereas cancer produced less than 25 percent).	These results do not provide support for a reduction in risk of any type of cancer by ascorbic acid. They cannot be interpreted, however, as contradicting that possibility. The mortality rate from cancer was not reduced as much with elevated vitamin C intake as were the total and heart disease rates, and the cohort size was substantially smaller. Any protective effect of vitamin C at one cancer site may have been masked by no effect at other sites, with the overall rate being apparently changed by a substantial but nonsignificant amount (22 percent) in a protective direction.
Gerber et al., 1991. (Ref. 5)	Montiplier, France observation of blood and cellular antioxidant levels in breast cancer cases and hospital controls	Cases: 48 women inpatients for breast cancer. Controls: 50 women first admission inpatient neurology without cancer or circulatory disease.	Blood levels of zinc, copper, selenium, vitamins E and C measured. Cellular levels of selenium, vitamins E and C evaluated in most subjects. Subject identity codes used.	Significantly higher mean levels of vitamin E, total cholesterol and E/total cholesterol ratio found in breast cancer cases than in controls. Effect lost when vitamin pill users excluded, except vitamin E. Leukocyte vitamin E level also significantly higher. Serum Zinc level sign higher. Elevated leukocyte vitamin C in cases borderline sign. Mean leukocyte vitamin E level sign after vitamin pill users excluded.	Sample size small. Elevated plasma vitamin E, leukocyte vitamin E, serum Zinc in breast cancer cases hypothesized to relate to facilitation of certain tumor growth by these antioxidants suggesting effect ultimately related to metabolic alteration. Future studies need to correlate tumor antioxidant level to resistance (chemo or natural) and tumor antioxidant level to blood level.

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Graham et al., 1991 (Ref. 3)	Case-control; New York; Postmenopausal breast cancer	439 incident cases; 494 age-matched community controls	Interview using dietary questionnaire on 172 foods; diet assessed 2 years before interview; all cases were histologically confirmed; results adjusted for age, education, age at first pregnancy, number of pregnancies, age at menarche, relative with breast cancer, and benign breast disease.	Cases and controls consumed same number of calories. Dietary carotene, vitamin C protective but no effect shown for supplement use; dietary fiber borderline protective RR = 0.7 (0.5 to 1.1); adjustment for total calories did not change results. Cases ate less of 10 fruits and vegetables in questionnaire.	Low participation rates may introduce bias: 56% of eligible cases and 46% of eligible controls participated in study, thus may not be able to generalize the results.
Gridley et al., 1992. (Ref. 13)	A population-based case-control study of oral and pharyngeal cancer, conducted during 1984 to 1985 in four areas of the United States.	The subjects included 1,262 controls and 1,114 oral and pharyngeal cancer cases.	Interview were administered to obtain information on demographic variables, tobacco and alcohol use, diet, occupation, and medical history. Vitamin supplement use questions addressed years of use, age started, types of multivitamin products used (including brand) and uses of single nutrient supplements, vitamin shots obtained, and mineral products used.	Use of supplements was significantly associated with reduced risk of oral cancer. Use of supplements was associated with being female, white, more highly educated, being a California resident, having a lower body mass, and consuming more fruits and vegetables. Protracted use did not increase the apparent effects of supplements on cancer risk. Users of supplements of individual vitamins, including A, B-complex, C and E were at lower risk after controlling for effects of tobacco, alcohol and other risk factors. After adjustment for use of other supplements, vitamin E supplementation was the only one that remained associated with reduced risk.	It is not clear that the lower risk among consumers of vitamin E supplements was due to the vitamin itself, because the finding are also associated with higher intakes of fruits and vegetable among supplement users. The findings are consistent with evidence from experimental animals, and should prompt further research on vitamin E in reducing the risk of cancer.

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Harris et al., 1991. (Ref. 12)	Case-control study during the year before diagnosi. with cancer in Oxford, U.K.	The subjects included 96 men with lung cancer, 75 men with other epithelial cancers, and 97 hospital controls.	Interviews were conducted within 1 year of diagnosis by one experienced interviewer who was the same for all subjects. The interviewer was not blinded about diagnosis. The questionnaire covered smoking history and usual dietary intake during the year preceding diagnosis. The known carotene values for the foods are for beta-carotene.	Calculated mean dietary intakes of beta-carotene were 24% lower for lung cancer cases than for controls, 10% lower for other epithelial cancer cases than for controls. Serum concentrations of beta-carotene, retinol, and vitamin E were lower in the cancer patients than in the controls by 58, 30, and 31 percent, respectively, for lung cancer, and 33, 11, and 14 percent, respectively for other epithelial cancer cases. The OR's were less than 1.0 in the two upper thirds of dietary carotene, with the trends having borderline significance. The OR's for intakes of fruits and vegetables were rather irregular, and the associated trends were weaker than the trends for beta-carotene.	The period of concern in the recall was the year prior to diagnosis, a time. By comparison, cases in the 2-year period following sampling or interview are often excluded from prospective studies because differences may be caused by the cancer. The results suggest that beta-carotene is protective against epithelial cancers, including lung cancer.
Herrero et al, 1991. (Ref. 8)	Case-control study multiple sites in Mexico, Central America, and Colombia.	748 cases invasive cervical cancer, 1,411 inpatient controls from neurology wards at these sites.	Assessment of consumption of 58 foods, including major sources of vitamin A, C, carotenoids, and folacin as well as medical and behavioral characteristics related to cervical cancer. Adjusted for age, study site, sexual and reproductive history, socioeconomic status, screening practice, and detection of human papilloma virus.	Slightly lower risk for highest quartiles of consumption of fruit and fruit juice. Risk of cervical cancer not reduced in groups with highest consumption vegetables, foods of animal origin, complex carbohydrates, legumes, or folacin-rich foods. Evaluation of nutrient indices identified decreased risk associated with vitamin C, beta carotene, other carotenoids. Including vitamin C and beta carotene in the same model attenuated the association for beta carotene, but not for vitamin C.	Results consistent with other studies that support a protective effect of nutrients in fruits and vegetables against the development of invasive cervical cancer, however specific category of nutrient responsible not readily apparent. Associations were driven by relationships between diet and cervical cancer at two study sites. Higher socioeconomic status of subjects at these sites leaves open possibility of selection bias or an unidentified dietary pattern.

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Knight et al., 1991. (Ref. 27)	Clinical trial of nitrosation of L-proline load by diet-derived nitrate, and inhibition by dietary ascorbic acid.	The first study had 16 subjects of both sexes, aged 23 to 56 years, all nonsmokers. The second study had 19 females aged 20 to 28 years, including 5 smokers. All subjects avoided known sources of the nitrosation product and vitamin supplements for 72 hours before test meal consumption.	Test Meal 1 was designed to supply a high level of dietary nitrate (172 mg/meal) accompanied by relative low levels of ascorbic acid (24 mg/meal). Test Meal 2 consisted of the same items as Test Meal 1, with the addition of foods rich in ascorbic acid (340 mg/meal). The nitrate level of Test Meal 2 was 197 mg. Both test meals contained 2.4 g dietary proline. In the first study, nitrosation was determined after consumption of low ascorbic acid meal (Test Meal 1) and, a week later, after consumption of the same meal with 500 mg of added L-proline. In the second study, all subjects had nitrosation determined with added proline, first with the low ascorbic acid meal and then a week later with the high ascorbic acid meal. Urine was collected for 24 hours after each test meal, and assayed for nitrosoproline (NPRO) and nitrate.	In the first study, the background excretion of NPRO was increased by addition of free L-proline. In the second study, a lower excretion of NPRO occurred with the high ascorbic acid meal. This occurred despite a slightly 13 higher nitrate intake from Test Meal 2, compared with that from Test Meal 1. Some subjects (Subgroup A) had a low NPRO excretion after Test Meal 1, this level was maintained with Test Meal 2. Subgroup B had high excretion of NPRO after Test Meal 1, and this was strongly decreased after Test Meal 2, containing high ascorbic acid foods.	Six subjects showed no change in NPRO after consumption of a test meal containing rich sources of ascorbic acid. These had low NPRO excretions with the low ascorbic acid meal. 13 subjects had much higher levels of NPRO excretion after the low ascorbic acid meal, but this was strongly inhibited by the inclusion of rich ascorbic acid sources in the meal, even though the ascorbic acid sources contributed some additional nitrate. The data suggest that not all individuals synthesized NPRO in vivo from the ingested precursors, and those who did not were the subjects who failed to show ascorbic acid inhibition of NPRO excretion. It was concluded that a normal western diet with plentiful content of fresh vegetables can provide sufficient nitrate to result in endogenous nitrosation, and that this process is substantially inhibited by inclusion of ascorbic acid rich foods.

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Knekt et al., 1991. (Ref. 11)	Prospective cohort, 20-year followup for lung cancer in cancer free Finnish men.	4,538 cancer free men ages 20 to 69, baseline examination 1966 through 1972.	Dietary history estimated based on total habitual intake for previous year. Intake of antioxidant vitamins based on previously published analyses of Finnish foods.	Inverse relationship between intake of vitamins A, E, and C and incidence of lung cancer in nonsmokers. Relative risk between lowest and highest tertile of intake 2.5, 3.1 and 3.1 respectively. Inverse gradient between yellow, green and red vegetables (source of carotenoids) and lung cancer. No inverse gradient between preformed vitamin A and lung cancer. Strong inverse association for margarine intake (source of tocopherol) and incidence of lung cancer; significant inverse gradient for fruit intake (vitamin C source) despite low intake in this cohort.	Misclassification of intake and changes in intake were possible over followup, especially supplement use. Other substances in foodstuffs rich in antioxidant vitamin (e.g., terpenes, flavones, and phenols) may be anticarcinogenic. Studies needed on dietary patterns, intake levels, and protective effects of other constituents of diets.
Knekt et al., 1991. (Ref. 18)	A nested case-control study of serum micronutrients and cancers of low incidence in Finland.	The subjects were a total of 115 cases of cancer in 8 anatomical location categories (9 to 20 cases in each category) and 211 controls.	The site of primary cancer and date of diagnosis obtained from the cancer registry were linked to data obtained in the health examination data. Serum concentrations were determined form alpha-tocopherol, beta-carotene, retinol, retinol-binding protein, and selenium.	The crude mean level of serum alpha-tocopherol was 30% lower in persons with melanoma than in controls. The laryngeal and esophageal cases had alpha-tocopherol levels that were nonsignificantly lower. Accordingly for alpha-tocopherol, the relative risks of melanoma and was 0.2 (significant) and for cancers of the larynx and esophagus, 0.48 and 0.39 (nonsignificant). For beta-carotene, the relative risk of melanoma was 0.03 (highly significant).	Only melanoma patients had significantly lower serum alpha-tocopherol and beta-carotene levels than controls. Because the numbers of cases were small, no strong conclusions can be drawn from the results until they are confirmed in studies based on larger cohorts or on pooled data from several small samples.

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Potischman et al.. 1991. (Ref. 7)	Case-control study 4 Latin American nations.	387 cases of invasive cervical cancer, 670 hospital controls.	Serum levels of eight micronutrients measured in cases and controls. Stage 1 and 2 cancer patients only included to minimize effects of disease on serologic markers.	Intake of retinol, cryptoxanthin, lycopene, alpha carotene, lutein and alpha tocopherol did not significantly differ between cases and controls. After adjustment for age, study site, sex and reproductive history, socioeconomic status, and papilloma virus higher serum beta carotene and gamma tocopherol levels associated with decreasing risk of disease.	Serum beta-carotene level constant as disease progressed, arguing against effect of disease progression on nutrient value, while gamma tocopherol level was higher in cases and progressed with disease. In this study dietary and serum effects of beta carotene concordant, both parameters indicate a possible association between intake of beta carotene and reduced risk of invasive cervical cancer.
Reed et al., 1991. (Ref. 26)	Clinical observations and ascorbic acid trial in patients at high-risk for stomach cancer.	Sixty-two English men and women with either atrophic gastritis, pernicious anemia (PA), partial gastrectomy, or vagotomy; ages ranged from 38 to 77 years.	Serum ascorbic acid and gastric juice nitrite and total extractable N-nitroso compounds were determined before treatment, weekly during 4 weeks of ascorbic acid treatment (4 g/day) and for 4 weeks after discontinuation of treatment. All patients consumed their normal diets, but avoided vegetable and fruit juices during the experiment.	Many patients had low baseline serum levels of ascorbic acid, and compliance with treatment was confirmed by a marked rise during treatment. The levels were still high 4 weeks after the patients had been instructed to stop taking ascorbic acid, implying that many of them had not discontinued treatment. Baseline levels of N-nitroso compounds were high in all groups compared with the levels previously found in normal controls, but a highly significant decrease was observed during treatment with ascorbic acid in all groups except those with PA. Treatment produced a marked decrease in gastric juice nitrite levels in all groups except those with PA.	These data support the conclusion that high-dose ascorbic acid treatment reduces the intragastric formation of nitrite and N-nitroso compounds.

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Riboli et al., 1991. (Ref. 2)	Case-control; Spain; Bladder cancer	432 cases (all males); 792 controls; two sets of controls: population-based and hospital-based	Interview using dietary questionnaire containing 60 food groups; dietary assessment covered year before interview. Cases histologically confirmed.	Adjusted for smoking and total calories, a higher vitamin E intake was associated with a marginally significant reduction in risk of bladder cancer. No association found for retinol or carotene intake.	Slightly low participation rates (cases: 72% and controls: 71% hospital and 66% population); results possibly biased by inclusion of 208 prevalent cases who may represent survivors of bladder cancer.
Richardson et al., 1991. (4)	Case-control; France; Pre- and Postmenopausal breast cancer	409 incident cases; 515 hospital controls (348 premenopausal and 575 postmenopausal for total study population)	Interview using dietary questionnaire on 55 foods; current diet assessed, but if changed over past 12 months, former diet was used; all cases were histologically confirmed; results adjusted for age, menopausal status, family history of breast cancer, history of benign breast disease, alcohol consumption, and age at menarche.	Antioxidant vitamin intake had no significant effects on risk of breast cancer in premenopausal women and postmenopausal women; however, fruits rich in beta-carotene had a marginal protective effect (RR=1.4, CI=1.0-2.0) on breast cancer in this same group. In post-menopausal women retinol had a marginal protective effect (OR 1.8, CI=1.2-2.8), Beta-carotene and vitamin E intake had no significant effects on risk of breast cancer.	Study adds support to the hypothesis that fruit consumption may have a slight protective effect against breast cancer in all women (both premenopausal and postmenopausal women).

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Shi et al., 1991. (Ref. 22)	Case-control study in Shanghai, China comparing urinary ascorbic acid and nitrate in patients with gastric cancer and normal controls; urine mutagenicity in normal controls, dysplasia and gastric cancer; and gastric juice N-nitroso compounds in controls, chronic atrophic gastritis, and dysplasia/gastric cancer patients.	Thirty cases of gastric cancer were selected and paired with dysplastic patients and normal controls of the same sex and age group.	All cases were diagnosed by endoscopy. Urinary ascorbic acid and nitrate were determined chemically. Urine mutagenicity was determined in the Ames test using Salmonella typhimurium TA98 and TA100 strains, each with and without an activating S9 fraction. Four individual and the total N-nitroso compounds were chemically assayed in gastric juice.	The reduced ascorbic acid content of urine was lower in the gastric cancer group than in normal controls, while the content of nitrate was significantly higher in the cancer patients than in the controls. No mutagenicity was seen in the urines of the controls, whereas a low fraction of the urines from the dysplasia patients and a high fraction of the urines from the gastric cancer patients were mutagenic.	The lower excretion of ascorbic acid in the urine of gastric cancer patients could be either a cause or a result of the disease, but it is consistent with the hypothesis that this vitamin reduces the risk of this disease. The higher excretion of nitrate probably reflects a higher intake. Mutagenicity of the urine was directly associated with severity of pathology of the stomach. Normal controls had low levels of N-nitroso compounds in gastric juice, compared with chronic atrophic gastritis, dysplasia, or gastric cancer. The mutagenicity of the urine may have been related to synthesis of N-nitroso compounds in the stomach and differences in this process may have been due to differences in intakes of ascorbic acid and nitrate. These results support the hypothesis that N-nitroso compounds may be the cause of gastric cancer.

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Sierra et al., 1991. (Ref. 25)	Comparison of urinary concentrations of nitrate and N-nitrosoamino acids in children from high- and low-risk areas for stomach cancer in Costa Rica.	One high-risk and one low-risk area for stomach cancer were chosen on criteria of rural location, large enough population of school age children and similar ethnic characteristics. From each area, 25 subjects aged 8 to 14 years were chosen at random for the oral treatments and urine collections.	Two samples of 12-hour overnight urine were collected from the children after they had ingested 500 mg proline with 200 mg ascorbic acid or 500 mg proline alone 1 hour after the evening meal. Urine samples were assayed for N-nitrosoproline and two other N-nitroso compounds, and nitrate.	All comparisons of levels of N-nitroso-proline were statistically significant. Thus, in both areas, the level was reduced by ingestion of ascorbic acid with proline, compared with that seen with proline alone. The level as higher in the high-risk area than in the low-risk area, for each type of dietary treatment. The N-nitrosoproline level correlated well with nitrate levels.	The results indicate that children living in a high-risk area have a higher potential for endogenous nitrosation than those living in the low-risk area. Nitrate exposure may explain at least part of this difference. The data confirm that proline nitrosation can be substantially inhibited by ascorbic acid supplementation.
Sobala et al., 1991. (Ref. 33)	Case control study 56 patients scheduled for stomach endoscopy in Lyon, France.	Fifty-six adult patients referred for endoscopic exam for possible gastritis with no previous stomach surgery.	Patients fasted overnight. Gastric juice aspirated for ascorbic acid, total vitamin C, total bile acid, nitrite, nitrate and total Nitroso compounds (NOC's), and an aliquot of plasma was collected for vitamin C levels. 2 stomach biopsies; 1 cultured for Helicobacter and 1 submitted for histopathology.	Of 56 patients, 12 completely normal on histopathology, 18 chronic superficial gastritis, 17 chronic gastritis with atrophy, and 9 had gastric reflux. 89% of chronic gastritis had Helicobacter infection. Intestinal metaplasia in this group significantly associated with gastric ascorbic acid, gastric vitamin C.	Age and gastric pH also significantly higher in chronic gastritis patients with intestinal metaplasia versus those without.

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
VanKenwyk et al., 1991. (Ref. 118)	A case-control study of cervical intra-epithelial neoplasia and dietary and serum carotenoids.	The subjects were 102 nonpregnant, nonpostpartum cases and matched controls from women who had no cervical cytologic abnormalities greater or equal to those of benign atypia.	Cases were identified with biopsy-confirmed cervical intraepithelial neoplasia (CIN) of grades I, II, or III. Participants completed a food frequency questionnaire provided by the National Cancer Institute. The conversion of foods to nutrients was performed with and without an adjustment for energy intake.	For serum lycopene, the odds ratios for CIN were significantly increased in the three lower quartiles. The finding for lycopene-rich foods were consistent with this result. CIN was not associated with lutein. Finding for alpha-carotene, beta-carotene and cryptoxanthin were ambiguous. The lower quartiles of dietary vitamin C were associated with significantly increased odds ratios for CIN.	The relatively low response rates (approximately 60 percent for cases and 50 percent for controls) could have introduced bias. An inherent limitation of case-control studies is the determination of exposure after the onset of disease, especially for serum studies--dietary behavior may have changed after diagnosis and before blood sampling. The finding of a protective association for lycopene but not other carotenoids indicates that caution must be used in attributing the effects of carotenoid-containing fruits and vegetables to beta-carotene, at least for this type of cancer.
West et al., 1991. (17)	Case-control study, Utah. Prostatic cancer.	Cases-358 men with prostatic cancer diagnosed between 1984 and 1985. Controls-679 population based controls matched for age and county of residence.	Histologically confirmed cases and controls interviewed using quantitative food-frequency questionnaire. Data was analyzed separately for middle (45 to 67) and older (68 to 74) age categories and by tumor aggressiveness.	Beta carotene had a nonsignificant protective effect for prostatic cancer in younger males. In older males, total vitamin A had a slight positive association with all prostate cancer OR=1.6, CI=0.9 to 2.4). There was little association vitamin C and beta-carotene and prostate cancer in older men.	The most significant association were seen for older males with aggressive tumors. Dietary fat was the strongest risk factor for these males. It was not possible to blind interviewers to the case or control status of respondents.
You et al., 1991. (Ref. 24)	Comparison of N-nitroso compounds concentrations in urine and gastric juice from subjects with different degrees of premalignant pathology of the stomach.	Twenty subjects with normal gastric mucosa, 20 subjects with chronic atrophic gastritis and/or intestinal metaplasia of the stomach, and 20 subjects with dysplasia of the gastric mucosa.	Twenty-four hour urine samples and gastric juice after an overnight fast were collected and assayed for N-nitroso-proline and two other N-nitroso compounds.	Levels of N-nitroso compounds in the urine were higher in subjects with gastric dysplasia than in normal controls or subjects with chronic atrophic gastritis/intestinal metaplasia. Levels of N-nitroso compounds were lower in gastric juice than in urine, and levels in gastric juice could not be evaluated by gastric pathology.	Persons with gastric dysplasia had elevated urinary levels of N-nitroso compounds, and these subjects are exceptionally prone to stomach cancer.

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Zaridze et al, 1991. (Ref. 6)	Case-control study, breast cancer, Moscow.	The subjects were 139 case-control pairs matched for age and neighborhood. Newly diagnosed cases of breast cancer between September 1987 to January 1989, and controls attending same clinics as cases for minor complaints.	Dietary assessment made with food frequency questionnaire for year prior to diagnosis of cases or attending clinic by controls. Assessment based on nutrient indices for 145 common food items. Data were analyzed separately for pre- and postmenopausal women.	Diet was a more important risk factor in breast cancer for postmenopausal women than for premenopausal women. After adjusting for age at menarche, energy intake, and education intake of vitamin C (OR 0.20), beta carotene (OR 0.09) retinol equivalent and cellulose were protective in postmenopausal women. Nonsignificant association for mono- and disaccharides. Increased risk of breast cancer with high intake of total fat. In general results indicate a high risk of breast cancer associated with nutrients from animal products, low risk associated with high intake of nutrients from vegetables and fruits.	Associations between dietary fat and breast cancer in postmenopausal women were nonsignificant. Socio-economic status and education were positively associated with higher risk. These confounding factors may relate to the access to health care, overestimation of intake based on serving sizes, and other influences which were not evaluated.
Zatonski et al., 1991. (Ref. 14)	Case-control; Poland; Pancreatic (Exocrine) Cancer; study conducted 1985 to 1988	110 cases (surrogates interviewed for 71%); 195 controls (all directly interviewed)	Interview using dietary questionnaire containing 80 food items assessed diet 1 to 2 years before diagnosis. 43% of cases were histologically confirmed, remainder diagnosed radiologically	Adjusted for smoking and total calories: Inverse association between intake of vitamin C and pancreatic cancer; nonsignificant protective effect association with retinol, fiber.	The statistically significant nutrients (and fiber) are associated with fruits and vegetables. Substantial use of proxy interview of cases introduces bias.

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Zhang et al., 1991. (Ref. 23)	The role of mutagenic/ carcinogenic N-nitrosamides in stomach cancer was studies by (1) measuring mutagenicity of extracts of a local fish sauce before and after nitrosation, (2) determining the carcinogenicity of these extracts in rats, (3) determining the N-nitrosamides in these extracts, and (4) correlation of N-nitrosamides in gastric juice with severity of pathological changes in the stomach of human subjects.	Fish similar fish sauces were collected from areas with high- and low-risk for stomach cancer, nitrosated, assayed for N-nitrosamides and mutagenicity, and fed to rats for 4 or 16 weeks. Gastric juice was collected from 12 normal control, 14 chronic atrophic gastritis, 13 gastric dysplasia patients, and assayed for N-nitrosamides.	Fish sauce samples were extracted with ethyl acetate and the extract was nitrosated with sodium nitrite under simulated gastric conditions. Mutagenicity was determined with the Ames test using Salmonella typhimurium strain TA100, a sister chromatic exchange assay, and a micronucleus test. The animal carcinogenicity assay was performed by gavaging for 3 days either nitrosated or nonnitrosated fish sauce extract to newborn rats and determining the effects in rats autopsied after 4 or 16 weeks. A total of 39 gastric juice samples were collected from patients after an overnight fast by fibroendoscopy.	In the absence of nitrosation, none of the fish sauce extracts was mutagenicity. After nitrosation, all samples had direct mutagenicity in the Ames test and induced sister chromatid exchange with a dose-response relationship. In the micronucleus test, fish sauce extracts from only two villages were active. Four weeks after treatment with fish sauce, only those rats treated with the sauce that was mutagenic in all three assays showed marked precancerous dysplasia. After 16 weeks, the same treatment group had cancerous ulceration in the glandular stomach, with dysplastic glands and cells that had penetrated the mucosa and infiltrated into submucosa and muscular layers of the gastric wall. The mean concentrations of N-nitrosamides in the nitrosated fish products were more than 15 times higher in the samples from a high-risk area than in the samples from a low-risk area. The N-nitrosamide concentrations in gastric juice were strongly positively correlated with the severity of pathological changes in the stomach.	These data strongly support the hypothesis that the etiology of human gastric cancer is closely related to intragastric formation of mutagenic/carcinogenic N-nitroso compounds, that the degree of pathological change is directly related to the exposure of these compounds, and that exposure to these carcinogens is higher in areas of high-risk for stomach cancer.

TABLE 2

Human Studies not Included in the Review of New Scientific Evidence.

Study	Study Design	Subjects	Methods	Results	Comments
Orenteich et al., 1991. (Ref. 41)	Case-control study in Northern California measuring sera beta-carotene levels 15 years prior to diagnosis of lung cancer versus sera levels collected from controls taken at same time.	The subjects were 263,000 individuals participating in routine Health Maintenance Organization check-ups; 151 lung cancer cases, 302 matched controls with similar sera storage time.	Comparisons were made with 123 case control triplets. Catalogued sera were stored at -40 C for 15 to 22 years and assayed using High Performance liquid chromatography. Relative risk of lung cancer was estimated by logistic regression, statistical significance of difference in mean calculated using single t test.	RR was 3.0 for lung cancer in lowest versus highest quintile of beta-carotene intake. Trend less evident for retinol and alpha-tocopherol.	Carotenoids are highly reactive, and decay may have varied in sera based on other substances present. It is also possible that the difference in sera carotenoid level in future lung cancer cases was not correlated with nutritional intake, but was associated with other factors such as smoking or alcohol use.
Tuyns et al., 1992. (Ref. 42)	A case-control study of gastric cancer in two provinces of Belgium.	Subjects were 449 cases 3,524 controls.	Diet data were obtained by interview using a validated dietary history questionnaire. Food were classified into groupings based source, such a vegetables, fruits, breads, meats, fish, and dairy products, and on raw versus cooked. RR and probability values were calculated.	Consumption of both raw and cooked vegetables, including leafy and root types, were associated with reduced risk. Consumption of raw fruit, but not stewed or canned fruit, was associated with reduced risk. Consumption of dairy products increased risk, and some types of meat and fish increased risk, whereas consumption of lean meats decreased risk. Consumption of high P/S ratio fats increased risk.	The results show that consumption of fruits and vegetables reduces risk. The destruction of protective effects by cooking of fruits, and the risk associated with polyunsaturated fat consumption suggest, but alone are not sufficient to demonstrate, that the antioxidant vitamins reduce the risk of stomach cancer.
Toma et al., 1992. (Ref. 43)	A clinical trial of beta-carotene (90 mg/day for three cycles of 3 months each) against oral, and evaluation after 24 months.	A total of 23 patients (aged 17 to 85) were included in the study and 18 (8 male and 10 female) were evaluated.	The leukoplakia lesions were examined macroscopically and microscopically at entry, and in the evaluated patients at the end of the study.	Among the 18 evaluated patients, 6 showed complete response, 2 partial response, 3 minimum response, and 6 stable disease.	The design examined the use of high-dose beta-carotene in treatment of preneoplastic conditions, and thus appear not to meet the 1990 amendments standards for dietary context or reduction of risk.
Swanson et al., 1992. (Ref. 44)	A case-control study of diet and lung cancer risk in Yunnan Province, China.	The subjects were 428 cases, aged 35 to 74 years, and 1,011 age-matched controls.	Interviews were conducted to obtain information about eating habits during adult life and to report usual intake frequency for 31 food items or groups.	The relative risk of lung cancer across increasing quartiles of food intake increased for consumption of meat. Cases tended to consume slightly more rice than controls. Risk decreased markedly across increasing quartiles dark green, leafy vegetables.	The specific constituent(s) responsible for the protective effects of vegetable consumption could not be identified, but carotenes other than beta-carotene, or compounds in cruciferous or Allium vegetables were stated to be possibilities.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Longnecker et al, 1992. (Ref. 45)	Pooled data from five previously published studies with serum alpha-tocopherol values were analyzed for reduced risk of several types of cancer.	The five studies, in Finland, Hawaii, Maryland, Switzerland. and the United Kingdom, included approximately 93,000 subjects, both male and female, but serum alpha-tocopherol assays were performed only on approximately 300 cases and 1,300 controls.	Blood specimens had been stored for 0 to 14 years at temperatures of -20 to -75° C when serum was analyzed for alpha-tocopherol.	In comparison of cases versus controls, alpha-tocopherol values were consistently nearly equal, and, when numerical difference occur, the cases tended to be slightly lower than the controls. The crude OR's for colon and rectum cancer were consistently lower for the highest quartile of serum alpha-tocopherol values than for the lowest quartile. The CI's of the collective data were quite wide, preventing significance of any real effects.	The results suggest that serum alpha-tocopherol concentration may be inversely related to risk of colorectal cancer. This is unclear, however, because the association between serum alpha-tocopherol level and decreased risk was modest, the confidence were wide, and the overall tests for trend in effect were not significant. Larger observational studies with dietary data are needed to determine whether vitamin E has a small but important effect on risk of colorectal cancer.
Fraser et al., 1991. (Ref. 46)	A prospective study with a 6-year followup from 1977 to 1982 on diet and lung cancer. California.	Subjects were 34,198 Seventh-Day Adventists, 61 of whom developed lung cancer in cohort.	A questionnaire was mailed to all subjects. Response exceeded 75% for non-Hispanic whites. Food frequency was determined for 51 different foods. Annual mailings in regard to hospitalization, and hospital record information were used to detect new cancer cases.	Fruit consumption had a strong protective effect for lung cancer; RR = 0.26 for highest tertile of consumption, CI = 0.10-0.70, p = 0.006.	This population is unique in that less than 4 percent admitted to smoking and approximately 50 percent are lacto-ovo vegetarians.
Stahelin et al., 1991. (Ref. 47)	A prospective study of men in Basel, Switzerland with a 12-year followup; plasma levels of antioxidant vitamins were correlated with mortality due to cancer at all sites.	The subjects were over 2,974 men from a cohort of 6,000 healthy volunteers employed in three pharmaceutical companies.	Serologic samples were collected from 2,974 men in 1971 to 1973 examination cycle. Information about deaths was obtained from employers and death certificates obtained. No vital statistics were obtained for eight individuals.	Overall cancer mortality was associated with low mean plasma carotene level adjusted for cholesterol, and vitamin C. Bronchus and stomach cancers were associated with low mean plasma carotene. Stomach cancer was associated with low mean vitamin C and lipid-adjusted vitamin A. Low levels of vitamin C increased the risk of stomach cancer (RR = 2.17, p = 0.05; and gastrointestinal cancer, RR = 2.46 in older subjects, significance lost in this group of subject with exclusion of first 2 years of followup.	Authors conclude that low serum antioxidant vitamin levels are associated with higher risk of subsequent cancer. Effects appear to be site specific. The role of nutrient intake, rather than serum levels, and other variables is unclear. Serum lipid, smoking, exercise, unidentified nutrients are associated with antioxidant vitamins may effect serum levels.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Baghurst et al., 1991. (Ref. 48)	A case-control study of diet and pancreatic cancer, in Adelaide, Australia.	The subjects were 104 cases of pancreatic cancer and 253 community controls.	A quantitative food-frequency questionnaire was used to assess intakes of 179 food items. Amount and contribution to diet were compared for 48 nutrients.	Cases consumed more eggs, sweet and fatty foods and less vegetables and fruits ($p < 0.01$ for dried grapes, lettuce, and broccoli consumption in females; $p < 0.01$ for dried grapes in males; $0.01 < p < 0.05$ for tomatoes, green beans, and coleslaw in males; and $0.01 < p < 0.05$ for brussels sprouts, cucumber, potato, and tomato in females). Cases consumed less beta-carotene, vitamin C, and vitamin E than controls.	Study supports view that fruit and vegetables have an important role in minimizing cancer of the pancreas, but provides information about relative, not quantitative, amounts of the antioxidant vitamins.
La Vecchia et al., 1991. (Ref. 49)	A case-control study of dietary indicators for pharyngeal and oral cancer in Northern Italy during 1987 to 1989.	The subjects were 105 cases of oral and pharyngeal cancer and 1,169 hospital controls with acute nonneoplastic conditions.	Data were collected on usual frequency of consumption of 10 indicator foods before onset of digestive illness. Subjective scores were given (low, medium, and high) for seven items including wholemeal bread, pasta, fats, condiments.	There was a significant protective association for consumption of six food items: milk, meat, cheese, carrots, green vegetables, and most strongly, for fruit (RR = 0.8 and 0.2, respectively, for two highest tertiles).	The associations may reflect poorer nutritional status in cases. The observation that fruit appeared to be particularly protective may be of significance in terms of etiology and protection.
Hu et al., 1991. (Ref. 50)	A case-control study of dietary indicators for colon and rectal cancer in Harbin City, Heilogjiang province, China during 1985 to 1988.	The subjects were 3,336 histologically confirmed cases of colorectal cancer (111 colon, 225 rectal) and an equal number of hospital controls with nonneoplastic diseases. Matched for sex, age, and residence.	Data on frequency and quantity of consumption of food items were collected. OR's and confidence limits were computed for intake and risk of disease.	Higher intakes of vegetables, especially green vegetables, chives, celery, were associated with a protective effect against colorectal cancer. Reduced intakes of meat, eggs, bean products, and grain were associated with increasing risk of rectal cancer.	The data are supportive of a protective effect of vegetable intake, especially green vegetables, against colorectal cancer. Protective effect of meat, eggs, bean products, and grain against rectal cancer may reflect lower level of nutrition in this region of China.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
De Vet et al., 1991. (Ref. 51)	A case-control study of dietary indicators for cervical dysplasia; a multicenter study in the Netherlands during 1984 to 1987.	The subjects were 257 cases of cervical dysplasia and 705 controls from the general population.	A questionnaire was mailed regarding frequency of consumption of various food items containing beta-carotene, retinol, vitamin C, and dietary fiber.	Increased risk of cervical dysplasia was associated with increased intake of beta-carotene; Relative Risk = 2.31, CI = 1.27 to 4.19. No relationship was found for retinol intake, but both vitamin C and dietary fiber intake showed a nonsignificant inverse relationship with cervical dysplasia.	The findings do not support hypothesis that beta-carotene protects against cervical dysplasia, but suggest a greater risk with higher intakes.
Graham et al., 1990. (Ref. 52)	A case-control study for gastric cancer in three counties in Western New York during 1975 to 1985.	The subjects were 293 histologically confirmed case and neighborhood-, age-, and sex-matched controls.	The cases came from hospital records in all but five hospitals in a three- county area. A 2.5-hour interview scheduled with each case and control was used to assess total nutrient intake. There were no surrogate interviews.	Carotene: there was substantial decrease in risk of male gastric cancer in the highest quartile of intake, but no dose-response relationship. There was no association in females. An increase in risk of gastric cancer occurred with higher retinol intake. No relationship to cancer was noted for vitamins C and E. Intake of specific vegetables had a significantly associated decreased risk of gastric cancer; male: cucumbers, tomatoes, green peppers, carrots, onions celery; female: onions, winter squash.	The study is supportive of a protective effect of specific vegetables against the risk of gastric cancer. Data does not provide specific support for a role of antioxidant vitamins in reducing the risk of gastric cancer.
Oreggia et al., 1991. (Ref. 53)	A case-control study cancer of the tongue in Uruguay, 1987 to 1989.	The subjects were 57 cases of lingual cancer and 353 hospital based controls. The study was restricted to males.	The subjects were interviewed with a standard questionnaire about the use of tobacco, alcohol, and dietary intake.	Infrequent consumption of vegetables was associated with tongue cancer; RR = 5.3, CI = 1.5-19.4. Tobacco and alcohol were the strongest risk factors.	The study does not provide direct support for a role of the antioxidant vitamins in cancer because of he limited data on nutrient intake presented.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Gridley et al., 1990. (Ref. 54)	A multicenter case-control study for oral and pharyngeal cancer in blacks in New Jersey, Atlanta, Los Angeles, and the San Francisco/Oakland area during 1984 to 1985.	The subjects were 248 cases of oral cancer in blacks contacted and 190 participated in the study; all were identified from cancer registries. Of the 262 controls contacted, 201 participated. These were matched to cases on age, race, and sex. Those under 65 years of age were chosen from random digit dialing and over 65 from Health Care Financing Administration rosters.	Interviews were conducted on diet, occupation, tobacco, alcohol, demographics, and medical history. Questions were asked about 61 food frequencies, food preparation, and recent dietary changes. Indices and serving size data were obtained from NHANES II.	All fruits and vegetables, except legumes were associated with decreased risk of cancer in men. A significant protection was associated with intake of noncitrus fruits, green leafy vegetables, and vegetables eaten raw. All fruits and vegetables, except dark yellow vegetables, especially cruciferous vegetables, were associated with decreased risk of cancer in women, A protection was most evident for pharyngeal cancer. Intakes of carotene and vitamin C were associated with significantly reduced risk in men, while vitamin C was significant for reduced risk in women.	Lower consumption of fruits and vegetables in blacks may contribute to elevated rates of oral and pharyngeal cancer versus general population. The study is consistent with a protective role of the antioxidant vitamins and also for the inducer compounds in cruciferous vegetables.
Rossing et al., 1989. (Ref. 55)	A case-control study for antioxidant vitamins and pharyngeal cancer in Washington State, 1980-1983.	The subjects were 166 cases (of 292 identified cases) between 20 and 74 years old. Surrogate next-of-kin were interviewed for 86 cases; the controls were 547 of 552 individuals from a population who were sex- and age-matched to the cases.	The subjects were asked to estimate food frequency in a questionnaire interview for 48 food items and vitamin supplements during the 1970's. USDA nutrient indices were used to estimate intakes.	A significant increase in risk of pharyngeal cancer was associated with low intake of vitamin C; RR = 2.3, CI = 1.5 to 4.2. The role of vitamin C supplementation was difficult to assess because of discrepancies between next of kin reporting and the remaining case group.	The study suggests a potential protective effect of vitamin C against pharyngeal cancer. The authors conclude that the data are compatible with other research reporting a protective effect of fruits and vegetables against pharyngeal cancer.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Ghardian et al., 1991. (Ref. 56)	A case-control study for nutritional factors and pancreatic cancer in Montreal, Canada, 1984 to 1988.	The subjects were 179 clinically diagnosed cases from 19 French-speaking hospitals and 239 controls matched for age, sex and residence.	A core questionnaire about lifestyle, occupation, drinking, smoking, medical history, etc. was administered. A food frequency questionnaire was given concerning 200 different items for times 1 year and 10 years before diagnosis. The controls were matched individually for same period.	The associations for antioxidant vitamin intakes (beta-carotene, vitamins C and E) and retinol to the risk of cancer were nonsignificant.	The authors suggest need for larger studies of the relationship between nutrient intake and pharyngeal cancer.
Heilbrun et al., 1989. (Ref. 57)	A nested case-control study of diet and colorectal cancer in Oahu, Hawaii, 1965-1985.	The cohort was 8,006 American Japanese men aged 65 to 85 years in 1985; there were 102 cases of colon cancer and 60 cases of rectal cancer, and 361 cancer-free males from cohort randomly selected as controls.	Nutrient intake estimates were based on representative 24-hour recall of fiber, vitamins, minerals, macronutrients.	For colon cancer, the lowest quintile intake of vitamin C had RR = 1.87, CI = 1.03 to 3.37. There was a nonsignificant association between carotene, vitamin A intake and colon cancer. There was no association between rectal cancer and intake of any of the antioxidant vitamins.	With exception of vitamin C intake and colon cancer, the study does not support a protective effect of the antioxidant vitamins against colorectal cancer.
Kato et al., 1990. (Ref. 58)	A case-control study of colorectal cancer, and adenoma in Nagoya, Japan, 1986 to 1990.	The subjects were 221 cases of histologically diagnosed colorectal cancer, 525 cases of colorectal adenoma, and 578 neighborhood controls.	The cases attended Aichi Hospital; the neighborhood controls were matched for sex, age, and residence and were selected by random dialing.	Daily vegetable intake was associated with lower risk of distal colon adenoma; RR = 0.59, CI = 0.39 to 0.89, and rectal cancer; RR = 0.46, CI = 0.25 to 0.84.	The study supports a protective effect of vegetables against colorectal adenoma and carcinoma.
Graham et al., 1990. (Ref. 59)	A case-control study esophageal cancer and nutrition in three counties in Western New York, 1975 to 1986.	The subjects were 178 cases of histologically diagnosed esophageal cancer, matched with neighborhood controls for sex and age.	The cases came from hospital records in all but five hospitals in the three-county area. A 2.5-hour interview was scheduled with each case and control to assess total nutrient intake. No surrogate interviews.	Risk of cancer increased with increased consumption of foods containing retinol, not carotene.	The authors concluded that further studies are needed to distinguish risks of cancer of esophagus and elsewhere associated with retinol and carotene.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 91N-0102]

RIN 0905-AD08

Food Labeling: Health Claims; Zinc and Immune Function in the Elderly

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing its decision not to authorize the use on the label or labeling of foods of health claims relating to an association between ingestion of zinc and immune function in the elderly. This rule is issued in response to provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) that bear on health claims, and is developed in accordance with the final rule on general requirements for health claims, issued elsewhere in this issue of the Federal Register. The agency has concluded that, based on the totality of the scientific evidence, there is not significant scientific agreement among qualified experts that increased intake of zinc will enhance immune function in the elderly. Therefore, FDA has concluded that claims on foods relating to zinc and immune function in the elderly are not justified.

EFFECTIVE DATE: May 8, 1993.

FOR FURTHER INFORMATION CONTACT: James E. Hoadley, Center for Food Safety and Applied Nutrition (HFS-227), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5593.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of November 27, 1991 (56 FR 60652), FDA proposed not to authorize health claims relating to zinc and immune function in the elderly. The proposed rule was issued in response to provisions of the 1990 amendments (Pub. L. 101-535) that bear on health claims and in accordance with the proposed general requirements for health claims for food (56 FR 60537, November 27, 1991). As amended in 1990, the Federal Food, Drug, and Cosmetic Act (the act) provides that a food is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition unless the claim is made in accordance with section 403(r)(3) or (r)(5)(D) of the act (21 U.S.C. 343(r)(3) or (r)(5)(D)).

Congress enacted the health claims provisions of the 1990 amendments to help U.S. consumers maintain good health through appropriate dietary patterns and to protect consumers from unfounded health claims. Section 3(b)(1)(A) of the 1990 amendments specifically requires the agency to determine whether claims respecting 10 nutrient/disease relationships meet the requirements of section 403(r)(3) or (r)(5)(D) of the act. The relationship of zinc and immune function in the elderly is one of the claims required to be evaluated. In the proposed rule (56 FR 60652), FDA reviewed the publicly available relevant data pertaining to zinc and immune function in the elderly and evaluated whether health claims relating zinc and immune function would be justified under the standard proposed in the companion document entitled "Food Labeling: General Requirements for Health Claims for Food" (56 FR 60537).

FDA published a notice in the Federal Register of March 28, 1991 (56 FR 12932), requesting scientific data and information on the 10 specific topic areas identified in the 1990 amendments, including zinc and immune function in the elderly. Relevant scientific studies and data received in response to this request were considered as part of the agency's review of the scientific literature on zinc and immune function, and were included in the proposed rule (56 FR 60652).

In the proposed rule (56 FR 60652), FDA requested written comments on its tentative determination not to authorize a health claim for zinc and immune function in the elderly. In addition, FDA held public hearings on January 30 and 31, 1992, on all aspects of the proposed rules published to effect the 1990 amendments (57 FR 239, January 3, 1992). The agency received approximately 20 comments in response to its proposal to deny health claims regarding zinc and immune function in the elderly. Several comments were received that were more appropriately addressed in other documents, and these comments were forwarded to the appropriate docket for response.

The relevant publicly available data evaluated by FDA in its proposed rule (56 FR 60652) included seven human studies (Refs. 29 through 35) in which elderly subjects were supplemented with zinc to determine its influence on immune system function. In the proposed rule (56 FR 60652 at 60661), the results of four of the earlier published studies (Refs. 29 through 32) suggested a zinc-associated enhancement of several measures of immune function. However, FDA noted that the reliability of three of these studies was limited due to inclusion of very few individuals, and the tested subjects were not representatives of the general elderly population. Moreover, FDA further noted that the results of these initial reports have not been substantiated by more recent, larger studies of more rigorous experimental design (Refs. 34 and 35).

FDA tentatively concluded that the later, larger studies showed no improvement of immunocompetence from zinc supplementation in the elderly. The agency also pointed out that zinc supplementation at levels in excess of 100 milligrams per day (mg/day) can result in suppression of immune system function (Ref. 48). For these reasons, FDA tentatively determined that claims on foods, including dietary supplements, relating to zinc and immune function in the elderly are not justified.

The Dietary Supplement Act of 1992 established a moratorium on the implementation of the 1990 amendments with respect to dietary supplements. The law says that FDA can grant health claims for foods, including dietary supplements, using the significant scientific agreement standard specified in section 403(r)(3)(B)(i) of the act. However, it may not act on such claims under section 403(r)(5)(D) of the act until it establishes a standard to implement that section of the act, which the new law says may not occur until December 1993. Section 3(b)(1)(A)(x) of the 1990 amendments directs the agency to evaluate the zinc and immune function claim based on the standard that FDA is establishing for determining the reliability of health claims under section 403(r)(5)(D) of the act. In the November 27, 1991 proposal, on general requirements for health claims, FDA proposed to adopt the standard that the 1990 amendments provide for conventional foods, which is set forth in section 403(r)(3)(B)(i) of the act, as the standard for dietary supplements. Given this fact, and the fact that zinc is found in numerous conventional foods as well as in dietary supplements, FDA broadened its inquiry to a determination as to whether it should grant a health claim on zinc and immune function in the elderly on any foods.

Because the Dietary Supplement Act provides that FDA may grant claims under section 403(r)(3)(B)(i) of the act, and given the breadth of FDA's November 1991 proposal, on zinc, FDA has decided to move forward to

determine whether it can authorize a claim under section 403(r)(3)(B)(i) for zinc and immune function.

However, this rule does not apply to dietary supplements. While a manufacturer of a dietary supplement can make a claim on zinc and immune function in the elderly without rendering its product misbranded under section 403(r)(1)(B) of the act, the manufacturer should assure itself that the making of the claim will not misbrand the product under section 403(a) of the act.

II. Comments to the Proposal and the Agency's Responses

A. General

1. Nine comments representing State attorney generals, State agencies, associations of public health officials, and professional associations of people employed in nutrition-related fields agreed with FDA's assessment of the evidence on zinc and immune function, including FDA's proposed decision not to authorize a claim on this nutrient-disease relationship. Several comments stated opposition to allowing health claims in general.

The agency acknowledges those comments supporting its tentative position not to authorize a health claim on zinc and immune function in the elderly. In response to those comments that oppose all health claims, however, the agency points out that the 1990 amendments provide sufficient safeguards to ensure that health claims are scientifically valid and will provide consumers with information that will promote good health.

B. Comments on the Available Data

2. One comment from a consumer-oriented nutrition magazine noted that the small number of participants in some of the studies cited in the proposed rule (56 FR 60652) makes their inclusion questionable. This comment also noted that results from studies using supplemental zinc levels no higher than the Recommended Dietary Allowance would likely be of little value.

FDA concurs with this comment. In its proposed rule, FDA noted that small (5 to 8 subjects), uncontrolled studies (Refs. 30 through 32) were included among those that it found in its review of the publicly available scientific literature. However, in the proposed rule, the agency stated that the significance of these reports to the agency's decision was limited because of the small number of subjects and the lack of substantiation of their findings by larger studies.

Of the three studies in which supplemental zinc was provided at the Recommended Dietary Allowance level (12 to 15 mg/day), two studies (Refs. 34 and 35) also included substantially higher supplemental zinc levels (100 mg/day). FDA stated that the third study (Ref. 31), which used a 15 mg/day zinc supplement, was of low reliability because of the limited number of subjects, absence of control subjects with which to compare those supplemented with zinc, and lack of blinding as to treatment received.

3. One comment submitted a list of recently published scientific studies, not cited in the proposed rule, suggesting that they bear directly or indirectly on the issue.

FDA reviewed the submitted studies and determined that not one of the articles is relevant to the topic of zinc and immune function in the elderly. Of the six references listed, five were of studies of zinc metabolism or nutrition, but did not involve immune function. One reference listed did concern zinc and immune function, but was available only as an abstract. FDA did not consider abstracts in its evaluation as experimental design and data are presented too briefly for adequate evaluation.

C. Life Science Research Office Report

4. Among the authoritative documents considered in the proposed rule was a preliminary report (Ref. 26) from a 1991 review of the literature on the relationship between zinc and immune functions in the elderly conducted by the Life Sciences Research Office (LSRO) of the Federation of American Societies of Experimental Biology (FASEB). The final version of the LSRO report ("Evaluation of Publicly Available Scientific Evidence Regarding Certain Nutrient-Disease Relationships: 2. Zinc and Immune Function in the Elderly", W. R. Beisel) was released by LSRO in December 1991, and filed in the docket as a comment on the proposed rule. The final version was not changed from the preliminary version cited and discussed in the proposed rule. It fully supports FDA's conclusions on the lack of a relationship between zinc and immune function in the elderly.

D. Canada

5. In two comments, the Canadian Government (Bureau of Consumer Affairs, and Health and Welfare Canada) noted that, under the Canadian Food and Drug Act, Section 3, the advertising and sale of foods represented as a treatment, preventative, or cure for specified diseases and health problems is prohibited in Canada. Although immune function is not included among the list of specified disorders, health claims respecting zinc and immune function on food labels would likely result in the foods being classified as drugs in Canada by virtue of the definition for "drug" in the Canadian law.

These comments are essentially identical to a comment submitted by the Canadian Government in response to FDA's notice requesting scientific data or information on this topic, which published in the **Federal Register** of March 28, 1991 (56 FR 12932). In its proposed rule (56 FR 60652), FDA did not propose to authorize health claims for zinc and immune function on food labels. Thus, no change in the proposed rule is appropriate in response to this comment.

III. Conclusion

FDA reviewed the scientific data in conformity with the requirements of the 1990 amendments, as well as comments received regarding the proposed rule that published in the **Federal Register** of November 27, 1991 (56 FR 60652), and concluded that there is not a sufficient basis to support the use of health claims relating to the topic of zinc and immune function in the elderly.

The agency's examination of publicly available evidence found that, although it is well accepted that adequate dietary zinc is essential for normal immune function, a specific protective role of zinc supplementation of the elderly population has not been demonstrated. Although some small early clinical studies suggested such a relationship, these results were not substantiated in subsequent research using better study designs and larger samples. Therefore, there is no evidence that immune function in healthy persons can be enhanced by zinc supplementation. Zinc is considered to be relatively nontoxic, particularly if taken orally. However, adverse effects, which include impaired immune function, are known to occur with zinc intake in excess of Recommended Dietary Allowances. Thus, FDA has concluded that the publicly available data on the role of zinc in immune system function do not provide a sufficient scientific basis from which to conclude that immune function in the general elderly U.S. population can be improved by zinc supplementation. Moreover, based on the totality of this evidence, there is not significant scientific agreement among qualified experts that a health claim for zinc and immune function in the elderly is supported by the evidence.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354 , FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that, although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

VI. References

The following references have been placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.71 is amended by adding new paragraph (e) to read as follows:

§ 101.71 Health claims: claims not authorized.

* * * * *

(e) Zinc and immune function in the elderly.

Dated: October 23, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 92–31516 Filed 12–28–92; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 91N-0094]

RIN 0905-AB67

Food Labeling: Health Claims; Calcium and Osteoporosis

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing its decision to authorize the use on the label and labeling of foods of health claims relating to an association between adequate calcium intake and osteoporosis. These rules are issued in response to provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) that bear on health claims and are developed in accordance with the general requirements in the health claims rule published elsewhere in this issue of the **Federal Register**. The agency has concluded that, based on the totality of the scientific evidence, there is significant scientific evidence and agreement among qualified experts that maintaining a diet adequate in calcium has a significant impact on bone health particularly during the critical bone forming years and after menopause and may help to reduce the risk of osteoporosis. The agency has therefore concluded that claims on foods relating the calcium content to a reduced risk of osteoporosis in susceptible populations are justified.

EFFECTIVE DATE: May 8, 1993.

FOR FURTHER INFORMATION CONTACT: Mona S. Calvo, Center for Food Safety and Applied Nutrition (HFF-265), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5434.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 27, 1991 (56 FR 60689), the agency proposed to authorize the use on foods, including dietary supplements, of health claims relating to the association between calcium and risk of osteoporosis. The proposed rule was issued in response to provisions of the 1990 amendments (Pub. L. 101-535) that bear on health claims and in accordance with the proposed general requirements for health claims for food (56 FR 60537). With respect to health claims, the 1990 amendments amend the Federal Food, Drug, and Cosmetic Act (the act) by adding a new provision (section 403(r)(1)(B) (21 U.S.C. 343(r)(1)(B)) that provides that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition unless the claim is made in accordance with section 403(r)(3) or (r)(5)(D) of the act.

Section 3(b)(1)(A) of the 1990 amendments specifically requires that the agency determine whether 10 nutrient/disease relationships meet the requirements of the section 403(r)(3) or (r)(5)(D) of the act. The relationship of calcium and osteoporosis was one of these areas. FDA published a notice in the **Federal Register** of March 28, 1991 (56 FR 12932), requesting scientific data and information on the 10 specific topic areas identified. Relevant scientific studies and data received in response to this request were considered as part of the agency's review of the scientific literature on calcium and osteoporosis and were included in the proposed rule (56 FR 60689). Because of time constraints, FDA addressed in that proposal only those comments submitted in response to the March 28,1991, notice that were in the form of scientific data. Comments of a more specific nature were not responded to at that time and are included among the comments responded to below.

Provisions of the proposed rule included qualifying and disqualifying criteria for the purpose of identifying foods eligible to bear a health claim. The proposal also specified mandatory content and label information for health claims statements and provided a model health claim and consumer summary statement. FDA also discussed potential safety issues relating to overfortification or oversupplementation with calcium. FDA requested written comments on the proposed rule, including comments on the issue of how to assess calcium bioavailability in products (conventional foods and supplements) to justify their eligibility to bear a health claim. Moreover, to ensure that calcium and osteoporosis claims will not mislead those individuals within the population for whom relatively higher calcium intake over a lifetime offers no apparent benefit to their bone health, FDA proposed that the subpopulations clearly at risk be identified on the label and solicited comments on how best to convey this information.

II. Summary of Comments and the Agency's Responses

In response to the proposed rule, the agency received more than 100 letters, each containing one or more comments, from consumers, consumer organizations, health care professionals, professional organizations, State and local governments, foreign governments, trade associations, and industry. In addition to these comments, the agency also considered statements made in a public hearing held on January 30 and 31, 1992 (57 FR 239, January 3, 1992) on a number of food labeling issues, including the proposed requirements for health claims. Some of the comments agreed with one or more provisions of the proposed rules without providing grounds for support other than those provided by FDA in the preamble to the proposal. Other comments disagreed with one or more provisions of the proposed rule without providing specific grounds for the disagreement. A few comments addressed issues outside of the scope of the regulations. Most of the comments provided specific support for their positions on the proposed regulations. The agency has summarized and addressed the relevant issues raised in all comments in the sections of this document that follow.

Before issuing the proposal, FDA contracted with the Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology to evaluate independently the scientific literature on dietary calcium and osteoporosis. The preliminary draft of the LSRO report, "Calcium and Osteoporosis" (Ref. 13), was one of the authoritative documents reviewed by FDA in developing its proposal. After the proposal was issued, LSRO completed its evaluation of the scientific literature and submitted its final report in February 1992. The agency placed a copy of the final report in the administrative file (Ref. 138), and has considered the report as a comment on the proposal.

A. Validity Issues

1. No comments disputed FDA's tentative conclusion that a lifetime of adequate calcium intake is important for maintenance of bone health and may help reduce the risk of osteoporosis, particularly for individuals at greatest risk. Most comments supported the agency's position.

The LSRO report (Ref. 138) concluded that "the weight of the evidence supports the hypothesized relationship between calcium intake and bone health as expressed both in increased bone mass and in reduced fracture risk." According to LSRO, "the focus of calcium as a nutrient related to osteoporosis lies in its importance both for achieving genetically programmed bone mass during about the first 30 to 35 years of life and in maintaining that

bone during the remaining years of life." The report stressed that osteoporosis is a multifactorial disorder, and that inadequate calcium intake is only one of several interacting factors that determine whether low-trauma fracture will occur. The report also noted that "the data concerning level of [calcium] intake required for bone health can be safely generalized only to Caucasian females."

FDA acknowledges the significant agreement on this matter and reconfirms its position that adequate calcium intake is important for maintenance of bone health and may help reduce the risk of osteoporosis, particularly for individuals at greatest risk. FDA notes that the LSRO report is consistent with required health claim statements about the mechanism by which calcium works (proposed § 101.72(d)(3), finalized at § 101.72(c)(2)(i)(C)) and the population at greatest risk (§ 101.72(c)(2)(i)(B)). As discussed in the proposal (56 FR at 60698), FDA agrees that the general population is not at significant risk of developing osteoporosis. For example, despite their generally lower calcium intake, data show that African Americans have higher bone mass at maturity and a very low incidence of osteoporosis-related bone fracture.

B. Advisability of Permitting Claims

2. One comment asserted that health claims pertaining to calcium and osteoporosis should not be permitted because (1) the target population for the claim is too small, and (2) older people with the condition may be misled into thinking the rate of bone loss will be slowed or reversed with increased calcium consumption.

FDA disagrees with this comment, which provided no support for its assertions. First, a large number of American women are at risk of developing osteoporosis (Ref. 18). Further, many of the elderly have low bone mass, and they continue to lose bone mass with further aging. These individuals will clearly benefit from information about how they may reduce their risk of the disease.

Secondly, as explained fully in the preamble of the proposal (56 FR at 60689), adequate calcium intake does help to slow the rate of bone loss in the elderly. Thus, while under § 101.72, claims may not imply that adequate calcium intake will reverse bone loss, under § 101.72 (c)(2)(i)(C), when reference is made to persons with a family history of the disease, menopausal women, and elderly men and women, the claim may state that adequate calcium intake is linked to reduced risk of osteoporosis through the mechanism of slowing the rate of bone loss. For these reasons, FDA disagrees that permitting claims to advise of the reduction in the rate of bone loss will mislead the elderly.

3. A few comments argued that a health claim should not be allowed because delay of the onset of osteoporotic fracture is not exclusively associated with adequate calcium intake. One of the comments justified this assertion by stating that many essential nutrients in addition to calcium, such as magnesium, copper, zinc, fluoride, and vitamins A, D, K, and C, are needed for normal bone growth and development.

FDA recognizes that many nutrients are essential for normal bone growth and development. However, FDA disagrees that this fact should preclude the agency from permitting a health claim pertaining to calcium and osteoporosis. The requirement in § 101.72(c)(2)(i)(A) that claims advise consumers of the importance of healthful diets is intended to alert consumers to the need to consume essential nutrients in addition to calcium. As the agency explained fully in the proposal (56 FR at 60689), national food intake surveys (Refs. 35, 54, and 105) provide evidence identifying calcium from dietary sources as a problem nutrient in a subpopulation at risk for osteoporosis, namely women between 11 and 35 years of age. Furthermore, FDA has concluded that based on the totality of the scientific evidence, there is significant scientific agreement among qualified experts that the evidence overwhelmingly supports the significance of calcium in maintaining bone health. Thus, FDA believes that the population at greatest risk of osteoporotic fracture in later life should be advised through food labeling of the benefits of adequate calcium intake.

C. Clarity of Provisions

4. A number of comments on the proposed rule on general requirements for health claims (November 27, 1991, 56 FR 60537) suggested that FDA revise provisions of all health claims rules to be more understandable.

FDA agrees that its regulations should be understandable. FDA has therefore made several nonsubstantive revisions in § 101.72 for the sake of clarity. For example, the provisions of the regulation have been grouped into general and specific requirements. The general requirements reference other regulations containing nutrition labeling requirements. The specific requirements are separated into requirements pertaining to the food and those pertaining to the claim. Finally, the model health claims have been simplified.

D. Qualifying Levels

5. A few comments addressed the issue of an appropriate qualifying level for calcium in a food. All of the comments strongly supported the requirement that a food bearing a calcium-osteoporosis claim be "high" in calcium (i.e., contain a minimum of 20 percent of the reference daily intake (RDI)). A number of the comments, however, asserted that the RDI was being set too low. One comment stated that the proposed RDI for calcium (900 mg) was an inadequate intake guideline for those individuals at greatest risk of osteoporosis. Another comment argued that there is substantial evidence that the population-weighted means used to establish the RDI's may seriously understate the nutritional needs of an estimated 52 million Americans.

For reasons explained fully in the preamble of the final rule on Reference Daily Intake and Daily Reference Values, which is published elsewhere in this issue of the **Federal Register**, FDA has adopted an RDI for calcium of 1,000 mg, the level in current § 101.9(c)(7)(iv). In view of the support for the proposal that only foods "high" in calcium qualify for calcium-osteoporosis claim, the agency has retained this requirement in the final rule in § 101.72(c)(2)(ii)(A) (proposed as § 101.72(c)(2)) with minor editorial revisions. Because the RDI for calcium is 1,000 mg, the reference amount customarily consumed for a food would need to contain at least 200 mg of calcium for it to qualify to bear the authorized calcium/ osteoporosis health claim.

E. Assimilability

All comments on this topic generally supported the concept of a requirement that the calcium content of the product be assimilable (proposed as § 101.72(c)(3) and finalized as § 101.72(c)(2)(ii)(B)). In response to an agency request in the proposal for comments about how to assess calcium assimilability (also referred to as "bioavailability"), a few comments suggested mechanisms to assess calcium bioavailability.

6. Several comments suggested that the agency establish a minimum standard that relates bioavailability to the amount of calcium actually absorbed from food. One comment cited the existence of a recognized data base describing the absorption of naturally occurring supplemental and fortified calcium in foods. However, the comment added that the cited data base

was actually a bibliography of various published articles describing calcium absorption from a variety of food sources. Another comment offered the following suggestion: "FDA should estimate the quantity of calcium in various foods that is rendered unavailable by oxalic acid, phytate, fiber, or other constituents and subtract this unavailable calcium from the amount of available calcium that the food would be expected to supply (which is usually only about half of the reported calcium content of food)." The comment suggested that FDA should not allow health claims on a given food if, after adjustment for oxalate and other constituents, the estimated quantity of "available" calcium is markedly lower than ordinarily expected, given the food reported calcium content. Similarly, another comment proposed the use of the indirect method of calciuric response to a calcium load as a convenient and reliable method of testing calcium absorbability and also proposed a test based on radiocalcium absorption.

FDA acknowledges these useful suggestions but notes that none of the proposed methods assesses calcium utilization. As discussed in the proposal, calcium bioavailability means both absorption and tissue utilization of calcium (56 FR at 60699). Appropriate tests for bioavailability need to include a measurement of the utilization of calcium by bone (calcium retention). A product that contains components that increase the urinary or fecal excretion of calcium or somehow impair the utilization of calcium by bone will not qualify for a calcium-osteoporosis claim. Monitoring only factors that alter absorption, such as the phytate content of a food, as suggested in the comment, would not allow estimation of the effects of factors that promote obligatory calcium loss such as increased urinary loss due to a high sulfate content. Both increased excretion and impaired utilization cause the decreased deposition of calcium in bone.

7. Some comments requested that FDA clarify an acceptable level of "assimilability," such as an acceptable percent bioavailability. The comments asserted that it would be unrealistic to require bioavailability data on all foods bearing a calcium claim, but that such a requirement might be a logical prerequisite for new sources of calcium used to fortify foods. A number of comments suggested that food and supplement manufacturers should bear the burden of proof of the bioavailability of calcium-fortified products and supplements in order to avoid indiscriminate fortification and marketing of poorly bioavailable supplements.

FDA reiterates that a product bearing a calcium-osteoporosis health claim must contain calcium that can be assimilated by the body. As noted in the proposal, it would be misleading to put a health claim for a substance on a food if consumption of that food will not provide the substance (56 FR at 60699). Such a food would be misbranded under section 403 (a) of the act (21 U.S.C. 343(a)). Given that most currently marketed products that are likely to bear a calcium-osteoporosis claim contain bioavailable calcium, FDA does not consider it necessary at this time to set a minimum acceptable level of bioavailability. If a food bearing a calcium osteoporosis claim does not contain calcium in a bioavailable form, the Government can take enforcement under the act against the product or its manufacturer. Calcium sources whose bioavailability has not been demonstrated would be at risk for such enforcement action.

There are sufficient scientific data in published literature to support the bioavailability of many sources of calcium in current use. However, instances may develop in which the bioavailability of the calcium source has not been shown, including the use of new fortificants or food products in which the combination of the component nutrients raises concerns about the assimilability of calcium from the product (e.g., a new bread rich in a novel high phytate fiber source and fortified with calcium).

As discussed in the previous comment, there are various ways of testing for bioavailability. FDA considers human or growing animal models to provide the most accurate assessments. One approach would involve collection of human data from calcium balance studies using stable isotopes or radioisotopes as evidence of reasonable or adequate bioavailability (assimilability), as well as evidence from well-controlled calcium supplementation or dietary intervention studies that measure calcium absorption and bone mass or density change over time. An appropriate standard reference would be calcium carbonate or milk.

FDA recognizes that establishing calcium retention in humans is a difficult and costly procedure. Another approach would use a growing animal model (rat) to demonstrate calcium retention in bone. Use of the growing rat model offers ease of bone mass or mineral content assessment, and, unlike human subjects, rats show limited between-subject variation in calcium absorption. There are a number of suitable studies in the literature that could serve as models and the basis for a study design (e.g., Refs. 139 through 141). The common end-measures shared by these animal studies include measures of apparent calcium absorption and determination of calcium content of bone, either directly by bone ashing and mineral analyses (Refs. 139 and 140) or indirectly by densitometric or histomorphometric methods (Ref. 141).

8. A number of comments proposed that superiority claims regarding the bioavailability or absorbability of calcium in a food or supplement compared to a reference food or supplement be permitted. One comment proposed milk as an ideal reference food against which to make the proposed comparisons and suggested the use of human bioavailability tests to provide evidence in support of superiority claims. Several comments suggested that a statistically significant difference in calcium absorption between two products using the proposed techniques should provide the basis for a superior absorbability comparative claim.

FDA advises that it is not appropriate to permit requested superiority claims under the provisions of the 1990 amendments that govern health claims. To the extent that the 1990 amendments provide for comparative claims, it is only with respect to claims that charaterize the level of a nutrient (section 403 (r)(1)(A) of the act). Regulations governing nutrient content claims, published elsewhere in this issue of the **Federal Register**, do not provide for superiority claims based on bioavailability. However, under § 10.30, an interested party can petition the agency to provide for superiority claims based on bioavailability. In considering such a petition, the agency would be concerned about ensuring that superiority claims are valid and nutritionally meaningful.

F. Disintegration and Dissolution of Calcium Supplements

9. The majority of comments concerned with the proposed requirement that calcium supplements meet the U.S. Pharmacopeia (U.S.P.) standards for disintegration and dissolution of calcium supplements (in proposed § 101.72(c)(4)) fully supported this aspect of the proposed regulation. The LSRO report strongly supported the proposed requirement noting that while the chemical form or solubility of the supplement makes little difference, the physical form of the salt and formulation of the tablet are critical. The comment stressed that "tablets so poorly formulated that they fail to disintegrate

under simulated gastric conditions appear to be widely distributed in the U.S. market." A public health advocacy group further suggested that since the U.S.P. is currently updating its standards for dietary supplements, the revised standards may include additional measures that FDA should adopt in the future. Two comments opposed this requirement. One argued that "the United States Pharmacopeia standards are not appropriately complete enough to be an exclusive condition for a product's health claim eligibility." The comment asserted that the U.S.P.'s are in vitro standards (meaning conducted in a test tube) and might not reflect human bioavailability of an individual calcium supplement, and they should therefore only establish a disqualifying presumption that would be rebuttable by the submission of human data supporting the product's bioavailability. Another comment emphasized the lack of justification for this testing, the inability to conduct all the tests since some of the calcium salts identified as safe for use as calcium supplements are not subject to U.S.P. dissolution requirements (calcium sulfate, and calcium oxide), the lack of fairness in that foods are not held to these criteria, the inappropriate application of drug standards set forth in the U.S.P. monographs to supplements, the "questionable expertise" of the U.S.P. convention members to judge nutritional property of compounds, and finally the lack of basis to require these standards in order to qualify for a health claim.

FDA has carefully considered these comments and agrees with several points. FDA agrees that disintegration and dissolution testing methods used to screen calcium supplements for bioavailability are imperfect, because these in vitro tests do not adequately mimic the physiologic environment of the human stomach, and U.S.P. standards are not available for all calcium-containing compounds. However, the agency considers the U.S.P. standards to provide sufficient assurance of dissolution and disintegration for those products where U.S.P. standards exist. A supplement that does not dissolve and disintegrate clearly does not provide calcium in an assimilable form and thus, a claim for such a supplement would be misleading because the supplement would not provide the nutrient that is the subject of the claim. Calcium supplements not in conventional food form can be formulated in a manner that prevents rapid dissociation and disintegration in the stomach, preventing assimilation. This unique aspect justifies the requirement in § 101.72(c)(2)(ii)(C) for supplements.

However, when U.S.P. standards do not exist, the agency recognizes, as pointed out by one comment, the need for an alternative method of establishing the bioavailability of supplements under the conditions of use stated on the product label. Demonstration of acceptable bioavailability in human or animal studies when conducted under the conditions of use stated on the product label (i.e, fed as an intact tablet, not crushed) would fulfill the requirement. Section 101.72(c)(2)(ii)(C) has been revised to require that dietary supplements meet the U.S.P. standards for disintegration and dissolution, except that dietary supplements for which no applicable U.S.P. standards exist shall exhibit appropriate assimilability under conditions of use stated on the product label. In order for a dietary supplement to bear the authorized calcium osteoporosis health claim, it must comply with all provisions of this final regulation.

G. Phosphorus Content

For reasons explained fully in the preamble of the proposal (56 FR 60689 at 60699 to 60700), FDA proposed that high levels of phosphorus (naturally occurring or added) in conventional foods or supplements that result in calcium to phosphorus ratios lower than 1:1 will disqualify the product from bearing a calcium/ osteoporosis health claim. FDA's tentative decision to place a limit on the amount of phosphorus that a food could have to be eligible to bear a claim was based on the ubiquitous distribution of this mineral in the food supply, the low ratio of calcium to phosphorus that typifies current intake patterns, and current evidence demonstrating that high levels of dietary phosphorus coupled with low dietary calcium adversely influence hormonal factors that regulate calcium and bone metabolism (Refs. 17, 21, 29, 32, 46, 93, 114, and 116). Many of the comments addressing this issue strongly supported the proposed phosphorus provision because of the reasons given by FDA in the proposal.

10. One comment questioned the need for any requirement that the phosphorus content not exceed the calcium content, asserting that "any reasonable fortified or enriched product will meet this condition."

The agency believes that it is incorrect to assume that all enriched, fortified, or modified products will contain more calcium than phosphorus, or even that products traditionally known to be rich sources of calcium will have lower levels of phosphorus than calcium. For example, a recent article (Ref. 142) on the reduction of fat in a newly developed processed cheese showed how processing techniques used to lower fat resulted in a calcium to phosphorus ratio lower than one to one. Some products naturally rich in phosphorus cannot meet this condition even after calcium fortification, and some products that are traditionally recognized as calcium rich foods, such as puddings, are now available in convenient instant versions in which the added phosphorus content far exceeds the calcium content. Therefore, FDA concludes that this comment does not provide a basis not to adopt a level of phosphorus that, if found in a food, would render the calcium osteoporosis claim misleading.

11. Several comments were in strong opposition to the requirement that a product not contain more phosphorus than calcium on a per weight basis. One comment contended that FDA relied on erroneous information relative to the consumption levels of dietary phosphorus supplied by food additives. The comment included data indicating little change in the estimated daily consumption of phosphorus from food additives from 1980 to 1990, based on the International Food Additives Council's estimated disappearance of food grade phosphorus in the United States. According to these data, the average per capita phosphorus consumption from food additives increased from 9.5 to more than 11 percent of the acceptable daily intake of phosphorus from 1980 to 1990.

FDA's statement in the proposal that phosphorus intake may be understated by as much as 15 to 20 percent due to phosphorus supplied by numerous additives was apparently misinterpreted by these comments. The agency did not intend to imply that phosphorus-containing food additive consumption had increased 15 to 20 percent. Rather, the agency was relying on the finding of Oenning et al. (Ref. 106), who demonstrated that nutrient estimates calculated from food intake records using current nutrient composition data bases underestimated phosphorus intake when compared to direct chemical analysis of the food from the dietary record. The underestimation of phosphorus content demonstrated in this study apparently was due to errors in the nutrient data bases, which have not kept abreast of changes in manufacturing techniques and in the use of phosphorus-containing food additives. FDA made this point to emphasize that currently in the United States, total phosphorus intake greatly

exceeds that of calcium, and that the levels may be even higher than surveys suggest because of flaws in the nutrient composition data bases used in these surveys.

The agency disagrees with the comment and interprets data presented by the comment as evidence of an important increase in phosphate food additive use over the last decade. These data indicate that estimated per capita daily consumption of phosphorus from food additives reported by the International Food Additive Council for 1990 was 470 milligrams (mg) phosphorus per day per capita as compared to an estimated 400 mg of phosphorus per day per capita for 1980, or approximately a 17 percent increase in per capita use over the last decade. Thus, more than one line of evidence points to the fact that the consumption of phosphorus-containing additives is on the rise and contributes to the high phosphorus intake observed in the United States population.

12. Another comment strongly opposed the proposed limit on phosphorus content for a number of reasons. The comment asserted that any health claim disqualifier must meet the same conditions as the claim itself, such as unanimous agreement among experts, and that no studies to date have demonstrated an adverse effect of excess phosphorus on bone in man or in monkeys or in calcium balance studies. This comment also asserted that there is a controversy over the effect of high phosphorus on calcium absorption and pointed to the fact that no single food contributes to the high phosphorus intake and to the remote possibility that reduction of phosphorus intake from one food will reduce total phosphorus intake.

The agency does not agree that any of these points warrants modification of the limit on phosphorus content in § 101.72(c)(2)(ii)(D). The limit on phosphorus is not a "disqualifying level" as that term is defined based on section 403(r)(3)(A)(ii) of the act. FDA is not limiting the phosphorus content because of its effect on the risk of a diet-related disease or health-related condition. FDA may have contributed to confusion in this regard by stating in the proposal that the level of phosphorus would disqualify a product from bearing a claim (56 FR at 60699). FDA is limiting the amount of phosphorus under the authority of section 403(a) of the act. As explained above, high levels of phosphorus when calcium intakes is low, would impair the utilization of calcium by bone. Thus, the presence of a calcium/osteoporosis claim on a food that does not have an appropriate calcium-phosphorus ratio would be misleading, because it would not be possible to get the full benefits of calcium from such a food.

In response to the criticism that no studies have demonstrated direct adverse effects of excess phosphorus on bone in humans or primate models, the agency points out that evidence in humans demonstrates that high levels of dietary phosphorus coupled with low dietary calcium intake adversely influence hormonal factors that regulate calcium and bone metabolism (Refs. 17, 21, 29, 32, 46, 93, 114, and 116). These changes were consistent with those observed in a variety of animal models where the hormonal changes were shown to induce bone resorption and ultimately bone loss (Ref. 46). The agency is particularly concerned about teens and young adults who typically consume more phosphorus than calcium (Ref. 105) and for whom such diets have recently been shown to produce changes in serum calcium and bone-regulating hormones that may adversely affect attainment of peak bone mass (Ref. 32). The health claim is an effective means of alerting this vulnerable population to foods that have the desired ratio of these two nutrients. Therefore the agency does not agree with the comment's suggestion that the limit on phosphorus content be dropped.

The agency does not disagree with the other assertions made in this comment. These points are minor and, given that health claims are authorized in the context of the total daily diet, not particularly relevant. The agency did not assert that excess phosphorus impaired calcium absorption and has maintained that phosphorus is ubiquitously distributed in the food supply. Given the effects of phosphorus on hormonal factors that regulate calcium and bone metabolism, FDA concludes that the limit on phosphorus content for a food that bears a calcium/osteoporosis claim is appropriate.

H. No Quantification of Reduction in Risk

13. One comment urged FDA to avoid any possible misinterpretation and potential abuse of the calcium/osteoporosis regulation by specifying in the regulation that "the claim shall not convey the misconception that dietary calcium intake can cure osteoporosis." The comment included examples of labels of dietary supplements found in health food stores.

The agency agrees with the comment's concern but remains confident that the claims being authorized will not mislead consumers into believing that calcium cures osteoporosis. This regulation authorize a health claim that relates calcium intake to a reduction in the risk of osteoporosis. A statement that calciun cures osteoporosis would constitute a drug claim under section 201(g)(1)(B) of the act (21 U.S.C. 321(g)(1)(B)), and a product bearing such a claim would be subject to regulation as a drug. In addition, § 101.72(c)(2)(i)(D) bars health claims on calcium and osteoporosis from attributing any degree of reduction in risk of osteoporosis to maintaining an adequate calcium intake throughout life

I. Limitations of Benefit to Bone Health

14. Several comments opposed the upper-limit-of-benefit statement proposed in § 101.72(d)(5), saying that this statement was an effort to limit the potency of supplements. A number of comments supported the statement but required that it be qualified. One comment requested that the statement only be placed on products in which the calcium level is greater than 50 percent of the originally proposed RDI of 900 mg or 450 mg of calcium (presumably per serving or per recommended daily dose). This comment reasoned that for products with lower levels of calcium, an unreasonable number of servings of food would need to be consumed to exceed 200 percent of the RDI, and thus the statement was not necessary.

FDA does not agree with the assertion that it is seeking to limit the potency of supplements. This regulation relates only to the type of health claim that a product may bear. It ensures that a material fact about the consequences of consumption of more than a specified level of calcium is presented as part of the claim. FDA agrees in principle with the suggested change in proposed § 101.72(d)(5) and believes that this modification may help curb overfortification. The agency has therefore added the following language to the proposed provision redesignated as § 101.72(c)(2)(i)(E)): "This requirement does not apply to foods that contain less than 40 percent of the recommended daily intake of 1,000 mg of calcium per day or 400 mg of calcium per reference amount customarily consumed or per total daily recommended supplement intake."

J. Safety

15. A public health advocacy association suggested that FDA require labels on high dose calcium supplements to disclose that high calcium intakes may increase the risk of kidney stones in susceptible people. The comment argued that levels greater than 1,000 to 2,500 mg calcium per day

may pose a risk to people with a history of kidney stones, and that, therefore, labels on supplements that contain 500 mg or more of calcium should inform consumers of this risk.

The agency does not agree that a warning is needed in addition to the statement on total dietary intakes greater than 200 percent of the RDI. Section § 101.72(c)(2)(i)(B) requires that the health claim identify the populations at greatest risk of osteoporosis, namely caucasian and Asian women in their bone forming years. Kidney stones are more prevalent in men than women. (With respect to calcium oxalate or mixed calcium stones, affected males outnumber affected females by three or four to one in the U.S. population (Ref. 143).) Thus, while men are at greater risk of the adverse affects of excess calcium intake due to their greater susceptibility to kidney stone formation, they are not at greater risk for osteoporosis and will not be targeted by the calcium-osteoporosis health claim. Consequently, there is no reason to expect that men will increase their consumption of calcium in response to the claim. Therefore, FDA concludes that the regulations offer sufficient protection without the proposed warning.

K. Consumer Summary

16. The comments specific to the proposed consumer summary were generally supportive, and some considered consumer summaries necessary to put any health claim into perspective as related to total diet. The use of the consumer summary on package inserts was suggested by several groups. Several comments suggested various ways to shorten the summary, while others suggested additional information to incorporate. One comment strongly opposed the consumer summary, stating that in light of the detailed, balanced information provided in the model claims, summaries are redundant, costly, and inconvenient to the manufacturer.

As discussed in the final rule on general requirements for health claims, consumer summaries are not required, although their use remains an option. For this reason, FDA has not included the proposed consumer summary on calcium and osteoporosis in this final rule.

L. Regulatory History of Calcium-containing Food Additive Use

The agency advised that, in order for calcium-containing food ingredients in conventional foods or calcium supplement products to be considered eligible to bear the authorized calcium/ osteoporosis health claim, they must meet the requirements in § 101.14, which include that they have been shown to FDA's satisfaction to be safe and lawful under the applicable safety provisions of the act (56 FR at 60699). Safety and lawfulness can be demonstrated in a number of ways, including through a showing that a food is generally recognized as safe (GRAS), affirmed as GRAS by FDA, listed in the food additive regulations, or subject to a prior sanction. Of the 36 or more calcium-containing ingredients identified by the agency as currently in use (Ref. 33), FDA advised that only the following 10 compounds had been demonstrated to be safe and lawful for use in a dietary supplement or as a nutrient supplement: calcium carbonate, calcium citrate, calcium glycerophosphate, calcium oxide, calcium pantothenate, calcium phosphate, calcium pyrophosphate, calcium chloride, calcium lactate, and calcium sulfate (56 FR at 60691).

17. One comment pointed out that the agency failed to include calcium ascorbate in this list of 10 compounds. The comment included also submitted an April 1989 letter from FDA stating the agency's lack of objection to the use of calcium ascorbate in dietary supplements. Another comment sought the addition of calcium hydroxide to the list of 10 calcium compounds discussed above, contending that "since calcium oxide is permitted and calcium hydroxide is simply the hydrate of the oxide formed on contact with water," calcium hydroxide should be included in the list.

As stated above, only 10 compounds have been demonstrated to FDA's satisfaction to be safe and lawful for use in a dietary supplement or as a nutrient supplement bearing a calcium/ osteoporosis health claim. In Ref. 33 of the proposal, the agency identified the calcium-containing ingredients currently in use, their functions, conditions of use, and limits on the levels at which they can be added to food. Only those ingredients with stated use as a nutrient supplement or in a dietary supplement are considered eligible for a health claim. Calcium ascorbate appears only under 21 CFR 182.3189 (Ref. 33) for use as a chemical preservative. Thus, FDA's failure to list it was not inadvertent. Calcium ascorbate is not eligible at this time for consideration for a health claim; however, a petition may be filed requesting a safety review for a new use of calcium ascorbate. Based on the outcome of this petition and review, calcium ascorbate may be considered eligible for a calcium/ osteoporosis health claim.

The agency declines to add calcium hydroxide to the list of 10 calcium-containing compounds that have been demonstrated to be safe and lawful for use in a dietary or nutrient supplement. In the list, FDA identified those ingredients with stated uses as a nutrient or dietary supplement, thus avoiding the use of potentially poorly suited or potentially harmful compounds. FDA's failure to include calcium hydroxide on the list does not imply that the agency considers the use of this substance to be unsafe for use as a calcium supplement, but rather reflects that it has not been demonstrated safe and lawful for this use. Manufacturers who would like to be abel to make a calcium/ osteoporosis health claim based on the presence of calcium hydroxide in their product should submit an appropriate petition to FDA.

M. Food Fortification

18. A public health and nutrition association expressed concern that manufacturers seeking a calcium/ osteoporosis health claim will fortify products of low nutritional value that do not naturally contain calcium. The comment recommended that FDA consider setting standards for the amount of fortification that is allowed and also suggested that FDA determine which products can be fortified.

Although the agency understands the concern expressed in the comment, the full implementation of these suggestions is beyond the scope of this rulemaking. The agency advises that fortification of foods to qualify for a health claim must comply with the final rule on general requirements for health claims published elsewhere in this issue of the **Federal Register**.

N. Nutrition Claims

19. One comment argued that claims relating to a nutrient's effect on the structure or function of the body are not health claims but nutrition claims. The comment suggested amending the proposed regulations to clarify the distinction between nutrition and health claims. In the event that FDA's rejected this proposal, the comment asked that the agency acknowledge that the relationship between calcium and bone health is a nutrition claim that is substantiated in the proposed calcium/ osteoporosis health claim regulation.

FDA rejects these suggestions. The distinction between nutritional guidance and health claims is discussed in the final rule on general requirements for health claims. The claim authorized

under this regulation relating calcium and osteoporosis is a health claim because it characterizes the relationship of a nutrient (calcium) to a disease or health-related condition (osteoporosis). A claim relating calcium to bone health would have to be evaluated on its own merits. Such a claim might be considered an implied health claim, rather than merely a statement about a food's effect on the structure or function of the body, and, if so, it would be subject to regulation under section 403(r) of the act.

O. Model Claim

20. Many comments discussed the length of the model health claim and its required components. Common to all comments was the complaint that the model message was too wordy. Comments were almost equally split between those supporting and those opposing the proposed model message. Supporting comments praised specific aspects of the model claim such as disclosure of other risk factors; the likely upper limit of beneficial calcium intakes; reflection of other factors that contribute to osteoporosis risk such as age, race, and sex; inclusion of the need for exercise; and disclosure of the mechanisms through which calcium may reduce the risk of osteoporosis. Opposing comments emphasized the burdensome length of the model claim. One comment stated that the length of the claim would not allow it to be translated into multiple languages on the label. Many comments requested that FDA remove the requirements that populations at special risk of osteoporosis and nondietary factors that can help prevent osteoporosis be identified. Several comments suggested that the length of the claim will limit its effectiveness and curtail manufacturers' incentives to make claims. An association of national advertisers asserted that no diet and disease relationship can be explained completely in one paragraph.

The agency agrees that the proposed model health claim was too long. However, as discussed in the proposal and elsewhere in this final rule, certain information is needed in the health claim in order for it to be truthful and not misleading to segments of the population that are not at high risk of developing osteoporosis or for whom no link between calcium and osteoporosis has been established. FDA notes that the proposed model claim contained optional as well as required information, and the example has been rewritten to demonstrate that all required information can be included in a model claim of less than 35 words: "Regular exercise and eating a healthful diet with enough calcium helps teen and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life." Foods that contain less than 40 percent of the recommended daily intake of 1,000 mg of calcium per day (400 mg calcium) per reference amount customarily consumed or per total daily recommended supplement intake may bear this claim. Other foods that contain higher levels of calcium must also carry an additional statement (see § 101.72(c)(2)(i)(E)).

Throughout FDA's responses to the comments in this preamble, the agency has presented various reasons that strongly support maintaining the requirements that make the claim lengthy. These points include the need not to mislead the public in thinking everyone is at risk for this disease, the need to identify those at greatest risk and thus to help individuals who are not at risk but who are susceptible to the adverse effects of oversupplementation with calcium avoid any problems, and the need to target the age group for which adequate calcium intake may have the greatest benefit for bone health and delayed risk of osteoporotic fracture.

P. Other Issues

21. One comment contended that FDA should permit health claims on OTC antacid products containing only calcium carbonate. Responding to a discussion on dual labeling in the proposal on general requirements for health claims (56 FR 60537), the comment asserted that FDA's objection to OTC drugs bearing health claims is not appropriate in the case of calcium-based antacids, because such products have been labeled for years with both food and drug labeling.

FDA has addressed the issues raised by this comment in the final rule on general requirements for health claims, published elsewhere in this issue of the **Federal Register**.

22. Another comment urged that the regulation require disclosure about the relationship between calcium and protein and suggested disqualifying high protein products based on the effect of dietary protein on the urinary loss of calcium, which affects bone health.

As mentioned in the preamble of the proposal (56 FR at 60699), the agency recognizes that high levels of dietary protein typically found in the American diet have been shown to increase the obligatory loss of calcium, i.e., the amount of calcium that the body must lose daily. The agency, however, did not propose to disqualify high-protein products from bearing a calcium/osteoporosis claim or to disclose the effect of high protein intake on calcium retention on the label. Like calcium, protein is not ubiquitously distributed in our food supply and is richest in specific food sources (Refs. 27 and 110). Relatively few foods are sources of calcium and protein, forcing consumers to be selective to meet the nutritional needs for both calcium and protein. Some protein rich foods, such as lowfat milk or lowfat milk products, contribute more than half the calcium and protein intake of some individuals, notably children. It would be misleading to the public not to allow an important food such as lowfat milk to have a calcium/osteoporosis claim due to its high levels of protein. To disqualify a product that is both rich in calcium and protein, and that would not be disqualified because of its fat, saturated fat, cholesterol, or sodium levels, because of its protein content, would effectively prevent several major food sources of calcium from bearing a claim.

Several other considerations reinforce the agency's position that protein content should not be a basis for disqualification from bearing a calcium/osteoporosis claim or for a disclosure statement. The scientific evidence demonstrating a persistent increase in the urinary loss of calcium when high protein intakes are sustained for months is weak and controversial. In addition, different protein sources have been shown to elicit varying degrees of calciuria (increased loss of calcium in urine), thus making it incorrect for the agency to consider all dietary protein sources equally potent in their calciuric effect. Moreover, no clear evidence exists demonstrating that high protein intake alters any of the hormones that control bone formation and resorption, or that high protein intake impairs bone mineralization.

FDA is making several minor changes in the regulation to improve its readibility and to make it consistent with other regulations that FDA is adopting that authorize health claims. The most significant of these changes is the fact that FDA is adding to the paragraph on optional information a provision that will allow the declaration as part of the claim of the number of people who are affected by osteoporous (§ 101.72(d)(2)). This change makes § 101.72 consistent with the other regulations in Subpart E. Therefore, FDA is rejecting the comment's suggestion to require a statement about the relationship between calcium and protein or to establish a level of protein

that would disqualify a product from bearing a calcium/osteoporosis claim. The agency concludes that a product high in protein can still be an important source of calcium and that it cannot conclude that a claim would be misleading if it fails to reveal the relationship between calcium and protein.

III. Review of Scientific Evidence

FDA updated its review of the scientific literature by examining articles published since the proposed rule was issued. FDA's evaluation of recent human studies meeting the criteria outlined in the proposal (56 FR at 60693) is presented in Table 1 (Refs. 144 through 150). In addition, FDA also considered several review articles that were published since the proposal (Refs. 151 through 156). FDA sought to answer the same questions posed in the proposed rule.

First, do any of the recent studies present evidence documenting the role of calcium in achieving peak bone mass? A cross-sectional study examining spinal bone density in Caucasian girls 8 to 18 years of age demonstrated that calcium intake may be a major factor in achieving peak adult bone density (Ref. 148). Chan et al. (Ref. 145) also demonstrated higher bone mineral content in Caucasian boys and girls consuming greater than 1,000 mg of calcium per day. In this study 70 percent of the subjects younger than 11 years consumed at least their RDA of 800 mg of calcium per day, while 63 percent of the subjects older than 11 consumed less than their RDA of 1,200 mg per day. After adjustment for phosphorus and protein intake, multivariate analyses showed only calcium intake was related to bone mineral status of the children in this study. Thus, the most recent data, although not definitive, continue to strongly support the link between adequate calcium intake and optimal peak bone mass.

The second question asked in reviewing these studies is whether added calcium or high calcium intake reduces the risk of fracture or slows the rate of bone loss in younger or older subjects. Andon et al. (Ref. 144) showed, in a cross-sectional study, that Caucasian postmenopausal women consuming less than 600 mg calcium per day had significantly lower spinal bone mineral densities than women with higher calcium intakes. Because individuals who malabsorb lactose normally avoid dairy products, Wheadon et al. (Ref. 150) assessed lactose absorption and dietary calcium intake in elderly women with and without hip fractures and in young women. While 60 percent of the women with hip fractures were lactose malabsorbers, dietary calcium intakes did not differ significantly among the three groups. However, the authors cautioned against putting too much weight on the findings of the small study (n=31) since the aversion to milk and milk products ascribed to lactose intolerance may be shown to decrease calcium intake in a larger population.

As discussed in the earlier literature review, the responsiveness of postmenopausal women to calcium supplementation depends largely on their menopausal age. Calcium supplementation had no effect on spinal bone density early in menopause, but for women late in menopause, the rate of bone loss could be significantly reduced with calcium supplementation, if initial habitual calcium intakes were low (Refs. 47 and 151). Three recent prospective intervention studies (Refs. 146, 147, and 149) shed further light on this observation. Elders et al. (Ref 146) reported a high rate of lumbar vertebral bone loss in late and early postmenopausal subjects, with the highest loss occurring in early postmenopause. However, no significant interaction was observed between menopausal status of the subjects and the effect of calcium supplementation. These authors reported a significant decrease in lumbar bone loss after 2 years for women treated daily with 1,000 mg and 2,000 mg of elemental calcium relative to controls. The effect of calcium supplementation was significant after the first year of supplementation but not after the second year. The authors speculate that calcium supplementation probably reduced bone turnover.

In a double-blind, placebo controlled trial in Caucasian, postmenopausal women, with low initial forearm bone density, Prince et al. (Ref. 147) showed significantly less bone loss in the distal forearm in those women treated with calcium and regular exercise, while a group treated with estrogen and regular exercise gained significant bone density at this site relative to the control group with normal initial bone density and the group treated with exercise alone. Thus, calcium supplementation and exercise slowed bone loss relative to exercise alone but less effectively than exercise combined with estrogen.

In the third prospective study, this one a 3-year study in 622 Caucasian women, Tilyard and co-workers measured rate of vertebral fractures in women treated twice a day with either 0.25 micrograms of calcitriol (a synthetic form of the active metabolite of vitamin D) or 1 gram of elemental calcium (Ref. 149). After 2 and 3 years, a significant reduction in the rate of vertebral fracture was observed in calcitriol-treated women relative to those treated with calcium alone. This study clearly demonstrates that supplementation of calcium intake alone is not adequate to prevent vertebral fracture in postmenopausal women. In the absence of placebo-treated controls, the contribution of calcium supplementation to the reduction in vertebral fracture cannot be estimated. The results of these three prospective clinical trials support the hypothesis that adequate calcium intake helps to slow the rate of bone loss in postmenopausal women, but that calcium alone cannot effectively arrest this process, especially in early postmenopause.

The third question considered in evaluating the recent literature was whether any of the studies showed a threshold effect for the level of calcium intake associated with changes in bone mass. None of the findings from the recent studies were pertinent to this question.

To summarize, these new findings were consistent with and strengthened the conclusion that adequate calcium intake has a significant impact on bone health and risk of osteoporotic fracture.

IV. Decision to Authorize a Health Claim Relating Adequate Calcium Intake to Osteoporosis

The agency has reviewed recently published research articles and review articles relevant to calcium intake and osteoporosis (Refs. 144 through 156) and has concluded that the new studies are consistent with the tentative conclusions drawn in its proposed rule on calcium and osteoporosis (56 FR 60689) . The agency also considered all comments received in response to the proposal. The overwhelming concurrence among the experts in this area and the totality of publicly available evidence supports an association between adequate calcium intake and risk of osteoporosis. Based on the totality of the publicly available scientific evidence, FDA has determined that there is significant scientific agreement among qualified experts that a health claim for calcium and osteoporosis is supported by the evidence. Under § 101.72, an authorized health claim will convey the message that an adequate intake of calcium throughout life may delay the development of osteoporosis and ultimately reduce the risk of bone fracture in some individuals later in life.

V. Environmental Impact

The agency has determined that under 21 CFR 25.24(a)(11) this action is of a type that does not individually or cumulatively have significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

VII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. DHHS, Public Health Service, "The Surgeon General's Report on Nutrition and Health," Washington, DC, DHHS (PHS) Publication No. 017-001-00465-1, U.S. Government Printing Office, 1988.

2. Committee on Diet and Health, Commission on Life Sciences, National Research Council, "Diet and Health: Implications for Reducing Chronic Disease Risk," Washington, DC, National Academy Press, 1989.

3. Food and Nutrition Board, Commission on Life Sciences, National Research Council, "Recommended Dietary Allowances," Tenth Edition, Washington, DC, National Academy Press, 1989.

4. USDA and DHHS, "Nutrition and Your Health: Dietary Guidelines for Americans," Home and Garden Bulletin, No. 232, U.S. Government Printing Office, Third Edition, 1990.

5. DHHS, National Institutes of Health, National Institutes of Arthritis and Musculoskeletal and Skin Diseases, "Osteoporosis—Cause, Treatment, Prevention," NIH Publication No. 86-2226, U.S. Government Printing Office, May 1984 and May 1986.

6. DHHS, National Institutes of Health "Osteoporosis Report of the 1984 Consensus Development Conference on Osteoporosis," *Journal of the American Medical Association*, 252:799-802, 1984.

7. DHHS, National Institutes of Health. "Consensus Development Conference: "Prophylaxis and Treatment of Osteoporosis," *American Journal of Medicine*, 90:107-110, 1991.

8. DHHS, National Institutes of Health, National Institutes of Arthritis, Musculoskeletal and Skin Diseases, "Osteoporosis: Research, Education, Health Promotion," NIH Publication No. 91-3216, U.S. Government Printing Office, 1991.

9. "Diet, Nutrition, and the Prevention of Chronic Diseases," Report of World Health Organization Study Group, Technical Report Series 797, World Health Organization, Geneva, CH, 1990.

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List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.72 is added to subpart E to read as follows:

§ 101.72 Health claims: calcium and osteoporosis.

(a) *Relationship between calcium and osteoporosis.* An inadequate calcium intake contributes to low peak bone mass and has been identified as one of many risk factors in the development of osteoporosis. Peak bone mass is the total quantity of bone present at maturity, and experts believe that it has the greatest bearing on whether a person will be at risk of developing osteoporosis and related bone fractures later in life. Another factor that influences total bone mass and susceptibility to osteoporosis is the rate of bone loss after skeletal maturity. An adequate intake of calcium is thought to exert a positive effect during adolescence and early adulthood in optimizing the amount of bone that is

laid down. However, the upper limit of peak bone mass is genetically determined. The mechanism through which an adequate calcium intake and optimal peak bone mass reduce the risk of osteoporosis is thought to be as follows. All persons lose bone with age. Hence, those with higher bone mass at maturity take longer to reach the critically reduced mass at which bones can fracture easily. The rate of bone loss after skeletal maturity also influences the amount of bone present at old age and can influence an individual's risk of developing osteoporosis. Maintenance of an adequate intake of calcium later in life is thought to be important in reducing the rate of bone loss particularly in the elderly and in women during the first decade following menopause.

(b) *Significance of calcium.* Calcium intake is not the only recognized risk factor in the development of osteoporosis, a multifactorial bone disease. Other factors including a person's sex, race, hormonal status, family history, body stature, level of exercise, general diet, and specific life style choices such as smoking and excess alcohol consumption affect the risk of osteoporosis.

(1) Heredity and being female are two key factors identifying those individuals at risk for the development of osteoporosis. Hereditary risk factors include race: Notably, Caucasians and Asians are characterized by low peak bone mass at maturity. Caucasian women, particularly those of northern European ancestry, experience the highest incidence of osteoporosis-related bone fracture. American women of African heritage are characterized by the highest peak bone mass and lowest incidence of osteoporotic fracture, despite the fact that they have low calcium intake.

(2) Maintenance of an adequate intake of calcium throughout life is particularly important for a subpopulation of individuals at greatest risk of developing osteoporosis and for whom adequate dietary calcium intake may have the most important beneficial effects on bone health. This target subpopulation includes adolescent and young adult Caucasian and Asian American women.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met.

(2) Specific requirements. (i) *Nature of the claim.* A health claim associating calcium with a reduced risk of osteoporosis may be made on the label or labeling of a food describe in paragraph (c)(2)(ii) of this section, provided that:

(A) The claim makes clear that adequate calcium intake throughout life is not the only recognized risk factor in this multifactorial bone disease by listing specific factors, including sex, race, and age that place persons at risk of developing osteoporosis and stating that an adequate level of exercise and a healthful diet are also needed;

(B) The claim does not state or imply that the risk of osteoporosis is equally applicable to the general United States population. The claim shall identify the populations at particular risk for the development of osteoporosis. These populations include white (or the term "Caucasian") women and Asian women in their bone forming years (approximately 11 to 35 years of age or the phrase "during teen or early adult years" may be used). The claim may also identify menopausal (or the term "middle-aged") women, persons with a family history of the disease, and elderly (or "older") men and women as being at risk;

(C) The claim states that adequate calcium intake throughout life is linked to reduced risk of osteoporosis through the mechanism of optimizing peak bone mass during adolescence and early adulthood. The phrase "build and maintain good bone health" may be used to convey the concept of optimizing peak bone mass. When reference is made to persons with a family history of the disease, menopausal women, and elderly men and women, the claim may also state that adequate calcium intake is linked to reduced risk of osteoporosis through the mechanism of slowing the rate of bone loss;

(D) The claim does not attribute any degree of reduction in risk of osteoporosis to maintaining an adequate calcium intake throughout life; and

(E) The claim states that a total dietary intake greater than 200 percent of the recommended daily intake (2,000 milligrams (mg) of calcium) has no further known benefit to bone health. This requirement does not apply to foods that contain less than 40 percent of the recommended daily intake of 1,000 mg of calcium per day or 400 mg of calcium per reference amount customarily consumed as defined in § 101.12 (b) or per total daily recommended supplement intake.

(ii) *Nature of the food.* (A) The food shall meet or exceed the requirements for a "high" level of calcium as defined in § 101.54(c);

(B) The calcium content of the product shall be assimilable;

(C) Dietary supplements meet the United States Pharmacopeia (U.S.P.) standards for disintegration and dissolution applicable to their component calcium salts, except that dietary supplements for which no U.S.P. standards exist shall exhibit appropriate assimilability under the conditions of use stated on the product label;

(D) A food or total daily recommended supplement intake shall not contain more phosphorus than calcium on a weight per weight basis.

(d) *Optional information.* (1) The claim may include information from paragraphs (a) and (b) of this section.

(2) The claim may include information on the number of people in the United States who have osteoporosis. The sources of this information must be identified, and it must be current information from the National Center for Health Statistics, the National Institutes of Health, or "Dietary Guidelines for Americans."

(e) *Model health claim.* The following model health claims may be used in food labeling to describe the relationship between calcium and osteoporosis:

Model Health Claim Appropriate for Most Conventional Foods:

Regular exercise and a healthy diet with enough calcium helps teen and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life.

Model Health Claim Appropriate for Foods Exceptionally High in Calcium and Most Calcium Supplements:

Regular exercise and a healthy diet with enough calcium helps teen and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life. Adequate calcium intake is important, but daily intakes above about 2,000 mg are not likely to provide any additional benefit.

Dated: December 17, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

Note: The following table will not appear in the annual Code of Federal Regulations.

BILLING CODE 4160-01-F

TABLE

Calcium and Osteoporosis: Effects of Calcium on Bone Status

Reference (author, date)	Study Design	Number and Description of Subjects	Duration of Study	Source and Identity of Test Material	Dosage of Test Material Used	Base Diet	Additional Treatments	Other Factors Affecting Interpretation of Data	Results	Comments
Aaron, M., et al. (1991) (Ref. 11)	Cross-sectional measured: vertebral bone density (L2-L4) by dual photon absorption	131 women, Caucasian aged 52 to 83 years mean age: 61.7 years mean year post menopause: 10.1 years	N/A	Habitual diet	Dietary calcium intake estimated from food frequency questionnaire		Controlled for other factors including body weight, estrogen and alcohol use	Multiple regression analyses used to estimate effect of calcium intake on spinal bone density. Subjects grouped according calcium intake of < or >606 mg Ca/day	significant correlation of body weight and dietary calcium with vertebral bone mineral density. Women consuming < 606 mg Ca per day had significant lower Bone mineral density than those consuming > 606 mg/day	study weakened by use of food frequency questionnaire not a reliable method of accurately estimating calcium intake
Chan, G. (1991) (Ref. 12)	Cross-sectional measured: bone mineral density of the distal third radius of nondominant side using single photon absorption and calcium intake Serum parameters also measured	164 healthy Caucasian children 83 boys 76 girls	N/A	Habitual Diet		Habitual nutrient intake was estimated from two, 2-day dietary histories		Correlation of age weight and height was significant to bone mineral content in all 164 children	70% of subjects < 11 years consumed at least 800 mg/day 63% of subjects > 11 consumed less than their Recommended Dietary Allowance of 1200 mg Ca/day mean intake =750 mg/girl While 53% of boys > 11 years consumed at least 1 200 mg/day Multivariate analyses showed only calcium intake related to children s bone mineral status (partial correlation coefficient= 0 18 P<0 05)	Employed a weak method of determining calcium intake Children consuming > 1,000 mg of Ca/day had higher bone mineral content

TABLE--CONTINUED

Reference (Author date)	Study Design	Number and Description of Subjects	Duration of Study	Source and Identity of Test Material	Dosage of Test Material Used	Base Diet	Additional Treatments	Other Factors Affecting Interpretation of Data	Results	Comments
Elders P , et al (1991) (Ref 146)	Prospective Randomized Clinical Trial measured: Bone mineral density of the lumbar spine (L2 L4) by dual photon absorption and combined metacarpal cortical thickness in second, third and fourth metacarpals of both hands	295 women, mostly Caucasian 45 to 55 years of age Menopausal status was assessed by menstrual history and classified into four menopausal groups	3 years	Supplemental calcium source was effervescent tablet with 5 23 g of calcium lactogluconate and 0 9 g calcium carbonate	3 treatments no calcium supplements - 1 000 mg calcium at night - 2 000 mg calcium in two doses at night and in morning	Habitual Intake	67 295 of the original subjects dropped out 44 of the calcium treated group switched forms of calcium to calcium citrate due to GI upset		A significant decrease in lumbar bone loss observed after 2 years for the 1,000 and 2 000 mg supplemented groups relative to control (1 3% 0.7% and 3 5% mean loss after 2 years) The effect of calcium on lumbar bone loss was significant after the first year, but not after the second Calcium did not significantly effect metacarpal cortical bone loss	Authors concluded that calcium supplementation retards lumbar bone loss in the first year of supplementation, probably through reduced bone turnover Rate of lumbar bone loss was significantly more pronounced in late peri and early postmenopause and was highest in early postmenopause
Prince, R et al , (1991) (Ref 147)	Double blind Placebo controlled Randomized Clinical trial Measured: Bone density at 3 forearm sites using single photon absorption every 3 months Urine and blood measurements every 6 months	120 women Caucasian, mean age, 56±4 years All had low forearm bone density 42 women mean age 55 5±3 years All has normal forearm bone density	2 years	Exercise alone: n= 41 Exercise + 1 g Ca (calcium lactategluconate n=39 Exercise + progesterone and estrogen	2 5 mg/day medroxyprogesterone acetate and 0 625 mg/day estropipate for 1 month then 1 25 mg/day for 23 months	Habitual diet No significant difference observed between treatment groups Mean calcium intakes for all treatment groups > 650 mg	All exercise regimens consisted of one weekly class and two brisk 30 minutes walks per week Every 6 months, physical activity recorded over 4 days and scored Four day dietary records were recorded at beginning and end	All women in treatment groups had initial forearm bone density not lower than one standard deviation below mean for normal control Among 3 treatments no differences in baseline physical activity score calcium intake or forearm density observed	At the distal site both the normal control and the exercise alone group lost significant forearm bone (> -2 5%/y) while exercise + Calcium group lost significant bone (0 05 %/y) and the exercise + estrogen group gained significant bone density (+2 7%/y)	A combined therapy of estrogen and exercise was the most effective in increasing forearm bone mass but with more undesirable side effects Calcium and exercise slowed bone loss relative to exercise alone but less effective than exercise + estrogen Exercise alone was not effective

TABLE--CONTINUED

Reference (author, date)	Study Design	Number and Description of Subjects	Duration of Study	Source and Identity of Test Material	Dosage of Test Material Used	Base Diet	Additional Treatments	Other Factors Affecting Interpretation of Data	Results	Comments
Gentipal, J., et al (1991) (Ref 140)	Cross-sectional Measured: Vertebral bone density by dual X-ray absorption (L1 L4) and current calcium intake	49 adolescent girls 0 to 10 years Caucasians	N/A	Habitual diet	Current calcium intake estimated from 4-day diet records		3-day activity records used to determine average daily energy expenditure 16% of 11 to 18 year olds met their Recommended Dietary Allowance of 1200 mg for calcium, while 67% of the 0 to 10 year olds met their Recommended Dietary Allowance of 800 mg calcium	Relative contributions to difference in vertebral body density contributed by calcium intake, age weight height, total energy expenditure, SMR, were estimated by total linear regression SMR = Tanner Sexual Maturity Rating	61% of the variance in vertebral bone density was contributed by SMR, age, and calcium intake	Data suggest that calcium intake may influence peak bone mass and may be a major limiting factor in achieving adult bone density
Tilyard, M., et al., (1992) (Ref 143)	Prospective multicenter single-blind randomized intervention study measured: Rate of vertebral fracture, as defined as a decrease of 15% or more during any 1 year in the anterior or posterior height of the vertebral body from T4 through L4 estimated from early roentgenograms	622 women Caucasian aged 50 to 79 years All had one or more nontraumatic vertebral compression fracture None on estrogens 515 completed 1 year 475 completed 2 years, 433 completed 3 years	3 years	Calcitriol group n= 314 Calcium group n= 308	0.25 ug calcitriol, twice/day 1 gram Calcium as 5.2 g calcium gluconate twice/day	Baseline dietary calcium intakes measured in both groups	Monitored serum chemistry changes relative to baseline over the 3 years of treatment	Measured incidence of nephrocalcinosis since both treatments are associated with it Measured calcium absorption status at 30 months	At year 1, fracture rate was 8.0 in Calcitriol and 10.3 in calcium groups At year 2, Fracture rates of spine were significantly reduced in Calcitriol and even more pronounced difference between treatments shown after 3 years Calcium group has a higher rate of vertebral fracture compared to calcitriol treated subjects at all times	Study lacked a compliance assessment High patient attrition, 31% of women did not complete the study Study clearly shows that calcium supplementation alone is not adequate to prevent vertebral fractures in menopausal women Calcium absorption status did not affect rate of fracture in groups

TABLE--CONTINUED

Reference (author, date)	Study Design	Number and Description of Subjects	Duration of Study	Source and Identity of Test Material	Dosage of Test Material Used	Base Diet	Additional Treatments	Other Factors Affecting Interpretation of Data	Results	Comments
Wheadon, H., et al. (1991) (Ref. 150)	Assessed lactose absorption and dietary calcium intake in elderly women with and without hip fractures Measured: Lactose tolerance and dietary calcium	Women with hip fractures: n= 15, type II osteoporosis mean age = 66±10 years Control: Normal n= 16 mean age = 65±9 years			Dietary calcium intake was estimated from a food frequency questionnaire			Since bone density was not measured, there is a strong possibility that the elderly controls also had type II osteoporosis, but had not sustained a fracture	60% of elderly hip fracture group were lactose malabsorber 19/31 total elderly subjects were lactose malabsorber Dietary calcium intakes did not differ significantly among the 3 groups	Authors were not able to show a decreased dietary calcium intake associated with lactose malabsorption, but the aversion to milk and milk products ascribed to lactose malabsorption may be shown to decrease calcium intake in a larger population In elderly, decreased calcium intake may exacerbate calcium bone from loss

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 91N-0103]

RIN 0905-AB07

Food Labeling: Health Claims and Label Statements: Omega-3 Fatty Acids and Coronary Heart Disease

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing its decision not to authorize the use on the label or labeling of foods of health claims relating to an association between omega-3 fatty acids and coronary heart disease (CHD). The agency has determined, based on: (1) The totality of the publicly available scientific evidence; and (2) the agency's review of comments received in response to its November 27, 1991, proposed rule on omega-3 fatty acids and CHD, including scientific information included in those comments, that there is not significant scientific agreement among experts that such evidence supports a health claim for omega-3 fatty acids and CHD. Further, FDA has determined that the new information does not change the conclusions that the agency reached on the basis of the information reviewed in its proposal. Therefore, FDA has concluded that such a claim is not justified. This action is in response to provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) that bear on health claims, and is developed in accordance with the final rule on general requirements for health claims, published elsewhere in this issue of the **Federal Register**.

EFFECTIVE DATE: May 8, 1993.

FOR FURTHER INFORMATION CONTACT: John C. Wallingford, Center for Food Safety and Applied Nutrition (HFS-465), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5461.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 27, 1991 (56 FR 60663), FDA proposed not to authorize a health claim relating diets high in omega-3 fatty acids to reduced risk of heart disease. The proposed rule was issued in response to provisions of the 1990 amendments (Pub. L. 101-535) that bear on health claims and in accordance with the proposed general requirements for health claims for food (November 27, 1991, 56 FR 60537). As amended in 1990, the Federal Food, Drug, and Cosmetic Act (the act) provides that a food is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition unless the claim is made in accordance with section 403(r)(3) or (r)(5)(D) of the act (21 U.S.C. 343(r)(3) or (r)(5)(D)).

Congress enacted the health claims provisions of the 1990 amendments to help U.S. consumers maintain good health through appropriate dietary patterns and to protect consumers from unfounded health claims. Section 3(b)(1)(A) of the 1990 amendments specifically requires the agency to determine whether health claims for 10 nutrient-disease relationships meet the requirements of section 403(r)(3) or (r)(5)(D) of the act. The relationship of omega-3 fatty acids and heart disease is one of the claims required to be evaluated. In the **Federal Register** of March 28, 1991 (56 FR 12932), FDA published a notice requesting scientific data and information on the 10 specific topic areas identified in the 1990 amendments. Relevant scientific studies and data received in response to this request were considered as part of the agency's review of the scientific literature on omega-3 fatty acids and CHD and were included in the proposed rule.

In addition, on January 30 and 31, 1992, FDA held public hearings on all aspects of the proposed rules (57 FR 239).

FDA requested in the **Federal Register** of November 27, 1991 (56 FR 60663), written comments in response to its proposed rule. FDA reviewed all of the comments it received, including new data submitted in the comments, and scientific articles referred to in the comments. FDA also reviewed additional scientific articles, reviews, and recommendations published from August 1991 through February 1992.

The Dietary Supplement Act of 1992 (DS Act) established a moratorium on the implementation of the 1990 amendments with respect to dietary supplements. The DS Act says that FDA can grant health claims for food, including dietary supplements, under section 403(r)(3)(B)(i) of the act. However, it may not act on such claims under section 403(r)(5)(D) of the act until it establishes a standard to implement that section of the act, which the DS Act says may not occur until December 1993. Section 3(b)(1)(A)(x) of the 1990 amendments directs the agency to evaluate the omega-3 fatty acids/CHD claims based on the standard that FDA is establishing for determining the reliability of health claims under section 403(r)(5)(D) of the act. In the November 27, 1991, proposal on general requirements for health claims, FDA proposed to adopt the standard that the 1990 amendments provide for conventional foods, which is set forth in section 403(r)(3)(E)(i) of the act, as the standard for dietary supplements. Given this fact, and the fact that omega-3 fatty acids are found in numerous conventional foods as well as in dietary supplements, FDA broadened its inquiry to a determination as to whether it should grant a health claim on omega-3 fatty acids and CHD for any foods.

Because the DS Act provides that FDA may grant claims using the significant scientific agreement standard specified in section 403(r)(3)(B)(i) of the act, and given the breadth of FDA's November 1991, proposal on omega-3 fatty acids, FDA has decided to move forward to determine whether it can authorize a claim under section 403(r)(3)(B)(i) for omega-3 fatty acids and CHD.

However, this rule does not apply to dietary supplements. While a manufacturer of a dietary supplement can make a claim on omega-3 fatty acids and CHD without rendering its product misbranded under section 403(r)(1)(B) of the act, the manufacturer should assure itself that the making of the claim will not misbrand the product under section 403(a).

II. Summary of Comments and the Agency's Response

FDA received 80 letters, each containing one or more comments, from consumers, health care professionals, universities and research institutes, health profession associations, consumer advocacy organizations, State and local governments, foreign governments, trade organizations, industry, and professional organizations. In addition to these comments, the agency also considered statements made on omega-3 fatty acids and CHD at the January 30 and 31, 1992, public hearings. Some of the comments agreed with one or more of the aspects of the proposed rule, without providing further grounds for support other than those provided by FDA in the preamble to the proposal. Other comments disagreed with one or more aspect of the proposal without providing specific grounds for the disagreement. A few comments addressed issues outside of the scope of this document and will not be discussed in this document. Most of the comments provided specific grounds in support of their positions concerning aspects of this health claim

as proposed. The agency has summarized and addressed the issues raised in the sections of this document that follow.

A. General Comments

1. Definition of omega-3 fatty acids and composition of omega-3 fatty acid supplements

1. One comment criticized the definition of omega-3 fatty acids used in the proposed rule, on the basis that omega-3 fatty acids were not distinguished from other polyunsaturated fatty acids (PUFA's).

In the proposed rule, FDA limited the term omega-3 fatty acids to eicosapentaenoic acid ((EPA), 20 carbons, 5 double bonds) and docosahexaenoic acid ((DHA), 22 carbons, 6 double bonds) (56 FR 60663 at 60664). FDA noted that most of the relevant research has used fish or fish oils rich in these two fatty acids.

FDA acknowledges that its statement defining omega-3 fatty acids did not explicitly refer to omega-3 fatty acids. The sentence: "Their unique characteristic is the location of the first double bond, which occurs at the third carbon from the methyl (or omega) end of the fatty acid." (56 FR 60663 at 60664) was intended to refer to omega-3 fatty acids. This definition distinguishes omega-3 fatty acids from other PUFA's, which have their first unsaturation at the sixth or ninth carbon from the omega end of the fatty acid.

2. One comment argued that the definition of omega-3 fatty acids should include land-based (primarily plant) omega-3 fatty acids (i.e., linolenic acid). (For the purposes of this document, the term linolenic acid is used to indicate the omega-3 fatty acid, alpha linolenic acid. In contrast, gamma linolenic acid has its first double bond at the sixth carbon from the omega end of the fatty acid, and is not an omega-3 fatty acid.)

FDA disagrees with this comment. FDA defined omega-3 fatty acids as EPA and DHA, primarily as a functional definition derived from the scientific literature. The hypothesis for a relationship between omega-3 fatty acids and CHD derived from correlations between low rates of CHD and high consumption of fish oils. Similarly, most of the intervention studies have used fish oil or fish as a source of EPA and DHA, not plant oils rich in linolenic acid. The comment provided no evidence that linolenic acid has biochemical effects comparable to EPA or DHA, nor has FDA found any evidence of a relationship between linolenic acid and CHD. Moreover, only a limited amount of linolenic acid is converted in the body to EPA and DHA (Ref. 100). Therefore, FDA believes it has represented the potential nutrient-disease relationship appropriately by limiting its attention to EPA and DHA.

3. Two comments stated that FDA's position on fish as opposed to the omega-3 fatty acids in fish was a tautology, because: "if polyunsaturated fatty acids have beneficial effects on CHD, and if fish oils are a member of this class of fatty acids, it should not be counted against their beneficial effects on CHD."

FDA disagrees with this comment. FDA considers the claim for omega-3 fatty acids to reflect the unique biochemistry of these fatty acids. In particular, the prevailing theory about the mode of action of omega-3 fatty acids is that they compete with omega-6 fatty acids (fatty acids with their first double bond at the sixth carbon from the methyl end, and which comprise the largest amount of dietary PUFA's). Thus, a clear separation of effects of omega-3 fatty acids from effects of other (primarily omega-6) PUFA's is needed to support a claim.

4. One comment stated that FDA did not consider the importance of the ratio of omega-3 fatty acids to arachidonic acid (AA), a 20 carbon omega-6 PUFA with four double bonds, and stated that evidence exists for a relationship between the saturated fat:unsaturated fat ratio in the diet and the omega-6:omega-3 fatty acid ratio in the diet and the risk of CHD.

FDA considers concerns about the ratio of AA to omega-3 fatty acids and the ratio of omega-6 fatty acids to omega-3 fatty acids to be reasonable in view of the competition between these classes of fatty acids in human biochemistry. FDA considered all types of foods and supplements used to provide omega-3 fatty acids in its evaluation of the claim. Although the AA content of the supplement was often reported, studies did not report data for total dietary AA. FDA is aware of only very limited data regarding the ratios of AA to omega-3 fatty acids, and of the omega-6 fatty acid:omega-3 fatty acid ratio in the diet and the risk of CHD. Therefore, it is not possible for FDA to draw any conclusions about these ratios and their possible modifying effects on the omega-3 fatty acids CHD health claim.

However, because the fish oils used contained high concentrations of omega-3 fatty acids, FDA believes that the amounts of fish oils supplemented to the various test diets would have affected the AA:omega-3 fatty acid ratio and the omega-6:omega-3 fatty acid ratio of the diets to some extent. FDA advises that interested persons may petition FDA under § 101.70 (21 CFR 101.70) to issue a regulation regarding a health claim that relates these ratios to the risk of CHD.

5. Another comment pointed out that supplements used currently have contained various amounts of short- and long-chain omega-3 fatty acids and that many supplements also contain saturated fat. The comment stated that some of the discrepancies in reported findings may be due to the type of supplement used.

FDA agrees that numerous supplements varying in fatty acid composition have been used, and that the variation in the fatty acid composition of supplements may have influenced the outcome. FDA reexamined the studies cited in its proposal and the new data submissions for evidence that the nature of the supplement used was related to the outcome. However, the agency found that the same results are observed regardless of the source of omega-3 fatty acids. For example, in eight well-designed studies cited in the proposal on the total serum cholesterol response among normal subjects (Refs. 6, 9, 14, 49, 54, 73, 156, and 166), six different sources of omega-3 fatty acids were used: Salmon oil, SuperEPA, MaxEPA, a fish oil triglyceride, Promega, and mackerel paste. None of these supplements produced a change in total serum cholesterol. Similarly, four different sources of omega-3 fatty acids (fresh water fish, salmon oil, purified EPA, MaxEPA) were shown in seven well-designed studies to reduce platelet aggregation in normal subjects (Refs. 2, 6, 24, 54, 96, 143, and 166).

FDA did note that some differences in response have been produced by supplements that vary in ratio of EPA to DHA. For example, one fish oil (pollock oil) with a high EPA:DHA ratio increased low-density lipoprotein (LDL) cholesterol, LDL triglyceride and apoprotein B (apoB) (a protein component of LDL) in comparison to a butter-rich diet, but two fish oils with a low EPA:DHA ratio (tuna oil, salmon oil with added palmitic acid) reduced apoB and LDL cholesterol, and increased LDL triglyceride to a smaller extent than the pollock oil in comparison to the butter-rich diet (Ref. 17). However, the effects of the two major omega-3 fatty acids have not yet been systematically investigated. FDA recognizes that purified EPA and DHA are now available for research; such supplements will enable the study of the individual effects of these fatty acids.

6. One comment stated that conservation of omega-3 fatty acids in

the body calls into question the importance of the amounts of omega-3 fatty acids used in scientific studies. However, the comment did not suggest any alternate method to describe intake.

FDA recognizes that fish is not ordinarily consumed daily. However, the 1990 amendments require that health claims on foods be stated in such a way as to enable the public to understand the relative significance of such information in the context of a total daily diet (section 403(r)(3)(B)(iii) of the act). Thus, a reasonable estimate of daily dietary intake of omega-3 fatty acids is needed when assessing the relationship between omega-3 fatty acids and the risk of CHD. Most of the studies reviewed by the agency used daily supplementation with a known amount of omega-3 fatty acids, but others estimated intake of omega-3 fatty acids from foods consumed in the daily diet. Both types of intake estimates are important. Daily supplementation is useful to relate changes to a carefully controlled amount of omega-3 fatty acids. The average daily intake of omega-3 fatty acids in nonintervention studies provides a basis upon which to determine whether the amounts of omega-3 fatty acids fed in supplementation studies are reasonable in the context of the total daily diet.

2. Criteria used in evaluating studies

In the proposed rule, FDA listed some of the criteria used in evaluating epidemiological studies on the relationship of omega-3 fatty acids to CHD: (1) The reliability and accuracy of the methods used in food intake analysis and measurements of disease endpoints, (2) the choice of control subjects, (3) the representativeness of the subjects, (4) the control of confounding factors in data analysis, (5) the potential for misclassification of individuals with regard to dietary exposure or disease endpoints, (6) the presence of bias, and (7) the degree of compliance and how compliance was assessed (56 FR 60667).

However, FDA stated that it considered randomized, double-blind, placebo-controlled trials to be more valuable than other types of human studies because they were less susceptible to bias, and because they allowed inference about the specific effects of omega-3 fatty acids. Studies in which the endpoint was CHD, by definition, provide the most persuasive type of evidence, but studies measuring CHD to date have not provided the specificity to show that the observed effects were due to omega-3 fatty acids.

7. Some comments expressed the concern that it was unlikely that additional clinical trials will be done due to their expense, and that, therefore, FDA should rely more heavily on epidemiologic studies, animal studies, and biochemical and physiological interventions that suggest an effect of omega-3 fatty acids on risk of CHD.

FDA has no basis upon which to agree or disagree with the comments' assertion that further clinical trials are unlikely. FDA disagrees that its emphasis on clinical trials was misplaced. Because the 1990 amendments addressed nutrient-disease relationships, FDA considered human studies that used CHD as the endpoint to be the most directly relevant studies, although these studies do not demonstrate that the effects are specifically due to omega-3 fatty acids. Human studies in which a surrogate marker for CHD risk was measured as the endpoint of the treatment were also considered carefully. The advantage of these studies is that they are able to demonstrate specificity of the effects due to omega-3 fatty acids. However, the relationships between many of these surrogate markers and risk of CHD are not well established, making it difficult to relate changes in these endpoints brought about by omega-3 fatty acids to the risk of disease. Biologic markers can serve as markers of a developing disease, but the relevance of such evidence depends directly on the strength of the association between the marker and the disease (Ref. 115).

FDA agrees that there are considerable additional data in animal studies, in vitro studies, and biochemical and physiological interventions regarding the effects of omega-3 fatty acids. However, it is not clear that the results of such studies are relevant to the risk of human disease. Thus, FDA believes that these other types of data are of secondary importance compared to clinical data that measure either CHD per se or established surrogate markers for CHD.

However, in response to the comments, FDA has provided a more thorough description of animal and in vitro studies that suggest a role for omega-3 fatty acids in reducing the risk of CHD, particularly with respect to the effects of omega-3 fatty acids on the development of atherosclerosis and with respect to the responsiveness of blood vessels to ischemia (see comments 38 and 49 and section II.C.3.a. of this document).

8. Many comments stated that the agency's position on omega-3 fatty acids and CHD was inconsistent with its position on other health claims, and argued that for each of the four claims proposed to be allowed by FDA, the data were no stronger than the data supporting the link between omega-3 fatty acids and CHD. The comments asserted that, by basing its decision on the relationship between the nutrient and a surrogate marker for the disease, or for a susceptible subpopulation, FDA held other claims to a less restrictive standard. One comment stated: "The FDA statement is internally consistent in denying health claims for omega-3 fatty acids, but this is only in the context of holding these food components to essentially impossible standards not required for other, allowable, claims."

Specific comparisons were made to the proposed claims on fat and CHD, fat and cancer, calcium and osteoporosis, and sodium and hypertension. Other comments indicated that qualified claims, such as that for calcium and osteoporosis, were appropriate models for the claim relating omega-3 fatty acids to CHD.

FDA disagrees with these comments. FDA believes that for these other claims there is significant scientific agreement among qualified experts regarding the relationship between the nutrient and the disease, whereas there is not such agreement regarding the relationship between omega-3 fatty acids and CHD, or between omega-3 fatty acids and agreed surrogate markers for risk of CHD. For example, based on the totality of the publicly available scientific evidence, FDA determined that there is significant scientific agreement about the role of calcium in maintaining bone mineral density (the relationship of the nutrient to the intermediate marker for the disease), and about the relationship between peak (maximal) bone mass and the risk of developing osteoporosis and related bone fractures later in life (the relationship between the intermediate marker and the disease itself) (see 56 FR 60689; see also the final rule on calcium and osteoporosis published elsewhere in this issue of the **Federal Register**). Similarly, FDA relied on a long history of Federal Government and other consensus statements to conclude that there is significant scientific agreement about the role of sodium as a causal factor in hypertension for a segment of the population. (See 56 FR 60825; see also the final rule on sodium and hypertension, published elsewhere in this issue of the **Federal Register**.) FDA also recognized the history of significant scientific agreement about the relationships between fat and cancer and between fat and CHD evidenced by statements in reports issued by Federal Government and other authoritative bodies. (See 56 FR 60764, 56 FR 60726; see also final rules on fat and cancer and

fat and CHD, published elsewhere in this issue of the **Federal Register**.).

Thus, these other nutrient-disease relationships have a history of being recognized in Federal Government and authoritative reports, indicating significant scientific agreement, whereas the relationship between omega-3 fatty acids and CHD has not been so recognized. For two of these other nutrient-disease relationships, the data relate to the disease itself, rather than to markers for the disease. In the other two, calcium and osteoporosis and fat and CHD, there is significant scientific agreement that the dietary factors are related to surrogate markers for the diseases, and that the surrogate markers are related to the diseases.

There is significant scientific agreement that serum cholesterol and blood pressure are risk factors for CHD, as indicated by the emphasis on these factors in Federal Government and other authoritative documents (Refs. 34 through 36, 100, 115, and 169). Data regarding the effects of omega-3 fatty acids on these endpoints have been carefully reviewed. However, the other endpoints measured in studies of the effects of omega-3 fatty acids, e.g., in vitro platelet aggregation, various growth factors, fibrinogen, have not achieved the same extent of scientific agreement.

Where authorized health claims include qualifications, the qualifications are intended to assure that the wording of allowed claims reflects those particular aspects of the substance-disease relationship for which there is significant scientific agreement, not to qualify the extent of agreement.

9. Some comments stated that FDA relied heavily on material published in the National Academy of Sciences 1989 report, "Diet and Health: Implications for Reducing Chronic Disease Risk" (Ref. 115) and the Surgeon General's 1988 report (Ref. 34), and did not place enough emphasis on information published since that time.

FDA acknowledges that the two reports in question were important to its assessment of the scientific evidence. However, the agency does not agree that it failed to give appropriate weight to subsequently published research. The 1990 amendments required the agency to consider the totality of publicly available scientific evidence in assessing nutrient-disease relationships. Given the time constraints imposed by the 1990 amendments for developing and publishing proposed regulations, FDA depended on Federal Government reports and reports of authoritative bodies (e.g, the National Academy of Sciences) for assessment of the scientific evidence published before 1988. The reports were also used as a way of determining whether there was significant scientific agreement among qualified experts that the evidence supports a relationship between omega-3 fatty acids and CHD. The agency's reliance on these reports is consistent with the 1990 amendments, which require the agency to consider reports from authoritative scientific bodies of the United States in assessing health claim petitions and to justify any decision rejecting the conclusions of such reports (section 403(r)(4)(C) of the act).

Recognizing, however, that considerable research had been published since these reports, and that these reports had not been updated, FDA also reviewed the available studies on humans published since 1988. FDA relied on its own review of individual studies rather than review articles, because review articles generally reflect the bias of the author and may not consider the totality of the evidence. FDA focused its independent review on primary papers published between January 1988 and August 1991. Surveys and cross-sectional or prospective studies that were published before 1988 and used to generate the hypothesis of a relationship between omega-3 fatty acids and CHD were also reexamined. Thus, by utilizing the two reports in question, supplemented with an independent review of the subsequently published research, FDA was able to assess the totality of the scientific evidence on omega-3 fatty acids and CHD in compliance with the statutory standard.

10. One comment suggested that FDA was inconsistent with the conclusions of the major reviews of this area, published after the Federal Government and other comprehensive reports. They stated that of the nine major reviews (excluding Kinsella, and Connor and Connor), eight concluded that omega-3 fatty acids played a beneficial role with factors affecting heart disease.

Although FDA did not rely on review articles to assess the strength of association between omega-3 fatty acids and CHD, each review was read, and the agency interprets these reviews as supporting the hypothesis in concept. However, each review contained reservations about the extent to which the relationship between omega-3 fatty acids and CHD was established. The cautionary statements suggest general agreement that the area of omega-3 fatty acids and CHD holds promise for further research along a number of lines, but that, at present, there are not sufficient data to have certainty about the relationship between omega-3 fatty acids and CHD. Placed in chronological order, the concluding sections from the cited review articles exemplify the lack of certainty as to the relationship between omega-3 fatty acids and risk of CHD.

The review of the relationship between omega-3 fatty acids and CHD by Leaf and Weber (Ref. 91) was considered in the National Academy of Sciences' "Diet and Health: Implications for Reducing Chronic Disease Risk" report (Ref. 115). FDA elected to include the Leaf and Weber review in its citations because it covered, in the most comprehensive manner of all available reviews, the state of scientific knowledge about omega-3 fatty acids in CHD at the time the Federal Government and other comprehensive reviews were published. Leaf and Weber wrote: "Despite claims that n-3 fatty acids can help prevent atherosclerosis, recommendations to the public on diet have been conservative; people have been advised to increase their consumption of fish by replacing two or three meals a week containing red meat with meals containing fish." Their concluding sentence was: "If prospective double-blind, placebo-controlled clinical trials *were to show* that n-3 fatty acids helped to prevent atherosclerosis, these agents apparently would represent one of the most benign interventions in our pharmacopeia." (Emphasis added.)

Bonaa (Ref. 10) wrote in his conclusion that the data on blood pressure:

> * * * provide some support for the hypothesis that dietary marine lipids influence blood pressure in man. Supplementation of n-3 PUFAs [polyunsaturated fatty acids] to Western diets consistently lowered systolic blood pressure, while results for diastolic blood pressure were conflicting * * *. There is no evidence of any substantial hypotensive response to marine lipids and further studies should be designed to detect small effects.

Lands (Ref. 89) did not review the relationship between omega-3 fatty acids and any specific disease, but presented the hypothesis that the balance of omega-3 and omega-6 fatty acids in the diet may be related to diseases associated with overproduction of eicosanoids from AA. He indicates in the introduction that, "We are now in an uncertain time of evaluating the benefits and risks of dietary n-6 and n-6 polyunsaturated fats."

Weber (Ref. 161) concluded:

> The promise of n-3 fatty acids deduced from biochemical and functional effects will have to be evaluated in ongoing and future carefully designed and conducted studies. So

far, published data of controlled clinical trials incorporating clinical endpoints after n-3 PUFAs are available only in abstract form. Therefore, the gap between biochemical and functional effects of dietary fatty acids *assumed to be* of clinical benefit in the prevention of atherothrombotic and allergic/inflammatory disorders is only beginning to be closed. (Emphasis added.)

Connor and Connor (Ref. 21) wrote in their summary:

The exact place of omega-3 fatty acids from fish and fish oil remains to be defined. However, this much seems certain. Fish provides an excellent substitute for meat in the diet. Fish is lower in fat, especially saturated fat, and contains the omega-3 fatty acids. Fish oil may have promise as a therapeutic agent in certain hyperlipidemic states, especially the chylomicronemia of type V hyperlipidemia. Fish oil has logical and well-defined antithrombotic and antiatherosclerotic activities since it depresses thromboxane A2 production and inhibits cellular proliferation responsible for the progression of atherosclerosis. As the years pass and more experiments are reported, it seems reasonable to place the omega-3 fatty acids from fish oil in a prominent position for specific hypolipidemic, antithrombotic and antiatherosclerotic activity.

Kinsella et al. (Ref. 82) wrote:

The cumulative findings concerning fish oils suggest that further amelioration of coronary heart disease may be feasible by dietary manipulation and by optimizing the intake of n-6 and n-3 PUFAs, not only to reduce plasma lipids but to ensure balanced eicosanoid metabolism—a prospect that deserves more research * * *. Overall, in view of the prevalence of coronary heart disease, consumption of n-3 PUFA oils should be considered as a useful complementary option for the amelioration of coronary vascular diseases.

Knapp (Ref. 84) introduced his paper stating: "The role of dietary polyunsaturated fats in the prevention of human vascular disease *has not been defined*, but population and intervention studies have *suggested* that w-3 fatty acids (FAs) from marine lipids *may have* a number of potentially beneficial effects." (Emphasis added.) And in conclusion he wrote: "The *proof of our hypotheses* must be derived from increasingly ambitious clinical trials, which assess the *potential* benefits of dietary polyunsaturates in particular clinical settings, the recent demonstration that three helpings of oily fish per week prolongs survival after MI (Ref. 16) is an example of this." (Emphasis added.)

Nestel (Ref. 111) concluded: "More basic understanding of the actions of fish oils is necessary before fish oils can be recommended widely to the public."

Nordoy and Goodnight (Ref. 112) cautioned that until additional data become available, "clinicians should be advised to follow the dietary recommendations of the National Cholesterol Education Program's expert panel," which is silent on omega-3 fatty acids and limits the total polyunsaturated fat to 10 percent of calories. These reviewers added their own recommendation that omega-6/omega-3 ratio of the PUFA's be approximately 3/1, with the omega-3 fatty acids from marine sources.

Weber and Leaf (Ref. 162) stated:

Despite all the laboratory, human, animal, and epidemiologic studies suggesting an anti-atheromatous action of w3 fatty acids, we have been lacking adequate clinical trials which will determine in prospective, placebo-controlled, randomized studies, whether all the above experimental and epidemiologic evidence adds up to a demonstrable effect of fish oils to prevent atherosclerosis, e.g., coronary heart disease in humans at high risk for heart attacks.

The Burr paper (Ref. 16) was described in Weber and Leaf's review, and thus was considered in the above summary statement.

In summary, these reviews indicate that what is agreed is that there is a plausible biochemical basis for a relationship between omega-3 fatty acids and CHD, and that there are some data supporting some of the hypothesized mechanisms by which omega-3 fatty acids might be related to CHD. What is not agreed, as indicated by the cautious tones of these concluding statements, is that such a relationship already has been established by the evidence.

11. A concern raised by many comments was that FDA's conclusions were different from the conclusions reached in the report from the Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology (Ref. 100), the most recent comprehensive review, and that FDA did not explain why it reached a different conclusion from that reached in the LSRO report.

The LSRO report was contracted for by FDA as an independent review of the scientific evidence about the relationship between omega-3 fatty acids and CHD. A draft of the tentative final report was received immediately prior to the publication of the proposed rule. Thus, there was insufficient time for the agency to prepare a detailed discussion of the report. The final report was submitted to FDA as a comment to the proposal. The LSRO report's conclusions on hypertension, thrombosis, the development of atherosclerotic plaque and intimal hyperplasia, plasma lipids and lipoproteins, diabetic and prediabetic patients, and epidemiologic observations are grouped with other comments on these topics and discussed in this document.

12. One comment considered FDA's caution against extrapolation of results from studies conducted in at-risk populations to the general population to be questionable, and possibly biased against hypertensives. The comment stated that the health claim should be allowed, based on data showing that omega-3 fatty acids reduce blood pressure among hypertensives.

FDA disagrees with this comment. FDA stated that, although it considered studies in the healthy population to be the most relevant, it also considered studies in a subpopulation with CHD or risk factors for CHD, in part because high risk populations may be more sensitive to showing a nutrient-disease relationship than the general population (56 FR 60663 at 60667). FDA stated that it extrapolated positive results from at-risk populations cautiously, and that comparable findings in the general population were needed to support a health claim.

13. Two comments discussed FDA's criteria for weighing various types of data. One comment stated that epidemiologic data are the "most significant class of evidence," and that FDA should give priority to various types of data in the same order that various types of data were reviewed in the proposal. One comment stated that FDA should not have considered epidemiological studies separately from clinical trials.

FDA considered the totality of publicly available scientific evidence in its assessment of the relationship of omega-3 fatty acids to CHD. However, some types of evidence were weighted more heavily than others because they were more useful in establishing whether or not the scientific basis of the claim was valid. In particular, the agency was concerned that both the substance (omega-3 fatty acids) and the disease (CHD) be carefully characterized. FDA also considered it important that the amount of omega-3 fatty acids tested was reasonably related to normal dietary intake, and that the findings apply to the general population. FDA agrees that epidemiologic studies in which the endpoint was CHD provide persuasive evidence for a relationship between fish consumption and CHD, but these studies did not provide the specificity to show that the observed effects were due to omega-3 fatty acids. Intervention trials using fish oil supplements often showed that the effects were specific to omega-3 fatty acids (by controlling with

other types of fatty acids) but typically did not measure the primary endpoint, CHD. Thus, these different types of data complement each other and must be considered together in assessing the totality of the scientific evidence.

14. One comment offered the services of the International Society for the Study of Fatty Acids and Lipids for the evaluation of the relationship between omega-3 fatty acids and CHD.

FDA appreciates this offer. In the final rule on general requirements for health claims published elsewhere in this issue of the **Federal Register**, FDA advises that it welcomes the input of any professional organization that can provide expertise in reviewing data and in developing a thoughtful and well-organized petition for a health claim on a particular topic. In fact, FDA has added to § 101.70(b) the provision that information submitted with petitions may include any findings, along with the basis of the findings, of an outside panel with expertise in the subject area at issue. FDA, however, retains the authority to review such petitions and, through rulemaking, to decide whether or not to authorize the claim.

15. Two comments stated that it was contradictory for the U.S. Government to contract for research on the omega-3 fatty acids through the biologic test materials program but not to allow a health claim. Another comment pointed out that the Food and Agriculture Organization and the World Health Organization support research on omega-3 fatty acids. Other comments stated that the tone of FDA's proposed rule was unduly negative and that, by taking such a position, FDA may retard further research.

FDA disagrees that Federal Government sponsorship of a program to provide test materials for research on the effects of omega-3 fatty acids and the denial of the omega-3 fatty acid-CHD health claim are contradictory actions. The purpose of the biologic test materials program is to develop and standardize a source of omega-3 fatty acids and enable carefully controlled research on the effects of particular omega-3 fatty acids. In the proposed rule, FDA's intent was to examine the total available scientific evidence, some of which was generated using omega-3 fatty acids from the biologic materials test program, and to state its conclusions about the relationship between omega-3 fatty acids and CHD.

In its proposal and in this final rule, FDA has identified a number of areas where agreement is lacking that an observed effect of omega-3 fatty acids is related to the risk of CHD, or where there are ambiguities in the data that may be resolved by further research. Thus, FDA's analysis should provide guidance for additional research rather than inhibit it.

B. Relationship Between Omega-3 Fatty Acids and CHD

In the proposed rule, FDA tentatively concluded that the totality of the scientific evidence does not provide a basis upon which to authorize a claim that omega-3 fatty acids are associated with the risk of CHD (56 FR 60663). FDA noted that.

> the epidemiological research on this topic revealed that the available studies applied only to the consumption of fish, which contain omega-3 fatty acids, and * * * it was not possible to ascribe any effects specifically to the omega-3 fatty acids. Examination of data from clinical studies revealed that the effects on blood lipids of fish oils containing omega-3 fatty acids were primarily a reduction of blood triglycerides, a blood lipid variable not considered to be an independent risk factor for CHD, but they had no effect on serum cholesterol, low-density lipoprotein (LDL) cholesterol, or high density lipoprotein (HDL) cholesterol, the blood lipid variables most closely associated with risk of CHD The scientific data are ambiguous on the effects of omega-3 fatty acids on blood pressure and other risk factors for CHD.

(56 FR 60663.)

A number of comments supported the agency's position on this health claim, but without any specific reasons for that support. One comment agreed with the agency's position in principle, but contested the agency's interpretation of the scientific information in some areas. Other comments disagreed with the agency's review of the scientific information and its conclusion regarding the strength of the evidence supporting the proposed health claim. Specific comments are summarized below.

1. Epidemiologic evidence

In the proposed rule, FDA reviewed correlational and cross-sectional studies, prospective studies, and intervention studies available since 1988. (See 56 FR 60663 at 60667 through 60668). Except for the intervention studies (which were typically clinical trials) these studies used fish as a source of omega-3 fatty acids. FDA concluded that those studies that used fish as the source of omega-3 fatty acids were: "ambiguous, because they are not capable of distinguishing the effects that are specific to omega-3 fatty acids from those that are related to fish consumption." (56 FR 60663 at 60668.)

16. A number of comments considered the evidence from epidemiologic studies that relates the consumption of fish inversely to CHD to be sufficient to support a health claim, but did not supply any new information or arguments to support their position.

FDA disagrees with the comments. FDA found that:

> Only a few studies found an association between fish intake and CHD, while others have found no association. Thus there was not consistency of findings. None of the studies that reported a relationship distinguished fish consumption from other factors associated with fish consumption, and therefore they did not demonstrate specificity. Even in those studies reporting a relationship between fish consumption and CHD, it was not clear that the effects were because of the omega-3 fatty acids in fish. Also, the omega-3 fatty acid content of the fish diet associated with reduced CHD was so low that the importance of omega-3 fatty acids is questionable * * *

(56 FR 60663 at 60672.)

17. One comment described the results of the Dolecek and Grandits analysis of multiple risk factor intervention trial (MRFIT) data (Ref. 38) as indicating a greater protective effect against CHD due to consumption of 0 6 gram (g) omega-3 fatty acids than all other conventional efforts combined (reducing saturated fat, cholesterol, cigarette smoking, and hypertension).

FDA agrees with this comment that the association between omega-3 fatty acid consumption and CHD mortality reported in this study has the potential to make a very important public health impact. Notably, the results were obtained on data adjusted for age, race, smoking at entry to the study, diastolic blood pressure, and high-density lipoprotein (HDL) and LDL concentrations. Furthermore, the omega-3 fatty acids were obtained in the normal diet, providing evidence that the amount of omega-3 fatty acids consumed in a normal dietary intake is sufficient for the effect.

The researchers' adjustments for lipoprotein measurements should control for some other dietary variables that have been associated with CHD through their effects on these lipoproteins, e.g., saturated fat, but other dietary variables associated with CHD were not controlled, e.g., alcohol. The association between omega-3 fatty acid consumption and CHD mortality described in this study is among the most provocative findings to date in this area, and merits additional study using a design that will document that the active dietary component is or is not the omega-3 fatty acids (i.e., specificity of the effect).

18. One comment pointed out that the Burr paper (Ref. 16) deserved close consideration, because, in contrast to

trials on lipid lowering drugs, it showed that consumption of fish containing omega-3 fatty acids or dietary supplements of omega-3 fatty acids may reduce the risk of heart disease. One comment stated that it considered the Burr paper to be a positive finding, but gave no reason for this conclusion. The LSRO final report, submitted as a comment, also recognized the Burr paper as a very important trial. LSRO pointed out that, although separate results were not shown for those consuming fatty fish and those consuming supplemental fish oil, the results were dramatic, especially since all-cause mortality was reduced, in contrast to results from trials of plasma lipid-lowering drugs. LSRO concluded that "future research will be needed to define the amount and duration of w-3 fatty acid supplementation required to produce the beneficial effects."

FDA agrees that the Burr paper provides valuable evidence consistent with the hypothesized relationship between omega-3 fatty acids and CHD. However, FDA noted in its proposal (56 FR 60663 at 60668) that there are two specific shortcomings in this paper: the absence of separate data for subjects who consumed fish and those who consumed fish oil capsules, and the absence of dose-response data. These data would have provided evidence for a specific effect of omega-3 fatty acids. Ideally, other data regarding the subjects' diet would also show that there was no difference in consumption of other dietary factors related to CHD. The study design specifically included two such dietary factors, dietary fat and dietary fiber, and the lack of significant effects of these components argues against dietary factors other than omega-3 fatty acids as responsible for the association.

FDA does not consider the Burr paper to have established a beneficial effect of omega-3 fatty acids, although its results are consistent with such an action. The LSRO conclusion indicates that neither the amount of omega-3 fatty acids necessary for beneficial effects nor the duration of their intake has been established. The specificity of the substance responsible for the beneficial effects, the quantitative amount needed to produce the effect and the duration of intake needed to produce the effect need to be established before FDA can authorize a claim linking omega-3 fatty acids to reduction of risk of CHD.

19. Some comments stated that the amount of fish in the Zutphen and Burr studies was so low that the association between fish consumption and reduced CHD mortality could not be explained by the displacement by fish of other atherogenic foods from the diet.

FDA is not persuaded by these comments. The limitation in these studies is that they did not control for dietary factors associated with CHD, not that fish consumption displaced other atherogenic foods. FDA noted in its proposal that the Zutphen study found significant correlations between fish consumption and other dietary factors (i.e., alcohol, polyunsaturated fats) related to CHD. Comparable correlations were not addressed in the Burr paper because dietary intake data were not reported. Also, the design of the Burr paper was to encourage consumption of fish, which would likely have resulted in a reduction in the consumption of red meat (and, therefore, saturated fat).

20. Two comments discounted the Curb et al. study (Ref. 25), which showed no association between fish consumption and CHD mortality among subjects in Hawaii. The comments stated that the dietary source of fish was likely tropical fish, and since tropical fish feed on coral they have a high content of AA, which would counteract the effect of omega-3 fatty acids.

FDA disagrees with the comments. No data regarding the AA content of the diet in this study, or in other correlational studies, have been reported. Indeed, most epidemiologic correlation studies have not quantified the intakes of omega-3 fatty acids, a fundamental measurement to establish an association between omega-3 fatty acids and CHD. Finally, there is an abstract reporting that the omega-3 fatty acid to omega-6 fatty acid ratio of tropical fish is comparable to or greater than that of fish in higher latitudes (Ref. 237). Thus, the comments' explanation for a negative finding must be considered theoretical.

21. One comment argued that the lack of an association between fish consumption and CHD in two populations in Canada, a prairie province and a coastal province (Ref. 74), was because the prairie population consumed more alcohol and the coastal population smoked more. This comment criticized FDA for not pointing out the cautions raised by the authors about potential confounders like the difference in alcohol consumption.

FDA believes it presented the results of this paper fairly. While the authors reported small differences in smoking (more in the coastal population) and alcohol consumption (more in the prairie population), they stated, "It seems unlikely that these differences are sufficiently large to offset any strong effect of fish consumption." FDA is keenly aware that dietary and behavioral factors (e.g., smoking, alcohol) must be controlled before meaningful conclusions may be drawn about the effects of omega-3 fatty acids. FDA notes that alcohol consumption was also a confounding factor in a study that reported an association between fish consumption and CHD (Ref. 87).

22. A few comments stated that many of the reported effects come from studies on fish consumption, but that all measured biochemical changes related to CHD that are produced by fish have also been produced with fish oil concentrates.

FDA agrees in part with this comment. The fact that the same biochemical results have been obtained using fish oils rather than fish provides strong evidence that particular biochemical markers are affected specifically by omega-3 fatty acids. Also, since most studies have used fish oils, these results add consistency to the effects reported for studies that used fish. However, FDA disagrees that the comparable findings in studies that used fish oils and fish are sufficient to support the health claim that omega-3 fatty acids reduce the risk of CHD, because the particular biochemical markers affected by both fish and fish oils are not recognized with significant scientific agreement as useful surrogate risk factors for CHD in the general population.

23. One comment argued that the fact that Greenland Eskimos ate diets with half the saturated fat and more polyunsaturated fat than Danes and had much less CHD than Danes strengthens the case for fish oil-derived omega-3 fatty acids.

FDA agrees with the comment that diets lower in saturated fat are consistent with reduced CHD mortality (see the final rule on "Dietary Lipids and Coronary Vascular Disease" published elsewhere in this issue of the **Federal Register**). The differences in saturated fat intake, however, do not strengthen the case for omega-3 fatty acids, because they do not distinguish omega-3 fatty acids from polyunsaturated fats. Rather, the differences in dietary fat intakes strengthens the argument that saturated fat is associated with CHD mortality. The numerous dietary differences between the Greenland Eskimos and Danes make it difficult to ascribe to any single dietary factor the differences in CHD.

24. One comment pointed out that, of the ten prospective studies cited in the proposal (including three in Table 1 of the proposal), six support an inverse relationship between fish consumption and CHD. The comment noted that one

study only showed a relationship in men under 45, and argued that this result is promising because one might expect to find positive effects of long-term fish consumption on CHD in younger, relatively healthy men rather than in older men.

FDA agrees that some but not all reports find an inverse relationship between fish consumption and CHD. FDA does not agree, however, that this effect would more likely be noticed among younger, relatively healthy men. Older men would have had a greater duration of intake of omega-3 fatty acids and a greater incidence of CHD than younger men. Both these factors would favor finding an effect in older men rather than in younger men.

25 One comment noted that only two studies found a positive dose-response. Another comment stated that the studies that show no effect are those where the base group already consumed fish, whereas in studies that showed an effect, the base group did not consume fish A third comment stated that there were data that described an inverse dose-response relationship between serum EPA and CHD deaths among Japanese, but did not identify a particular study.

FDA disagrees that only two studies found a dose response correlation. Each study that reported a relationship between fish consumption (or, in one study, the calculated intake of omega-3 fatty acids) and CHD found a dose-response relationship. FDA agrees that most of the dose-response relationships reported suggest that the primary difference in rate of CHD is between those who consume no fish at all and those who consume a small amount of fish, and that there appears to be little additional benefit from consumption of large amounts of fish (Ref. 88). An alternate way of describing these data is that those who consume no fish have an increased risk of CHD These data merit followup, because a showing that the relationship is due to the omega-3 fatty acids may provide evidence that the long-chain omega-3 fatty acids are essential in the diet.

In its proposal, FDA reviewed a study that described an inverse dose-response relationship between serum EPA and CHD mortality among two groups of Japanese (Ref. 78). FDA concluded that these cross-sectional, correlational data were useful in generating a hypothesis. Other notable dietary factors (including a difference in salt intake of 50 percent) and risk factors for CHD (prevalence of hypertension) also differed between the two groups, so it is not possible to conclude that differences in CHD mortality were due to differences in dietary omega-3 fatty acids.

26. Two comments stated that FDA had erred in stating that no biochemical data were reported in the Burr paper (Ref. 16).

FDA agrees with this comment, and stands corrected. Burr et al. (Ref. 16) did report that the geometric mean percentages of EPA were 0.59 percent and 0 46 percent in men given advice to consume more fish and those not so advised, respectively, a highly significant difference ($p < 0.01$). The fact that a geometric mean rather than an arithmetic mean was reported implies that there was substantial skewing of the data.

It is not clear from the article whether these differences were for the 6-month time into the trial, or for the end of the trial. The authors did not correlate plasma EPA concentrations directly with myocardial infarction (MI) or CHD deaths.

27. One comment argued that it was highly misleading to state in Table 1 that Kromhout et al. (Ref. 87) reported that, "lean fish, low in omega-3 fatty acids, had some protective effect against CHD," because Kromhout did not distinguish between the effects of lean and fatty fish.

FDA disagrees with this comment. The authors made two statements about lean fish that imply that additional data analyses were conducted, although (as the comment correctly notes) results of these analyses were not included in the paper. The authors wrote, "Lean fish was also inversely related to mortality from coronary heart disease," and "Thus, the inverse relation between lean fish and coronary heart disease cannot be explained by eicosapentaenoic acid."

FDA interprets these comments as a caution to the reader against assuming that EPA was the active component responsible for the observed reduction in CHD among fish-consuming subjects.

28. LSRO included in its report two studies that correlated plasma omega-3 fatty acids with dietary intake of these fatty acids (Refs. 213 and 225). Two other papers reviewed by LSRO but not included in the FDA proposal were correlation studies of mortality from different diseases among Greenlanders and Danes (Ref. 176) and diet-disease correlations in Japan (Ref. 284).

FDA agrees with LSRO's descriptions of these studies. FDA notes that the authors of the studies that correlated intake and plasma levels of omega-3 fatty acids did not relate their data to CHD The correlation studies of mortality did not provide any specific data regarding omega-3 fatty acids.

29. One comment provided new dose-response data from additional analyses of data of the Dart study, previously reported in part by Burr et al. (Ref. 16), that related the dietary intake of EPA at 6 months into the trial to the risk of CHD events (heart attacks, or MI's) or CHD mortality. The 947 subjects for whom dietary data were obtained were grouped according to EPA intake; 114 consumed less than 1 g per week (1 g/week), 373 consumed 1 to 2 g/week, and 460 consumed 2 or more g/week. The percentage of subjects that experienced either a nonlethal heart attack or died from a heart attack decreased as dietary EPA increased. For heart attacks the rates were 7.9 percent, 7.0 percent and 6.7 percent, for the less than 1 g/week, 1 to 2 g/week and 2 or more g/week groups, respectively. The percentages in each group who died were 6.1 percent, 5.1 percent, and 4.1 percent, respectively. There were no statistical analyses of these data reported.

FDA notes some limitations in these data as reported that caution against strong conclusions. Most notably, the analysis excluded the events and deaths during the first 6 months of the trial, when about half of all events and deaths occurred. This clearly diminishes the sensitivity of the analysis, and may result in an underestimation of the true effect, since the difference in survival between the group advised to eat more fish and the group not advised to eat more fish was most pronounced during the first 6 months. Alternatively, if the healthiest subjects were also the most compliant subjects, the reduced death rate in the highest EPA-consumption subjects may reflect the underlying health of those subjects, and the importance of dietary EPA may be overestimated.

Also, the unequal group sizes for this analysis places a greater weight on each subject in the smallest group (less than 1 g/week) than in the other groups. This may be particularly important because the smallest group includes those who consume no fish, and who may differ from fish consumers in other dietary or behavioral factors associated with CHD risk. The sensitivity of the results to small changes in outcomes is shown by example: one fewer death (6/114 rather than the reported number, 7/114) makes the CHD death rate of the less than 1 g/week group equal to the rate in the 1 to 2 g/week group.

Finally, although the dietary intake data at 6 months are useful, this study also assayed plasma fatty acids. Use of plasma EPA (or EPA plus DHA) in the dose-response analysis would have been a more powerful analysis, because it eliminates errors in the diet record data,

corrects for losses during food preparation and individual differences in bioavailability of the fatty acids, and integrates intake of omega-3 fatty acids over a longer period than the diet record data.

Therefore, FDA finds these dose-response data to be consistent with the hypothesis that omega-3 fatty acids reduce the risk of CHD, but the shortcomings discussed above limit their usefulness in establishing a relationship between omega-3 fatty acids and risk of CHD.

2. Evidence relating omega-3 fatty acids to intermediate or surrogate markers of CHD

In the proposed rule (56 FR 60663 at 60668), FDA stated that most information about the effects of omega-3 fatty acids on CHD has been derived from clinical trials using concentrated fish oils enriched in EPA and DHA, and in some cases purified methyl or ethyl esters of EPA and DHA. FDA concluded that:

> * * * there are a few established effects of omega-3 fatty acids from fish oils on thrombosis and hemostasis. Standardized bleeding times are increased, and platelet aggregation and function are reduced. However, direct relationships between the changes in bleeding times or platelet function and risk of CHD have not been established. While there is an established relationship between blood pressure and CHD, it has not been shown that omega-3 fatty acids specifically affect blood pressure in normal subjects in a way that would provide a protective benefit toward the risk of CHD. Effects of omega-3 fatty acids on other markers linked with CHD, e.g., fibrinogen or lipoprotein (a) have not been established.

(56 FR 60663 at 60671).

a. Atherosclerosis

i. Blood lipids

30. Numerous comments criticized FDA's focus on blood cholesterol as a surrogate marker for risk of CHD, although one comment noted that such an emphasis would be expected, given the importance of cholesterol in CHD. Another stated that the focus on cholesterol ignores other factors that determine blood cholesterol such as heredity, exercise, and stress, etc.

FDA disagrees with the comments that it overemphasized the importance of studies in which cholesterol was measured as a surrogate marker for CHD. The considerable attention given to blood cholesterol measurements (and measurements of other blood lipids and the protein components of blood lipoproteins) was the consequence of two factors: (1) There was a large number of studies on the effects of fish oils or fish containing omega-3 fatty acids on these blood lipid measures; and (2) there is general agreement that certain blood lipids are strongly associated with the risk of CHD.

FDA undertook to evaluate findings in these studies whether or not fish or fish oils were used as the source of omega-3 fatty acids and whether or not the outcome measures were generally recognized as predictive of CHD. This approach allowed the identification of biologic activities of omega-3 fatty acids that may be related at some point to risk of CHD, and identified areas where additional research is needed. FDA included in the summary of its proposed rule (56 FR 60663) only measures of generally recognized risk factors. FDA did not intend to imply that data on alternate markers were not considered in its decision.

FDA agrees that other factors contribute to blood lipid measures, but believes that randomization should control for these factors. In nonrandomized studies, these sources of potential bias limit the conclusions that can be inferred from the data. This is an important reason that data from correlation studies do not conclusively establish a relationship between omega-3 fatty acids and risk of CHD.

31. The LSRO report paid considerable attention to changes in blood lipids after increased consumption of omega-3 fatty acids, and reached some conclusions about effects of omega-3 fatty acids on blood lipids that differed from those reached by FDA. LSRO abstracted three studies from before the period covered by FDA review (Refs. 284a, 267, and 257). These studies were considered in Federal Government and other comprehensive reports reviewed in the proposed rule and not discussed further by FDA. LSRO also included three studies not reviewed by FDA in its proposal (Refs. 168, 226, and 301). Agren et al. (Ref. 168) studied healthy students randomly assigned to their normal diet (one fish meal per 2 weeks), a fish diet, or a fish diet low in saturated fat for 15 weeks. There was no change in total serum cholesterol on the control diet or fish diet, but the low-fat fish diet produced a reduction in total cholesterol. Jensen et al. (Ref. 226) studied 18 healthy subjects supplemented sequentially for 4-week periods with 4-week washouts between, with fish oils containing 1, 3, and 6 g EPA plus DHA, and found no change in total or LDL cholesterol. Wolmarans studied healthy subjects fed a meat diet or fish diet containing 6.1 g EPA plus DHA for 6 weeks each in a crossover design, and found reduced total cholesterol and LDL cholesterol during the fish diet phase. There was no difference in total fat of the two diets. However, there was significantly less saturated fat in the fish diet, so it is not certain that the omega-3 fatty acids were responsible for the decrease in the cholesterol measures.

FDA is concerned that the studies abstracted by LSRO do not accurately represent the totality of publicly available scientific evidence. For example, in its proposal, FDA included five studies among normal subjects (Refs. 2, 6, 24, 73, and 143) and three studies among subjects with preexisting lipid or lipoprotein abnormalities (Refs. 18, 73, and 93) not included in the LSRO report that had data for effects of omega-3 fatty acids on plasma lipids or lipoproteins. FDA determined that seven studies that reported changes in total cholesterol had the most rigorous designs and the largest numbers of normal subjects. None of these seven studies (Refs. 6, 9, 14, 49, 54, 73, and 166) in normal subjects found a significant change in total cholesterol after fish oil supplementation. FDA found similar results with regard to hyperlipidemic subjects.

Only two of these seven strongest studies in normal subjects were abstracted in the LSRO text, and two others were not cited at all by this report. LSRO did not distinguish between normal and hyperlipidemic subjects in its summary or conclusions. LSRO summarized the evidence on total cholesterol by stating, "Decreases in total cholesterol * * * have *also* been reported," (emphasis added), without mentioning that the predominant finding is that there is no effect on total cholesterol.

Similarly, FDA stated that the strongest studies among normal subjects (Refs. 6, 9, 14, 49, 54, 73, and 166) found no change in LDL cholesterol, and one reported an increase in LDL cholesterol (Ref. 54). Indeed, most studies on hypertriglyceridemic or hypercholesterolemic subjects reported an increase in LDL cholesterol following fish oil supplementation (56 FR 60663 at 60669). Consequently, FDA disagrees strongly with the summary statements in the LSRO report:

> Effects of fish oil upon LDL have been variable, in part because of different doses. In normolipidemic individuals, LDL has generally declined significantly. In *some* patients with primary hypercholesterolemia, consumption of fish (sic) has not resulted in altered plasma cholesterol levels; other studies have shown decreased cholesterol and LDL levels. (Emphasis added.)

32. Two comments stated that FDA had not considered all relevant data on HDL_2 cholesterol, and cited additional

studies that reported increased HDL_2 cholesterol after fish oil supplementation. One comment stated that overall HDL cholesterol tends to rise, and cited a review paper by Harris (Ref. 62). The LSRO report also concluded that HDL was increased by fish oil supplementation.

FDA disagrees with the comment regarding the overall HDL cholesterol change after fish oil supplementation. The agency considered HDL changes separately for normal, healthy subjects and for hyperlipidemic subjects (56 FR 60663 at 60669). Nearly all studies on normal subjects found no significant change in HDL cholesterol level. Some investigators reported increased HDL_2, but the data on HDL_2 were equivocal.

FDA also disagrees with the conclusions of the LSRO report regarding HDL cholesterol, because it does not represent the totality of publicly available scientific evidence. The LSRO summary states, "In *some* studies HDL concentrations have actually increased with consumption of fish oil" (emphasis added), not acknowledging that the balance of available scientific evidence on HDL indicates no change. In the review by Harris cited in the comment, the changes in HDL cholesterol in each study were weighted according to the number of subjects in the study, giving a per-subject change. This method of pooling data from different studies does not account for the variation of the response of subjects in each study, the amount of omega-3 fatty acids fed, the duration of feeding, or the source of the omega-3 fatty acids. Therefore, it must be considered only an estimate of the effects of omega-3 fatty acids on HDL cholesterol. Harris calculated the average HDL cholesterol change for normal subjects to be an increase of approximately 3 percent, a net change smaller than the usual variability in the test used to measure HDL.

The agency agrees with the comment that not all HDL_2 data were considered in the proposed rule, although FDA noted (56 FR 60663 at 60669) that some studies among normal subjects found increases in the HDL_2 fraction of HDL cholesterol, and that these reports were the most promising changes in blood lipids. Of the six references cited by the comments as not included among studies showing increased HDL cholesterol after omega-3 fatty acids, two were published after the time period covered in the proposed rule (Refs. 235 and 252). One other paper not cited by FDA in its proposal, although it was published during 1988 (Ref. 291), dealt with insulin-dependent diabetics. The other three papers were cited by FDA in other contexts, but data from these papers regarding HDL_2 cholesterol levels were not discussed (Refs. 1, 32, and 148).

FDA reexamined those papers that it cited but from which it did not present data regarding HDL_2, together with the newer papers. When fractions of HDL cholesterol have been reported, an increase has generally been found in the HDL_2 fraction (Refs. 1, 32, 148, 235, 251, and 291), with a comparable decrease in the HDL_3 fraction (Refs. 1, 235, and 251). This represents a shift within the HDL fractions toward a lipid-rich lipoprotein, and away from a protein-rich lipoprotein, similar to that reported for LDL, below. This shift has been reported when there is (Refs. 32, 148, 235, and 291) or is not (Refs. 1 and 251) a change in total HDL cholesterol. This raises the possibility that a shift occurred in other studies where total HDL was reported as not changed.

However, the importance of the shift in subfractions of HDL is not clear. FDA noted in its proposal (56 FR 60663 at 60669) that there is evidence that the HDL_2 fraction is the one most closely linked to risk of CHD. However, the agency was unable to find evidence that there was significant scientific agreement that HDL_2 was the fraction of HDL most closely associated with CHD. The National Institutes of Health's National Heart, Lung, and Blood Institute (NHLBI) consensus development conference on Triglyceride, High Density Lipoprotein and Coronary Heart Disease (Ref. 255), anticipated in the proposal (56 FR 60663 at 60664), concluded that, "It is not known to what extent these alterations of HDL contribute to atherogenesis."

Therefore, data on changes in HDL subfractions after increased consumption of omega-3 fatty acids do not provide a sufficient basis for a health claim, because there is not significant scientific agreement that HDL_2 is directly related to risk of CHD. If the risk of CHD becomes linked with HDL_2, these findings in normal subjects may be of great importance.

33. Many comments indicated that high triglycerides are causally related to decreased HDL, that triglycerides are an independent risk factor for CHD, or that statistical manipulations of data and imprecise measurements of triglycerides obscure the importance of triglycerides as a risk factor for CHD. One comment provided additional citations regarding the relationship between triglycerides and HDL, but these did not bear on risk of CHD. One comment stated that it was generally agreed that triglycerides were not independently associated with CHD.

FDA disagrees with all but the last comment. FDA is aware that there has been, and still is, substantial interest in the potential role of triglycerides in the etiology of CHD (e.g., Ref. 208). Because of the continued interest, the relationship between triglycerides and CHD was the topic of a consensus development conference sponsored by NHLBI on February 26 through 28, 1992. NHLBI had previously addressed this topic in 1983 and concluded at that time that the relationship was controversial. The recent conference (Ref. 255) concluded, "For triglyceride, the data are mixed; although strong associations are found in some studies, the evidence on a causal relation is still incomplete."

FDA agrees that the statistical methods previously used to study the relationship between triglycerides and CHD have lessened the likelihood that triglycerides would be found to be a significant, independent predictor of CHD. Furthermore, the agency believes that study design and analytic measurement methods have contributed to variation in triglycerides that may have resulted in reducing the statistical association between triglycerides and CHD. FDA believes that these sources of variation in triglycerides can be reduced by careful study design and standardized analytical measurement techniques, and also that clinical studies designed to lower triglycerides could provide a basis upon which to reconsider the importance of triglycerides in CHD.

34. Some comments stated that some very recent evidence from the Helsinki Heart Study supports a protective effect of lowering triglycerides, at least for a selected subpopulation of people with a high ratio of LDL cholesterol/HDL cholesterol and very high triglycerides.

FDA agrees that fish oils reduce plasma triglycerides. In its proposal FDA wrote, "The predominant blood lipid effects of fish oils * * * are decreased plasma triglycerides and VLDL." (56 FR 60663 at 60669.) In this regard FDA and LSRO were in agreement. The LSRO summary states, "The most striking effect is lowering of plasma triglyceride and VLDL concentrations."

FDA disagrees, however, that triglycerides have been established as an independent risk factor for CHD. The recent results from the Helsinki Heart Study (Ref. 242) were discussed at length at the NHLBI consensus development conference (Ref. 255). While the reduction in CHD mortality following drug intervention was dramatic (i.e., approximately 7-fold) for a particular subgroup with both elevated

triglycerides and elevated LDL to HDL ratio, this result was obtained by a post hoc analysis of earlier results. Because the combination of factors used to connote the high-risk group (i.e., high LDL cholesterol to HDL cholesterol ratio *and* high triglycerides) was determined after the data were collected, these results are not the results of the testing of a hypothesis, but are the origins of a new hypothesis. The authors indicate that the cut-off points for the ratio of LDL to HDL and triglycerides chosen were to some extent arbitrary. The actual number of cardiac events in the study was small (e.g., 18 events among 138 subjects in the highest risk subgroup), and the reduction in all-cause mortality due to the lipid-lowering drug, gemfibrozil, was not significant. Finally, independent of LDL to HDL ratio, increased triglycerides alone were not associated with an increased risk of heart attack.

The dramatic reduction of triglycerides by omega-3 fatty acids has resulted in their use in the treatment of a rare genetic hypertriglyceridemia (type V) to prevent noncardiovascular effects of high triglycerides (i.e., pancreatitis), but the usefulness of lowering triglycerides as a general strategy in prevention of CHD is not generally agreed. Therefore, FDA believes that the triglyceride-lowering effect of fish oils for some at-risk persons does not provide a basis for a health claim at this time.

35. Numerous comments indicated that postprandial triglyceridemia is a mechanism of action in the development of atherosclerosis. Some comments indicated that the relationship of elevated triglycerides to risk of CHD would be discussed at the NHLBI consensus development conference (Ref. 255). Others pointed out that LSRO had concluded that elevated very low density lipoproteins (VLDL) and triglycerides were atherogenic. LSRO stated that the reduction of postprandial hyperlipidemia is a "most important anti-atherogenic action." LSRO wrote in the summary that, "Since postprandial lipemia has been identified as an atherogenic risk factor, its prevention by w-3 fatty acids *would be* a most desirable effect" (emphasis added), and in its conclusions LSRO wrote:

> Fish oil has a generally accepted hypolipidemic effect without depressing HDL. This applies most to VLDL and triglyceride, lipids now believed to be atherogenic. There is little doubt that there is a reduction of postprandial hyperlipidemia following the ingestion of dietary fat if the background diet contains relatively small quantities of w-3 fatty acids. This may be a most important anti-atherogenic action.

FDA agrees that fish oils do not generally lower HDL. FDA also agrees that major blood lipid effects of omega-3 fatty acids are reductions of triglyceride and VLDL. The role of omega-3 fatty acids in the reduction of postprandial triglycerides was described in three papers abstracted by LSRO (Refs. 15, 59, and 163). While the first two papers used high levels of omega-3 fatty acids (30 and 9 g of EPA plus DHA/day, respectively), the recent paper used only 5 g of fish oil, containing 1.7 g EPA plus DHA. These studies showed that the concentration of plasma chylomicrons after a high-fat test meal was significantly less if the subjects had been consuming a fish oil diet than if they had been consuming a saturated fat or olive oil supplemented diet. Thus, FDA agrees that fish oils reduce postprandial lipemia.

However, FDA disagrees that there is significant scientific agreement that VLDL and triglycerides are atherogenic, or that the reduction in postprandial hyperlipemia is a most important anti-atherogenic action. Neither the Federal Government nor other authoritative reports have included these blood lipid measures among those they consider to be independent risk factors associated with CHD (Refs. 34 through 36, and 115). Furthermore, postprandial lipemia was discussed at the February 1992 NHLBI consensus development conference. The summary of that conference stated, "Postprandial triglyceride may be more important than the fasting triglyceride levels [to CHD], but little is known about this at the present time." (Ref. 255).

FDA notes that the only paper in the LSRO report cited in support of this hypothesized mechanism of action of omega-3 fatty acids in the prevention of CHD was a review paper published in 1979 (Ref. 305). Therefore, FDA believes that there is not significant scientific agreement at this time that postprandial triglycerides are related to the risk of CHD.

ii. Vessel wall effects

36. One comment indicated that two new studies support the use of omega-3 fatty acids to prevent restenosis, the closing of a mechanically opened blood vessel (Refs. 172 and 259). This comment suggested that FDA discounted the findings of the Dehmer study (Ref. 30) on the basis that it employed simultaneous treatment with drugs and fish oils.

FDA considered the use of omega-3 fatty acids to prevent restenosis to be a drug usage (56 FR 60663 at 60670), and notes that patients in these studies are under a physician's care. FDA's description of the Dehmer study points out a limitation of the data that is common in other reports of no effect of omega-3 fatty acids in restenosis (Refs. 56, 106, and 121), that the studies have not controlled for generalized effects of PUFA's that are not specific to omega-3 fatty acids. A better balanced experimental design would be comparison of drugs plus omega-3 fatty acids to drugs plus alternate PUFA's (e.g., corn oil).

FDA agrees that the new studies provide some support for the role of omega-3 fatty acids in prevention of restenosis, although neither was designed to distinguish effects of omega-3 fatty acids from effects of omega-6 PUFA's.

Nye et al. (Ref. 259) studied 79 men and 29 women who were referred for angina and underwent coronary percutaneous transluminal angioplasty (PCTA), i.e., a mechanical opening of a closed heart blood vessel. The subjects were randomly assigned to one of three treatments: (1) A combination of aspirin plus dipyridamole (an anti-platelet combination of drugs), (2) olive oil placebo, or (3) 12 milliliters (mL) fish oil containing 3.2 g EPA plus DHA/day. Subjects were restudied 1 year later or before if symptoms recurred, and 93 percent of all subjects were followed for the year. Although there was no significant difference in angina among the groups, the rate of restenosis, defined in this study as a loss of 50 percent or more of the luminal diameter increased by PCTA, was significantly less in the fish oil group (11 percent) than in the placebo group (30 percent).

The use of olive oil as the placebo did not control for effects due to PUFA's (omega-6). Also, it is notable that the restenosis rate in the aspirin group was somewhat higher (17 percent) than in the fish oil group, because aspirin is a much more potent inhibitor of platelet function than EPA in fish oil. Nonetheless, these results are consistent with an effect of omega-3 fatty acids in reducing restenosis.

The full "Quebec study" was published after the receipt of the comment, but because it was cited in the comment it will be discussed here. In this study, Bairati et al. (Ref. 172) conducted a double-blind, randomized intervention with either fish oil containing 4.5 g EPA plus DHA/day, or olive oil placebo in 205 patients undergoing first PCTA. The treatments were started 3 weeks before the procedure, and continued for 6 months after. Restenosis was assessed angiographically, using a quantitative

computer analysis program. Restenosis was reduced in the fish oil group compared to the olive oil group according to 3 of 4 definitions of restenosis. It was not reduced according to the clinical definition used by Nye et al. (Ref. 259), above, of a loss of 50 percent or more of the luminal diameter increased by PCTA.

This study also collected dietary data. The third of the subjects with the highest consumption of omega-3 fatty acids (0.15 g/day) and the third of the subjects with intermediate consumption of omega-3 fatty acids (0.033 to 0.15 g/day) had significantly lower rates of restenosis than the third consuming the least amount of omega-3 fatty acids. In fact, dietary omega-3 fatty acids (other than the supplement) were associated with a greater reduction in chance of restenosis than was the supplement. This result was somewhat surprising, since the supplement contained 30 times the amount of omega-3 fatty acids in the diet. No differences in rate of restenosis were found according to intake of total fat, polyunsaturated fat, monounsaturated fat, saturated fat, cholesterol, or total seafood consumption. These results suggest that chronic consumption of low amounts of omega-3 fatty acids may be as useful in preventing restenosis as much larger amounts consumed for a few weeks prior to and after PCTA.

In general, the results of Bairati et al. (Ref. 172) and Nye et al. (Ref. 259) are consistent, even though they obtained different results according to one identical definition of restenosis. The Bairati et al. study, like Nye et al. 1990, used olive oil as the control. If the mechanism of action of omega-3 fatty acids in restenosis is through competition with AA, this control is suitable, and an omega-6 fatty acid oil would have made the difference due to omega-3 fatty acids even more pronounced. If, however, the mechanism of action is through nonspecific effects of highly unsaturated fatty acids, then a control of a PUFA (e.g., corn oil) might have reduced the apparent effect of omega-3 fatty acids. It is notable that the only study of restenosis that has used a polyunsaturated fat control (an olive oil-corn oil mix) did not find an effect (Ref. 56).

37. Five studies in humans relevant to the actions of omega-3 fatty acids on the vessel wall were referenced in comments (Refs. 200, 213, 259, 268, and 277), including two published since the time period covered by FDA's review in its proposed rule (Refs. 200 and 268). Hamakazi et al. (Ref. 213) found a slower aortic pulse wave velocity (an electro-physiologic measurement) in persons from a Japanese fishing village compared to those from a farming village. Other data showed the populations differed in their intake of omega-3 fatty acids. Rapp et al. (Ref. 268) measured the amount of omega-3 fatty acids in the atherosclerotic lesion after consumption of omega-3 fatty acids at a high level (6 percent of calories, 16 to 21 g EPA plus DHA/day) for 6 to 120 days prior to planned surgical intervention, and found that the amount of omega-3 fatty acids in the lesion continued to increase throughout the time of ingestion. Force et al. (Ref. 200) studied the effects of fish oils and aspirin on the production of urinary metabolites of AA and EPA. Fish oil feeding resulted in a slight decrease in the amount of thromboxane A_2 made in the platelet, a decrease in the amount of AA-derived prostacyclin made in the endothelial cell, and an increase in the amount of EPA-derived prostacyclin made in the endothelial cell. Schmidt et al. (Ref. 277) described decreased monocyte chemotaxis among hypertensive patients after fish oil feeding. The Nye et al. study is discussed in comment 36 of this document.

FDA considers these studies to be observational, not clearly associating omega-3 fatty acids with risk of CHD. The correlation data of Hamakazi et al. do not indicate a specific role for omega-3 fatty acids. The Rapp et al. data verify that it is possible to incorporate omega-3 fatty acids into preexisting atherosclerotic plaque, but the relevance of incorporated omega-3 fatty acids has not been established. The studies of Force et al. and Schmidt et al. relate to a potential mechanism of action of omega-3 fatty acids, but the importance of these actions in reducing risk of CHD has not been established.

38. Many comments stated that the biochemical and physiological actions of omega-3 fatty acids are anti-atherogenic because they favor vasodilatation and inhibit vasoconstriction. One comment by a manufacturer of omega-3 fatty acids considered these actions have potential for future significance. Two comments cited a list of effects of omega-3 fatty acids, suggesting that each of the effects in the list was anti-atherogenic, and other comments referred to one or more of the components in the list. The listed changes were:

decreased thromboxane;
increased prostacyclin and leukotriene (LTB_4);
decreased fibrinogen;
decreased platelet activating factor (PAF);
decreased platelet-derived growth factor (PDGF);
decreased superoxide;
decreased interleukin-1 (TNF);
increased endothelium-derived relaxation factor (EDRF);
decreased lipoprotein (a) (Lp(a));
reduced inflammatory response; and
increased fibrinolytic activity.

The LSRO report stated that other mechanisms, such as cellular growth factors, interleukin-1 and cytokins, and EDRF may be important in the development of atherosclerosis, and be affected by omega-3 fatty acids. However, except for a single in vitro study on PDGF, no data are described in the report regarding these factors, nor is their relevance to human CHD discussed.

FDA addresses fibrinogen, Lp(a), and fibrinolytic activity in comment 46 and in section II.C.2. of this document. FDA does not agree that omega-3 fatty acids produce changes in all of the listed parameters. FDA has determined that for some of these endpoints the changes have not been shown to be specific to omega-3 fatty acids, but may be due to polyunsaturated fats instead. FDA disagrees that the changes brought about by omega-3 fatty acids will prevent atherosclerosis. Most of the data regarding changes in these endpoints brought about by omega-3 fatty acids have been derived from tissue culture or animal experiments, and the relevance to human atherosclerosis has not been demonstrated.

Thromboxanes and prostacyclins are compounds derived from omega-3 fatty acids and omega-6 fatty acids that affect the relaxed state of the blood vessels. Thromboxanes are produced primarily in platelets, and prostacyclins are produced primarily in the endothelial cells of the blood vessels. The thromboxane made from an omega-6 fatty acid called AA, thromboxane A_2, is a potent vasoconstrictor. EPA competes with AA for the enzyme that makes thromboxane A_2, and thereby diminishes the rate of production of thromboxane A_2; the thromboxane made from EPA is a much less potent vasoconstrictor. The prostacyclins made from AA or EPA in the endothelial cells are vasodilators. Thus, the relative amounts of AA and EPA in platelets and endothelial cells play a role in determining the form and amounts of the prostaglandins and thromboxanes that affect the tension of the vessel wall. Excessive constriction may lead to an occlusion, resulting in a heart attack. While there is general recognition that these vasoactive compounds may play a role in the formation of clots and thereby in heart attacks, there is no

agreement about the extent of changes needed in the concentrations of the vasoactive compounds in order to have an effect on heart disease. Changes in the amounts of these vasoactive compounds, produced by consumption of fish oil, are only useful as marker for CHD only insofar as there is significant scientific agreement that the magnitude of the changes is related to CHD. FDA is not aware of any such agreement, nor did the comments provide any evidence of agreement that particular changes in the levels of these vasoactive compounds were related to a reduction in risk of disease. Furthermore, the amount of omega-3 fatty acids needed to produce these changes in humans is not known.

For PDGF the evidence is confined to animal studies (Ref. 201), and the relevance to human disease has only been suggested, not demonstrated. The animal studies on PDGF also did not show that the effect was specific to omega-3 fatty acids. For example, the PDGF effect was observed also after polyunsaturated fats, and was abolished by anti-oxidants, suggesting that any highly unsaturated fatty acids prone to oxidation would have the effect. The experiments on EDRF (Ref. 181) also did not show that the effects were specific to omega-3 fatty acids, since the experiments were carried out in the presence of indomethacin, which blocks the eicosanoid effects of EPA. In fact, the authors consider changes in membrane fluidity to be a reasonable explanation for the effects. In yet other cases, e.g., TNF, there are conflicting results depending on the species (Refs. 41 and 236), and the findings must be considered preliminary.

FDA considered the effect of omega-3 fatty acids on chemotaxis, one aspect of inflammatory response (56 FR 60663 at 60670). A complete discussion of the role of fish oils in inhibition of the inflammatory process is outside of the scope of this rulemaking, but the relationship between omega-3 fatty acids and inflammatory response could be the subject of a petition for a health claim that includes the necessary information about this relationship.

FDA agrees that the biochemistry of the products formed from the omega-3 fatty acids in vivo (i.e., eicosanoids) have been shown under experimental conditions, usually in vitro, to have pronounced effects on the vessel wall. However, demonstration of isolated biochemical effects is not a sufficient basis upon which to make a claim regarding the outcome of a multifactorial process. Intermediate markers of CHD are useful only insofar as there is significant scientific agreement that changes in these markers produced by omega-3 fatty acids are causally related to CHD.

b. Thrombosis and hemostasis

39. A few comments stated that the mode of action of omega-3 fatty acids may be through stabilization of arrhythmia, and noted the reduced rate of death after heart attacks (MI's) in the Dart study (Ref. 16). This comment also stated that certain animal data were consistent with this hypothesis. The comments stated that the fibrillation mechanism suggested by DART was compelling, because 60 percent of sudden deaths are caused by ventricular fibrillation following reperfusion. Many commented that data from nonhuman primate models show that omega-3 fatty acids abolish arrhythmias, whereas polyunsaturated fat (safflower oil) had a lesser effect.

FDA disagrees with these comments. FDA's review of the literature regarding the usefulness of omega-3 fatty acids in arrhythmia and ventricular fibrillation found only one study on arrhythmias in humans, and it reported no significant effect of omega-3 fatty acids (Ref. 58). A review in 1989 also concluded that, even among the animal studies, there was no significant difference between omega-3 fatty acids and other polyunsaturated fats on arrhythmias (Ref. 269).

The data from the studies in nonhuman primates (i.e., the marmoset monkey) were published only as a nonpeer-reviewed paper in a book (Ref. 188). Two papers by the same author on the same topic were cited in 1990 as in press in a peer-reviewed journal, but have not yet been published. Therefore, FDA regards the data on nonhuman primates as preliminary only. Furthermore, the data for the marmoset monkey were obtained after prolonged feeding for 12 or 24 months with a supplement of DHA-rich fish oil at a level of 8 percent of the diet by weight. FDA calculates that this would provide 2.5 g of omega-3 fatty acids from fish oil/kilogram (kg), over 50 times the usual rate of supplementation in human studies (10 g fish oil or 3 g omega-3 fatty acids/day for a 70 kg subject), and over 300 times the amount of omega-3 fatty acids associated with reduced risk of CHD in the epidemiologic literature (Refs. 16, 38, and 87 report 300 to 660 milligrams (mg)/day). Thus, the relevance of these studies to omega-3 fatty acids in the human diet is questionable.

FDA is aware of in vitro data that show a specific protective effect of EPA against toxicity of heart muscle cells in culture. These results provide a biochemical basis for the hypothesized stabilization of cardiac arrhythmias by omega-3 fatty acids. Although this study (Ref. 212) was performed in vitro on heart cells from rats, it showed that the protective effect was specific to omega-3 fatty acids (EPA) because a similar effect was not obtained when a highly unsaturated omega-6 fatty acid (AA) was used instead.

FDA also regards the evidence from the Burr study of reduced death following a heart attack among those men advised to increase fish consumption as consistent with a stabilization of arrhythmias (Ref. 16). FDA agrees that this postulated mechanism of action is of great potential public health significance. However, the agency finds the clinical data available at this time are not in agreement with animal and in vitro data. Because the clinical data are not in agreement with these other types of data and because of the limitations in the animal studies, FDA concludes that there is not sufficient basis for protective effect specific to omega-3 fatty acids on arrhythmias, and, therefore, CHD in humans.

40. One comment criticized the 6-week clinical study by Hardarson et al. that found no effect of omega-3 fatty acids on arrhythmias (Ref. 58), arguing that the time for incorporation of omega-3 fatty acids into heart phospholipids was too short for an effect to be observed.

FDA agrees in part and disagrees in part with this comment. Generally, the time needed for incorporation of omega-3 fatty acids into cellular phospholipids is short; studies in animals show such incorporation in a period of weeks (Ref. 249). In the Hardarson study (Ref. 58), a substantial amount of cod liver oil was fed (20 mL/day) and a 230 percent increase in plasma phospholipid EPA was found. There was no trend toward reduced arrhythmias. Other data, however, show that although plasma phospholipids increase the omega-3 fatty acid content during the first few weeks of supplementation, the incorporation of omega-3 fatty acids in human atherosclerotic plaque continues to increase through 120 days (Ref. 268). Therefore, FDA agrees with the comment the supplementation period in the Hardarson study (Ref. 58) may have been too short to find an effect of fish oils on occurrence of arrhythmias. Also, the agency notes that the absence of a difference in CHD mortality during the first 6 weeks of the Burr study (Ref. 16) is consistent with the hypothesis that prolonged intake of omega-3 fatty acids (longer than 6 weeks) is needed to observe an effect on arrhythmias or

other mechanisms that reduce CHD mortality. FDA agrees that effects of long-term consumption of omega-3 fatty acids on arrhythmias, other platelet or vessel wall functions, and even some blood lipid measures have not been sufficiently studied.

i. Bleeding times

41. Two comments stated that there is no evidence of increased bleeding even among patients who had ingested 6 to 8 g of EPA plus DHA/day and underwent emergency surgery, coronary artery bypass surgery or angioplasty. The comments argued that increased bleeding has not a safety concern.

FDA agrees that there are few reports of excessive bleeding after ingestion of omega-3 fatty acids. However, FDA notes that the cited reports are for subjects with CHD, and evidence of the lack of excessive bleeding complications in this population is not sufficient to assure safety of omega-3 fatty acids in the general population. FDA believes that changes in bleeding due to consumption of omega-3 fatty acids remains a valid safety concern (see comment 52 of this document).

ii. Platelet aggregation

In the proposal, FDA stated:

> The relationship between platelet aggregation and the risk of heart attacks or CHD death in the general population is an important line of evidence that would support drug claims and perhaps health claims for omega-3 fatty acids. Although there is some evidence that changes in platelet aggregation may help prevent second heart attacks * * * it has not been shown that changes in platelet aggregation in the general population will reduce the risk of CHD.

(56 FR 60663 at 60670.)
The agency added: "What has not been established, however, is that platelet aggregation is a bona fide surrogate risk factor for CHD in the general population." (56 FR 60663 at 60672.)

42. Many comments argued that platelet aggregation is completely substantiated as a marker for risk of CHD, based on the results of the Physicians' Health Study (Ref. 66). One comment qualified this conclusion stating that the primary effect of omega-3 fatty acids in vivo was to reduce platelet deposition at sites of aortic lesions.

FDA acknowledges that aspirin studies provide evidence that platelet aggregation is a risk factor for CHD. The effect of aspirin in inhibiting platelet function has been shown. Among persons who have already had an MI, aspirin is effective in preventing a second infarction. FDA has proposed that aspirin be used to reduce the risk of death and/or nonfatal heart attack in patients with previous infarction or unstable angina pectoris as a professional labeling indication (provided to health professionals, but not to the general public), in the tentative final monograph for over-the-counter internal analgesic, antipyretic, and antirheumatic drug products (November 16, 1988, 53 FR 46204 at 46259). However, FDA does not consider the effects of aspirin in the Physicians' Health Study sufficient to establish that dietary omega-3 fatty acids would have the same effect in the general population. The Physicians' Health Study did not evaluate omega-3 fatty acids. The study population was highly selected; the rate of heart attacks was approximately 10-fold lower than in the general population, and cardiovascular mortality was only 15 percent of that expected for the general population of white men of the same age. Also, the results of the Physician's Health Study are not as straightforward as presented in the comments. The chairman of the Physicians' Health Study reported that there was a reduced risk of MI in the aspirin group, predominantly in nonfatal MI, but that there was no significant effect on overall cardiovascular mortality (a 2 percent reduction, not statistically significant) (Ref. 66). In addition, the aspirin group in this study had a greater number of sudden deaths (Ref. 282).

In the other primary prevention trial (Ref. 265), aspirin did not have any significant effect on heart attacks, on stroke, or on total vascular mortality. There was a significant increase in disabling stroke in the group taking aspirin.

On the basis of these studies there has not been an endorsement of the use of aspirin as a prophylactic measure against CHD by the general population by the American Heart Association or by the Canadian Medical Association (Ref. 187). Notably, "1992 Heart and Stroke Facts" published by the American Heart Association (Ref. 169) makes no reference to platelet aggregation as a risk factor for heart attacks (although sticky platelets are mentioned to be a consequence of cigarette smoking in the section on stroke), nor is aspirin discussed as an option for CHD prophylaxis, even though other drug and surgical treatments are discussed.

Therefore, FDA concludes that there is not significant scientific agreement at this time that platelet aggregation is a surrogate marker for CHD in the general population.

43. The LSRO report, submitted as a comment, contained abstracts of 19 studies in humans that contained data regarding changes in platelet function following omega-3 fatty acid consumption. LSRO concluded that omega-3 fatty acids prevented platelet aggregation.

In its proposal, FDA stated: "Platelet aggregation is generally considered to be decreased by fish oil consumption." (56 FR 60663 at 60670.) The agency also stated: "* * * platelet aggregation and function are reduced. However, direct relationships between the changes in * * * platelet function and risk or CHD have not been established." (56 FR 60633 at 60671.) Thus, FDA agrees with the conclusions of LSRO about effects of omega-3 fatty acids on platelet aggregation.

Two of the studies described by LSRO were not considered by FDA in its review, because they were published before 1988, and had been considered by Federal Government and other authoritative reports. One study (Ref. 227) used a large amount of fish oil (50 mL/day) not reasonably related to normal dietary intake. The other study (Ref. 211) involved 13 insulin-dependent diabetics, and therefore is of questionable relevance for the general population.

In its proposed rule, FDA considered 13 of the other 17 studies that were abstracted by LSRO. One of the four studies not addressed by FDA was a study on the effects of added vitamin E to fish oil on fibrinogen and fibrinolysis (Ref. 210). Two papers (Refs. 234 and 244) were published after the time period covered by FDA review. Marckmann et al. (Ref. 244) compared the effects of a fish diet and a lean meat diet on plasminogen activator (t-PA), plasminogen activator inhibitor (PAI-1) and the activity of the inhibitor (PAI-1 activity). Li and Steiner (Ref. 234) described changes in in vitro platelet adhesion after fish oil supplementation. The fourth paper was an uncontrolled observation study that found a high frequency of nosebleeds in adolescents supplemented with fish oils (Ref. 189).

Six other papers on thrombosis were not described in the LSRO text, but were included in the table (Refs. 203, 204, 209, 226, 245, and 254). Of these six, one was not relevant to the nutrient-disease relationship (Ref. 245) because it did not study EPA and DHA. Jensen et al. (Ref. 226) found no significant change in bleeding times in normal subjects after 1, 3, or 6 g EPA plus DHA/day in healthy subjects. Green et al. (Ref. 209) found no change in platelet aggregation or platelet count in 27 hyperlipidemic subjects in a randomized double-blind placebo controlled crossover trial. The treatments were 15 g/day fish oil

containing 4.3 g EPA plus DHA and a 50:50 mix of corn:olive oil, with each treatment lasting 8 weeks, and a 4-week washout between. Blood viscosity was decreased by fish oil. Gazso et al. (Ref. 204) found decreased platelet aggregation in healthy subjects after consumption of EFAmol-marine compared to olive oil in a double-blind randomized crossover study. These results of studies confirm others cited by FDA. The other studies (Refs. 203 and 254) pertained to regulators of bleeding and are discussed below.

Eight papers on platelet function were reviewed by FDA but not by LSRO (Refs. 2, 6, 18, 24, 73, 93, 131, and 143). Three studies were uncontrolled (Refs. 18, 93, and 143), while two were randomized (Refs. 2 and 131). Three were randomized, double-blind, placebo-controlled trials that used saturated vegetable oil (Ref. 6), vitamin E (Ref. 24) or wheat germ oil (Ref. 73) as the placebos. The two studies that used vegetable oil or vitamin E as controls found a reduction in platelet aggregation after omega-3 fatty acids, where no difference was reported in the trial that used a wheat germ oil placebo, although the data were not provided in this paper.

FDA and LSRO reached the same conclusions with regard to the effects of omega-3 fatty acids on platelet function. LSRO also concluded that platelet survival is also enhanced, but the only two studies published since 1987 that reported increased platelet survival (Refs. 94 and 144) were both uncontrolled, so the effect cannot be attributed specifically to omega-3 fatty acids.

44. One comment agreed in principle with the agency's assessment of the effects of omega-3 fatty acids on bleeding times, platelet aggregation, regulators of bleeding and blood pressure. The comment pointed out the extent of inhibition of platelet adhesion is as much as 60 percent, a marked reduction in adhesion.

FDA agrees that the reported extent of reduction of platelet adhesion from omega-3 fatty acid intake is remarkable (Ref. 234). The agency notes that this effect appears specific to omega-3 fatty acids at reasonable intake levels. FDA notes that animal studies (Refs. 230 through 233) published since the proposed rule provide evidence of reduced platelet adhesion to blood vessel endothelium in vivo in response to agents that provoke such adhesion. Because of the magnitude of the effect of omega-3 fatty acids on platelet adhesion, FDA considers this action of omega-3 fatty acids on blood platelet function to have great potential with regard to the development of atherosclerosis and the risk of CHD. However, as for platelet aggregation, FDA does not believe that there currently is significant scientific agreement that platelet adhesion is an accepted risk factor for CHD in the general population.

iii. Regulators of bleeding

In its proposal (56 FR 60663 at 60670 through 60671), FDA reviewed data on the effects of omega-3 fatty acids on other factors that are involved in the regulation of bleeding—fibrinogen, fibrinolytic activity and Lp(a)—and that have been associated with CHD.

45. Some comments, including the LSRO report, stated that omega-3 fatty acids increase fibrinolysis.

FDA disagrees with these comments. FDA found that there was no clear relationship between omega-3 fatty acids and factors involved in dissolving blood clots (56 FR 60663 at 60671). FDA noted that the data did not establish that omega-3 fatty acids reduced fibrinogen, because most studies did not control for other factors that might have reduced fibrinogen, e.g., other PUFA's.

FDA has reviewed the relevant studies again, as well as studies brought to its attention in the LSRO report. LSRO cited three papers on fibrinogen or fibrinolysis not cited by FDA. One placebo (vitamin E) controlled study found no change in fibrinolytic activity (Ref. 210). Mullertz et al. (Ref. 254) supplemented seven healthy adults with 0.55 g EPA plus DHA/day for 21 days and found increased levels of PAI-1, but no change in t-PA, suggesting that fish oil decreased fibrinolytic capability. Gans et al. (Ref. 203) reported no change in fibrinogen concentration after EFAmol-marine compared to corn oil, which is rich in polyunsaturated fat. These studies do not support the conclusion that omega-3 fatty acids reduce fibrinogen, or increase fibrinolysis.

The selection of studies abstracted by LSRO may not have represented the publicly available scientific evidence. For example, five papers abstracted found either a decrease in fibrinogen or an increase in fibrinolytic activity (Refs. 57, 71, 98, 104, and 117). In contrast, two studies found no change in fibrinolytic activity (Refs. 150 and 166), and only one found increased fibrinogen (Ref. 144), leaving the impression that omega-3 fatty acids usually have been reported to enhance fibrinolysis.

However, three other studies not abstracted by LSRO but included in their tables reported no effect of omega-3 fatty acids on fibrinogen compared to corn oil (Refs. 10, 118, and 203). One found a decrease compared to olive oil (Ref. 49) and one found a decrease compared to soybean oil only when 30 mL of fish oil were consumed, but not when 15 mL were consumed (Ref. 57). Additional well-designed studies not cited by LSRO, but considered in the FDA proposal, reported no change (Ref. 24) and an increase (Ref. 131) in fibrinolytic activity.

Therefore, FDA stands by its earlier conclusion that the publicly available scientific evidence does not support a relationship between omega-3 fatty acids and decreases in fibrinogen or increases in fibrinolysis. This conclusion is supported by findings that consumption of other PUFA's have effects comparable to those produced by consumption of omega-3 fatty acids.

46. Two comments cited unpublished data by Kostner and Herrmann, reporting reduced Lp(a) after fish oil consumption.

FDA was unable to find the full paper by these authors showing the decrease in Lp(a). FDA did find a paper by these researchers published in 1991 (Ref. 241) that reported no effect of fish oils on Lp(a) and did not cite conflicting work from their laboratory.

iv. Blood pressure

In its proposal, FDA considered the relationship between omega-3 fatty acids and blood pressure, one of the recognized risk factors for CHD. FDA stated:

> These results for effects of omega-3 fatty acids on blood pressure of normal subjects are ambiguous. Some studies found a reduction in systolic blood pressure after consumption of fish oils containing omega-3 fatty acids, whereas others did not. None of the studies found a significant reduction in diastolic blood pressure. Therefore, it also remains to be established that the normal, healthy population will reduce their risk of CHD via a reduction in blood pressure following consumption of omega-3 fatty acids.

(56 FR 60663 at 60671.)

FDA also stated that it was not known whether or not the magnitude and duration of the effect would persist after longer term supplementation. FDA recognized that studies among hypertensives found an effect more consistently than studies among normal subjects, although sometimes large amounts of fish oils were used.

47. Some comments considered the effects of omega-3 fatty acids on hypertension as evidence of a reduction in CHD risk. Other comments called for FDA to reassess the studies on blood pressure. One of these comments argued that the results of studies on blood pressure are not "completely"

ambiguous. One comment agreed in principle with the agency's assessment of the blood pressure studies. One comment considered a number of animal models to be relevant for hypertension. The LSRO report also considered the evidence relating omega-3 fatty acids to blood pressure to be important in relation to CHD. The LSRO report concluded that, "Fish oil probably has a mild hypotensive effect, especially in high doses."

FDA disagrees that the publicly available scientific evidence supports a relationship between omega-3 fatty acids and hypertension. At best, as stated in the proposal, the data are ambiguous. Qualifiers are needed to indicate that the reductions in blood pressure have not generally been shown to be specific to omega-3 fatty acids. Also, many valid studies have reported no effect.

LSRO reported a total of 13 studies on hypertension. Four were published before 1988, and were not reviewed by FDA in the proposed rule. Three of these studies used fish as the source of omega-3 fatty acids and therefore did not show the effect specifically to be due to omega-3 fatty acids. In fact, in one study (Ref. 292), the control diet of meat produced a decrease in blood pressure comparable to that of the fish diet. The study that used fish oils (Ref. 271) used an olive oil control, rather than an oil high in PUFA's. This study is the only study to show an effect of omega-3 fatty acids on diastolic blood pressure in normal subjects.

Of the other 10 studies on hypertension described in the LSRO report, 6 were also reviewed by FDA (Refs. 11, 57, 80, 85, 95, and 101). The LSRO and FDA interpretations of the results from these papers did not differ in any significant regard, except that FDA specifically noted that two of these studies (Refs. 85 and 95) used very high amounts (50 mL) of fish oil to show the effect. In fact, FDA singled out the Bonaa et al. (Ref. 11) and Kestin et al. (Ref. 80) studies as well-designed studies that showed an effect specific to omega-3 fatty acids in hypertensive and normal subjects, respectively (56 FR 60663 at 60671).

The LSRO report reviewed four papers not originally reviewed by FDA (Refs. 190, 285, and 299), including one study on linolenic acid outside of the scope of the definition of omega-3 fatty acids as used in this regulation (Ref. 262). Two other papers that appeared in the LSRO table but not in the text (Refs. 203 and 247) were also not reviewed by FDA in its proposal.

FDA agrees with the LSRO interpretation of the Wing et al. study (Ref. 299), where subjects remained on blood pressure lowering medications and no effects of added fish oils were observed.

FDA disagrees with the LSRO descriptions of the Singer and Cobiac studies. The placebo in the Singer study (Ref. 285) was olive oil, but this was not pointed out in the LSRO text. The reduction of blood pressure observed after fish oil, therefore, may have been due to a general unsaturated fatty acid effect not specific to omega-3 fatty acids. In the description of the Cobiac et al. study (Ref. 190), LSRO did not note that fish oil treatment alone (without simultaneous reduction of salt) had no effect on blood pressure.

Two other studies were cited in the LSRO tables but not in the text and were not included in the FDA review. Neither of these found an effect on blood pressure. Gans et al. (Ref. 203) used a randomized double-blind, placebo-controlled design and found a reduction in diastolic blood pressure for both fish oil and corn oil (placebo). Meland et al. (Ref. 247) carried out a randomized, double-blind multicenter trial among 40 mildly hypertensive subjects, using 6.8 g EPA plus DHA/day, but found no difference in blood pressure compared to a 50:50 olive:corn oil control.

Three other large and appropriately controlled studies not in the text of the LSRO report but included in its table were also reviewed by FDA. Two randomized studies on normal subjects (Refs. 9 and 49) and one controlled study among mildly hypertensive subjects (Ref. 20) reported no differences in blood pressure attributable to omega-3 fatty acids.

FDA reviewed in its proposal three other randomized, double-blind, placebo-controlled studies among healthy subjects that were not included in the LSRO review. Two of these studies were on normal, healthy subjects (Refs. 6 and 24) and found a decrease in systolic blood pressure compared to a saturated vegetable oil or vitamin E, respectively. The third study (Ref. 73) found that omega-3 fatty acids did not affect blood pressure in hypertensives or normal men compared to wheat germ oil.

Therefore, FDA concludes that the evidence of an effect of omega-3 fatty acids on blood pressure in normal subjects is ambiguous, because some studies reported a blood pressure lowering effect, whereas other equally well-designed studies found no specific effect. Studies among hypertensives found an effect more consistently than studies among normal subjects, although sometimes large amounts of fish oils were used, and many studies did not show that omega-3 fatty acids were more effective than other polyunsaturated fats.

48. Comments stated that other lines of evidence were not discussed in the proposal. Examples given were changes in plasma viscosity, increased vascular compliance, and reduced white blood cell (WBC) count.

FDA disagrees with the comment with respect to plasma viscosity and vascular compliance. In its proposed rule, FDA acknowledged that plasma viscosity was decreased and red cell deformability was increased by omega-3 fatty acids, but that the importance of these effects on the risk of CHD had not been established (56 FR 60663 at 60670).

The agency agrees that it did not systematically consider WBC count among the effects produced by omega-3 fatty acids. WBC count was not included among the actions of omega-3 fatty acids considered in major reviews. FDA notes that WBC count has only recently been identified as associated with risk of CHD by the Caerphilly Collaborative Heart Disease Study (Ref. 301a). Only two papers among literature from 1988 to present have reported a reduction of WBC count after fish oil supplementation (Refs. 183 and 253).

3. Other relevant information

a. Animal studies

49. Numerous comments asserted that animal studies did not receive an appropriate amount of discussion. One of these same comments stated that animal studies are not sufficient to support the claim, and that clinical trials on effects of omega-3 fatty acids directly on CHD are needed. One comment criticized FDA's review of animal studies because the negative findings have been in inappropriate models and should not have been discussed. Another comment stated that they did not believe that there is an appropriate animal model for human cardiovascular and CHD. The LSRO report considered animal studies to provide important evidence for an anti-atherogenic effect of fish oils, stating, "Omega-3 fatty acids have been shown to retard the development of the atherosclerotic plaque in experimental animals including the pig and rhesus monkey."

FDA agrees that the evidence from studies in animals warrants additional discussion. FDA has reviewed here those animal studies that were cited in its proposed rule and those that were cited in the LSRO report that were relevant to the development of atherosclerosis. Other animal studies relevant to the development of

atherosclerosis, and animal studies on aspects of CHD other than atherosclerosis are reviewed under section II.C.3.a. of this document.

In its proposal, FDA cited eight animal studies and one abstract on the development of atherosclerosis that were not included in the LSRO review (Refs. 19, 51, 65, 81, 97, 123, 126, and 151), seven of which reported either no beneficial effect or an adverse effect in fish oil supplemented animals. Only one animal study on the effects of omega-3 fatty acids on restenosis was abstracted by LSRO, although the others cited by FDA were described in the LSRO tables.

Three studies in nonhuman primates have been reported (Refs. 27, 47, and 116). In the Davis et al. (Ref. 27) and Parks et al. (Ref. 116) studies, the polyunsaturated fat intake was higher in the fish oil groups, and polyunsaturated fat is known to lower total plasma cholesterol. Also, the control diet of the Davis et al. study had more saturated fat than the fish oil diet. Thus, the effects on atherosclerosis may not have been specific for omega-3 fatty acids.

In these studies, the total cholesterol values for the fish oil groups were substantially lower than for the control group, which may explain the observed differences in atherosclerosis. In support of this interpretation, Parks et al. (Ref. 116) noted that one of monkeys fed the fish oil diet responded differently than the other 11 monkeys fed fish oil. This one monkey had a plasma cholesterol level comparable to that of the lard-fed control monkeys, and also had atherosclerosis comparable to the lard-fed monkeys.

Changes in total cholesterol levels were noted by authors of another study in pigs that showed a reduction in atherosclerosis concomitant with a reduction in time-weighted total cholesterol (Ref. 81). Since cholesterol concentrations are not changed by fish oils in humans, animal studies where fish oil treatment lowered total cholesterol levels are of questionable relevance to the role of omega-3 fatty acids in the development of human atherosclerosis.

A recent study (Ref. 47) in nonhuman primates (vervet) compared the effects of fish oil supplementation to sunflower oil supplementation in either an atherogenic diet (high fat, low polyunsaturated fat to saturated fat ratio, high cholesterol) or, following the atherogenic diet, in a therapeutic diet (low fat, high polyunsaturated fat to saturated fat ratio and low cholesterol). Animals in each diet group were matched for serum cholesterol. Sixteen separate measures of atherosclerosis were scored, including various measures of the extent of plaque, loss of endothelium, intimal thickening, and inflammation. Overall there was no benefit of fish oil; in some cases, the atherosclerotic measure indicated more disease in the fish-oil fed animals.

The LSRO report considered the amount of fish oil in the diets in this experiment (1.3 to 1.8 percent of calories) too low to observe an effect. In fact, FDA calculates a lower percent of calories from fish oil (1.0 to 1.5 percent) than calculated by LSRO. This level is about half the amount used in short-term human studies (i.e., 10 mL/day), and FDA agrees that the low level makes it less likely that an effect would be observed than if a higher amount had been used. However, diets were supplemented for a prolonged period of time (20 months) and in the therapeutic diet other dietary factors were also changed that might have made the effects of omega-3 fatty acids more noticeable (e.g., ratio of polyunsaturated to saturated fatty acids). Finally, the fact that there were differences between the fish oil-supplemented group and the polyunsaturated fat group while on either the atherogenic or therapeutic regimens suggests that there was sufficient sensitivity in the experimental design to detect protective effects of omega-3 fatty acids.

In some animal studies that showed a protective effect of fish oils, an invasive procedure was used to accelerate atherosclerosis, either mechanical injury (Ref. 122) or vein grafts (Refs. 90 and 186). These studies may be most relevant to the late stages of atherosclerosis, and to CHD in humans following invasive procedures. All of the animal studies cited in the LSRO report except Kim et al. (Ref. 81) and Fincham et al. (Ref. 47) did not control for PUFA's, so the effects observed have not been shown to be specific to omega-3 fatty acids. Additionally, the level of use of fish oils has been high, e.g., 22 percent of calories in Parks et al. (Ref. 116) and 25 percent of the diet in Davis et al. (Ref. 27), which limits the extrapolation of findings in these studies to levels that might be reasonably consumed by humans.

FDA disagrees with the summary of the literature in animals, as expressed in the LSRO report, because that report fails to mention important limitations in the data. FDA notes that most studies did not have an adequate design to show specificity of effects as due to omega-3 fatty acids. Furthermore, reductions in total cholesterol in the fish oil fed animals may explain the reported reductions in atherosclerosis. Since reasonable amounts of fish oils in human diets do not alter serum cholesterol concentrations, the results from these animal experiments are of questionable importance regarding human atherosclerosis. Finally, LSRO did not review numerous animal studies that found no effect or an adverse effect of supplementation with fish oils, and therefore the LSRO conclusion does not represent the totality of publicly available scientific information.

With these qualifications in mind, FDA notes that some of the reported effects of the dietary interventions with fish oils on the development of atherosclerosis have been dramatic. Also, FDA recognized that animal studies are of great importance for study of long-term effects on chronic diseases of consumption of amounts of omega-3 fatty acids, particularly in amounts that might be obtained in a reasonable diet. Therefore, FDA encourages further research in this area using rigorous study designs and amounts of omega-3 fatty acids reasonably available in a normal diet to elucidate any effects specific to these fatty acids.

After closer scrutiny of the animal studies cited in FDA's proposal and in the LSRO report, the agency has reached the same conclusion that it reached in its proposed rule: there are some data in studies from animals which suggest the possibility of a beneficial effect of omega-3 fatty acids on CHD; however, the data are equivocal. (56 FR 60663 at 60671.)

b. Safety considerations

50. One comment stated that the increases in LDL cholesterol observed were a chance occurrence, and another stated that increased LDL should not be considered an adverse finding in light of the results of the Burr study.

FDA disagrees with this comment. FDA found that increased LDL cholesterol was ordinarily found when hyperlipidemics or diabetics were given fish oil supplements. This may be due in part to the fact that fairly large amounts of omega-3 fatty acids (i.e., 5 g EPA plus DHA/day or more) were used in these studies. Increased LDL is not ordinarily seen in the studies on normal subjects.

FDA does not consider the Burr study (Ref. 16) to have established that omega-3 fatty acids reduce the risk of CHD, and therefore remains concerned that increases in LDL cholesterol could be adverse for some subjects. FDA notes that concern about increased LDL cholesterol was expressed in the report of the NHLBI consensus development conference (Ref. 255).

51. One comment stated that it was inappropriate to consider adverse effects

in subpopulations without describing the advantages of omega-3 fatty acids in those same populations.

FDA disagrees with this comment. As noted in the final rule on general requirements for health claims, published elsewhere in this issue of the Federal Register, it would be a violation of the agency's responsibility under the act to authorize a health claim about a substance without being satisfied that the use of the substance was safe. The agency attempted to examine all available scientific evidence regarding the effects of omega-3 fatty acids. FDA separated out the potential adverse effects discovered during its review, because it wanted to draw attention to these issues as impediments to a health claim for omega-3 fatty acids and CHD. Such potential adverse effects must be resolved, and may be important in setting the conditions under which FDA would allow a health claim to appear on the label and labeling of foods and food supplements.

52. Two comments stated that the safety issues raised in the Mitre Corp. report (Ref. 72) were outdated but did not indicate which issues, or suggest why they were outdated.

FDA recognizes that there has been considerable debate regarding the clinical importance of bleeding times since the publication of the Mitre Corp. report (Ref. 72). However, the agency believes that the issues raised in that report have been restated in subsequent literature, and that all issues of safety are important in deciding whether or not to authorize a health claim.

53. A few comments recommended that FDA balance the benefits of reduced risk of CHD against the risk of reduced glycemic control among diabetics when deciding whether or not to authorize a health claim. One comment stated that physicians could adjust the dose of insulin if omega-3 fatty acids reduced their glycemic control, but another comment stated that glycemic control must be considered a real adverse effect.

FDA agrees that limitations on the use of a substance by a subpopulation (e.g., diabetics) do not necessarily exclude a substance from bearing a health claim for the general population, because the claim may be appropriately restricted. However, FDA agrees that the loss of glycemic control is a potentially serious adverse effect that must be fully addressed before a health claim could be authorized.

54. Another comment stated that a major concern about omega-3 fatty acids not mentioned in the proposed rule is that they may be oxidized and, as oxidized products, may have adverse effects.

FDA agrees that oxidation of omega-3 fatty acids is a concern. In fact, there are many studies that have been reported since the publication of the proposed rule, or that were not included in FDA's literature review, that indicate such a concern (Refs. 184, 210, 217, 229, 240, 248, 263, 283, and 290).

Antioxidants have been successfully added to supplements and may be adequate to protect the omega-3 fatty acids in foods. It may be necessary to establish conditions that protect against oxidation of omega-3 fatty acids and incorporate those conditions into any future regulation authorizing health claims for omega-3 fatty acids.

55. A related comment indicated that the majority of the fish oil preparations that have been used are severely oxidized, including National Institutes of Health Fish Oil Test Materials. However, no data regarding the extent of oxidation, the nature of the oxidation products, or the physiologic action of these products was provided.

FDA agrees with this comment. Many of the biologically active products of omega-3 fatty acids are oxidation products. Oxidation of test materials may explain some contradictory findings in the literature.

56. One comment pointed out that increased prothrombin times and possibility of increased stroke were not discussed.

FDA agrees with this comment. FDA did not specifically review data on prothrombin times, although data on bleeding times as a measure of hemostasis were discussed for both normal subjects and for subjects with risk factors for CHD. The importance of the increase in bleeding time brought about by supplemental fish oils or increased fish consumption is not clear. FDA noted in the proposal that most reports suggest that serious bleeding is not an issue in patients supplemented with omega-3 fatty acids, and also that standardized bleeding times do not closely correlate with clinically significant bleeding. However, concerns about untoward bleeding after supplemental fish oils have been raised in the literature (Refs. 106, 120, and 189).

FDA did not discuss the possibility of increased occurrence of stroke as a consequence of increased consumption of omega-3 fatty acids. The papers that reported a correlation between high consumption of omega-3 fatty acids from fish and other marine animals and low rate of CHD mortality also noted an increase rate of stroke, particularly hemorrhagic stroke (Refs. 8 and 84). Also, the possibility of increased rates of stroke are raised by the data from studies on aspirin (Ref. 66).

Thus, FDA considers these potential adverse reactions to be legitimate concerns, primarily in the context of very high intakes of omega-3 fatty acids.

57. One comment stated that even if adverse effects were only suspected in a medical disorder, pronounced warnings or contraindications would be required.

As noted above, the agency must be satisfied that the use of a substance is safe before it will authorize a health claim about the substance. Thus, suspicions about potential adverse effects would need to be resolved prior to the authorization of a claim. Certain health claims may require appropriate qualification as a way of minimizing potential safety concerns.

C. New Scientific Data

To determine whether or not new scientific data published since the proposed rule provided a basis for modifying FDA's conclusions regarding the relationship between omega-3 fatty acids and risk of CHD, FDA conducted a search of the scientific literature for relevant studies. Reviews published since the period covered in the literature review in FDA's proposed rule were used to identify recently published studies.

1. Epidemiologic studies

a. Cross-sectional studies and surveys (Table 1)

Bulliyya et al. (Ref. 185) found lower total serum cholesterol and higher HDL cholesterol in a fish-consuming coastal village population than in a nonfish-consuming population from the interior of India. These correlational data are consistent with a beneficial effect of omega-3 fatty acids on blood lipids, but many possible confounding variables prevent strong conclusions regarding a specific role for omega-3 fatty acids.

In a retrospective study, Popeski et al. (Ref. 266) found that women from communities with higher marine oil consumption had significantly lower diastolic pressure in the last 6 hours of pregnancy than women from communities with low fish oil consumption. Pregnancy associated hypertension was 2.6 times more common in communities with low fish consumption. These correlational data are consistent with an effect of omega-3 fatty acids on blood pressure in this particular situation. Again, many possible confounding variables prevent strong conclusions regarding a specific role for omega-3 fatty acids.

b. Prospective studies (other than intervention studies) (Table 1)

Bjerregaard and Dyerberg (Ref. 176) reported age-standardized mortality rates per 10,000 person-years for CHD in men in Greenland settlements (5.3) as half of that reported for men in Denmark (10.0). There was an increasing rate of CHD from settlements to towns in Greenland. The difference in rates of CHD in women were less apparent, with lower rates in Denmark than in towns in Greenland. These studies do not have sufficient specificity to identify omega-3 fatty acids as causal in reducing CHD, but are consistent with the hypothesis that they are.

Van Houwelingen et al. (Ref. 294) found that, while men from a high fish consumption group had higher concentrations of plasma phospholipid EPA and DHA than men from a low fish consumption group, there was no significant difference in collagen-induced platelet aggregation, cutaneous bleeding time, ATP-release in whole blood, or platelet number between the two groups. This study suggests that the outcome measures found commonly to be affected in clinical studies may not be related to consumption of omega-3 fatty acids in the free-living population.

c. Intervention studies

There were no new prospective intervention studies measuring occurrence of heart attacks or CHD mortality.

2. Evidence relating omega-3 fatty acids to intermediate or surrogate markers of CHD (Table 2)

a. Atherosclerosis

i. Blood lipids

Through its own literature review, FDA has found another 34 studies not reviewed in the proposal that report data for serum cholesterol after consumption of fish containing omega-3 fatty acids or fish oil concentrated in omega-3 fatty acids. Among these, 25 found no change in blood cholesterol levels, 3 found an increase, and 6 found a decrease.

Studies among normal healthy subjects generally reported no change in total cholesterol (Refs. 168, 196, 202, 210, 217, 220, 235, 241, 253, 254, and 277), although none of these studies was controlled for nonspecific effects of the omega-3 fatty acids as polyunsaturated fats.

One study among normal subjects found that feeding a high fish diet did not change total cholesterol, unless combined with a low total fat and low saturated fat diet (Ref. 168). Another study (Ref. 301) reported decreased total cholesterol after switching from a meat diet to a fish diet, but the fish diet had significantly less saturated fat than the meat diet. One study (Ref. 283) found a slight increase after 5.4 g EPA plus DHA/day from MaxEPA (with 30 percent saturated fatty acids), and one study (Ref. 224) found a slight reduction in total cholesterol after 2.7 g purified EPA/day, but neither study was placebo controlled for effects of polyunsaturated and saturated fat contained in the supplements.

Similarly, nearly all of the 17 studies on subjects in at-risk subpopulations, including all of the studies that controlled for PUFA's (Refs. 203, 209, 247, and 258), found no effect of supplemental omega-3 fatty acids on total cholesterol (except for a post hoc analysis of a subgroup in one study, (Ref. 209)). One study in diabetics (Ref. 252) found an increase in serum cholesterol, but the statistical significance of the result may have been due in part to a change in the opposite direction in the control group. One study among hyperlipidemics (Ref. 191) found decreased cholesterol after relatively high doses (4.6 to 6 g EPA plus DHA/day) but not after 3.6 g EPA plus DHA/day, and did not control for PUFA effects of the supplements. The other study that reported decreased cholesterol after supplemental omega-3 fatty acids (Ref. 268), similarly, found the effect after a high level (6 percent of calories, 16 to 21 g EPA plus DHA/day) and did not control for the polyunsaturated fat effects of the supplement.

These studies support the conclusion reached in the proposed rule, that among normal, healthy subjects there is no significant effect of omega-3 fatty acids from fish or fish oils on total serum cholesterol.

FDA concluded in the proposed rule that the best studies among normal subjects found no effect of fish oils on LDL cholesterol. All of the additional studies among normal healthy subjects obtained in FDA's updated literature search have reported no change in LDL cholesterol (Refs. 220, 253, 253, and 277).

One study (Ref. 224) reported that purified EPA produced a significant decrease in a subfraction of large, light LDL cholesterol (LDL_1), and a significant increase in small, dense LDL cholesterol (LDL_2), but FDA calculates no change for the sum of these two fractions of LDL cholesterol. Some clinical studies reviewed in the proposed rule (Refs. 1, 43, 53, and 129) described changes in the composition of LDL particle after consumption of fish oil.

The relative importance of various subfractions of LDL particles (and the associated composition of the particles), however, is still controversial. While Homma et al. (Ref. 224) suggest that large, light LDL are the fraction associated most closely with atherosclerosis, Austin et al. (Ref. 171) report that the phenotype of small, dense LDL is the fraction most closely related to increased CHD risk. The February 1992 NHLBI consensus development conference (Ref. 255) included among its recommendations for further research the identification of the atherogenic and anti-atherogenic subfractions that may be present in VLDL and HDL; the uncertainty about the relevance of changes in the amounts of subfractions of these two lipoproteins similarly applies to LDL.

In at-risk populations, there have been some additional reports of increased LDL cholesterol after fish oil supplementation (Refs. 170, 191, and 251), a concern raised in the proposal. However, most studies have found LDL cholesterol not changed by fish oils (Refs. 174, 189, 205, 209, 219, 258, and 278). Moreover, each of the studies that used a polyunsaturated fat placebo control group found no change in LDL cholesterol (Refs. 203, 209, and 258).

Therefore, FDA concludes that these most recently reviewed studies support the conclusion reached in the proposed rule, that for the general population, there is no significant effect of omega-3 fatty acids on LDL cholesterol. The results of recent studies among at-risk subjects, however, are not in complete agreement with the conclusions in the proposed rule, and suggest that omega-3 fatty acids may not uniformly increase LDL cholesterol. Additional study is needed to determine the conditions under which LDL cholesterol is increased by omega-3 fatty acids.

Among more recent studies in normal healthy subjects found in FDA's updated literature review, about half have found no effect of fish oils or fish on HDL cholesterol (Refs. 202, 206, 217, 219 (after 1.25 and 2.5 g/day EPA plus DHA), 226 (after 1 and 3 g/day EPA plus DHA), 241, and 244), but about half have found increased HDL (Refs. 210, 219 (after 3.75 and 5 g/day EPA plus DHA), 220, 226 (after 6 g/day EPA plus DHA), 235, 253 (compared to baseline, significant compared to olive oil control), 278, 283, and 301), including a metabolic ward study that very carefully controlled for total fat and saturated fat intake (Ref. 253). Weintraub et al. (Ref. 298) found decreased HDL after fish oil compared to a saturated fat diet.

FDA attempted to ascertain how those studies that reported an increase in HDL cholesterol after increased intake of omega-3 fatty acids differed from those studies in which no effect was found. However, there was no apparent difference between the studies that reported that omega-3 fatty acids reduced HDL cholesterol and those that reported no change. Most of the studies that found a change used supplements containing substantial amounts (e.g., 30 percent) of saturated fatty acids, raising the possibility that the saturated fatty acids in the supplements were responsible for the increase in HDL (Ref. 17). However, some supplements had low amounts of saturated fatty acids (Ref. 278) or saturated fat in the diet was specifically controlled (Ref. 235), and in one study the control diet was reported to have significantly more saturated fat than the fish diet (Ref. 301), so the saturated fat intake during omega-3 fatty acid supplementation cannot be the factor responsible for increased HDL.

The amounts of omega-3 fatty acids used in those studies that reported increased HDL tended to be high (e.g., more than 5 g EPA plus DHA/day), but some studies that found a change used lower amounts (Ref. 278) and some studies that used high amounts found no change (e.g., Ref. 241 (used 6.7 g EPA plus DHA/day) and 253 (used 8 g/day)). Some studies in which fish was fed, rather than fish oil, found an effect (Refs. 235 and 301), but others did not (Refs. 206 and 244). There was no systematic difference in sample sizes of the studies that found an effect and those that did not; seven of the negative studies reviewed in the proposed rule or in the present document had 30 or more subjects, compared to only one of the positive studies. Small studies (n = 10 or fewer) may not have observed a significant difference because of small sample size, but larger studies did not find a significant difference, even though some found a trend toward increased HDL after fish oil supplementation (Ref. 217).

Finally, the enrichment of plasma phospholipids with EPA and DHA tended to be higher for subjects in studies where increased HDL was found than that for subjects in the studies where no change in HDL was found, reflecting the tendency of higher doses to produce increased HDL. In particular, all studies in which the plasma phospholipid EPA value was 3.9 percent or more found increased HDL. However, the studies that fed the highest amounts of EPA but that did not find an effect on HDL did not report data for phospholipid EPA, so it is not clear whether high phospholipid EPA is uniformly associated with increased HDL. Comparable results were found after inspection of data on phospholipid DHA after supplementation, however, because not all studies reported phospholipid fatty acid values, no conclusion can be drawn about the relationship between phospholipid DHA and HDL concentration. Notably, recent data suggest a direct correlation between plasma EPA and HDL, but an inverse relationship between plasma DHA and HDL (Refs. 177 and 178), underscoring the importance of reporting these data in future studies.

Among subjects with risk factors for CHD fewer reports found increased HDL (Refs. 191 (for type IV on SuperEPA only), 195, 203, 209 (for type IIb), and 219) than found no change (Refs. 170, 174, 189, 191 (for type IIb and type IV on MaxEPA), 209 (type IV), 224, 258, 263, 277, and 299).

Few studies have controlled for effects of PUFA's by giving a PUFA supplement. Two papers found no change in HDL in normal subjects fed fish oil as Promega (Ref. 73) or MaxEPA (Ref. 166) compared to wheat-germ oil or safflower oil (Refs. 73 and 166, respectively). Cobiac et al. (Ref. 20) reported increased HDL for mildly hypertensive subjects fed salmon and sardines in sild oil compared to those given a safflower-olive oil mix, but in comparable subjects, Meland et al. (Ref. 247) found no change in HDL cholesterol after MaxEPA fish oil compared to when the subjects were given a corn-olive oil mix. Very recent results, also for a mildly hypertensive population, found increased HDL after either, ethyl esters of EPA and DHA, or after corn oil (Ref. 177). Thus, for normal and hypertensive subjects, the change in HDL appears to not be a specific effect of omega-3 fatty acids, but may be related nonspecifically to increased PUFA's, either omega-3 fatty acids or omega-6 fatty acids.

In contrast, there are two reports of increased HDL cholesterol in subjects with type IIb hyperlipidemia fed fish oil compared to safflower oil (Ref. 166) or a corn-olive oil mix (Ref. 209), and one report of increased HDL in type IIa hyperlipidemics after fish oil or olive oil compared to corn oil (Ref. 286). Others found fish oil did not change HDL in type IV hyperlipidemics (Refs. 166 and 209) or patients with CHD (Ref. 258) compared to PUFA controls.

Therefore, at this time, FDA concludes that there is some evidence that omega-3 fatty acids, in some form and amount and in some selected populations, may increase HDL cholesterol, but that current data are ambiguous because the conditions under which fish oils reliably increase (total) HDL cholesterol have not been established, either in a specific subpopulation, or in the general population.

When fractions of HDL cholesterol have been reported, an increase has generally been found in the HDL_2 fraction (Refs. 1, 9, 54, 148, 191, 202, 203, 220, 235, 251, and 286), with a comparable decrease in the HDL_3 fraction (Refs. 202, 235, 251, and 286). Interestingly, the two recent reports that failed to find increased HDL_2 both used esterified omega-3 fatty acids rather than the fish oil triglyceride (Refs. 191 and 224), although others using ethyl esters have found increased HDL_2 (Refs. 9 and 286).

These studies suggest that fish oils produce a shift within the HDL fractions toward a lipid-rich, and away from a protein-rich lipoprotein, as well as within the LDL fractions. This shift may occur whether or not there is any change in total HDL cholesterol. FDA noted (56 FR 60663 at 60669) that some studies among normal subjects found increases in the HDL_2 fraction of HDL cholesterol, and that these reports were the most promising changes in blood lipids. New studies published after the period covered in FDA's review of the literature, however, found that both HDL_2, and HDL_3 were correlated with reduced risk of MI (Refs. 185a and 287a), and the NHLBI consensus conference (Ref. 255) concluded that, "The current studies of HDL_2 and HDL_3 levels have not shown consistent associations with CHD." Therefore, data on changes in HDL subfractions after increased consumption of omega-3 fatty acids do not provide a sufficient basis for a health claim, because there is not significant scientific agreement that the endpoints are directly related to risk of CHD. If the risk of CHD becomes linked with particular subfractions of these lipoproteins, these findings in normal subjects may be of great importance.

However, FDA also notes that recently published data from a prospective study demonstrate an effect of aspirin consumption in reducing the incidence of first heart attacks among women (Ref. 243). Another study shows a relationship between spontaneous platelet aggregation in vitro and incidence of CHD (Ref. 288). Both studies were conducted in the general population and their results support the hypothesis that platelet aggregation is a useful marker for CHD risk in the general population. Additionally, preliminary data from the Caerphilly Collaborative Heart Disease Study (Ref. 302) supports a relationship between platelet aggregation and the incidence of

ischemic heart disease; final data from this study will be available in the near future. These recently published and forthcoming studies may provide the basis for significant scientific agreement regarding the use of platelet function as a surrogate marker for CHD risk among the general population.

ii. Vessel wall effects.

New human studies on the effects of omega-3 fatty acids on vessel wall effects were discussed in response to comments 35 through 37 of this document. A recent meta-analysis of studies on use of fish oils in the prevention of restenosis concluded that the most plausible interpretation of the results was that there was a small to moderate beneficial effect of fish oils, but that chance could not be ruled out as a cause of the results (Ref. 260). The authors noted a significant heterogeneity in the findings and concluded that data from a large clinical study are necessary to confirm their interpretation. No study of restenosis to date has compared fish oil to an alternate polyunsaturated oil to control for nonspecific effects of PUFA's.

b. Thrombosis and hemostasis

i. Bleeding times

A number of studies have reported data that show no significant effect of fish oils on standardized bleeding time tests (Refs. 179, 218, 253, 268, and 277). However, others have found a significant increase in bleeding time due to fish oil (Refs. 195, 219, 220, and 278) or salmon (Ref. 297) or have reported increased bleeding as a side effect of treatment (Refs. 189 and 295).

ii. Platelet aggregation.

Consistent with the literature previously reviewed, recent studies show that fish oil tends to decrease platelet aggregation to numerous stimuli including AA (Refs. 179 and 256), adenosine diphosphate (ADP) (Refs. 204, 256, and 297), collagen (Refs. 218, 241, 251, and 297), thrombin (Ref. 241), and PAF (Ref. 251). Only one of these studies controlled for effects due to PUFA's (Ref. 204). The importance of the polyunsaturated fat control is less critical for studies on platelet function than for studies on blood lipids, because nonomega-3 PUFA's (i.e., omega-6 fatty acids derived from plant oils) produce effects in the opposite direction in platelets as omega-3 fatty acids (whereas many of the blood lipid effects of these two classes of fatty acids are in the same direction). Thus, the effects of omega-3 fatty acids on platelet responsiveness are not likely to be produced by PUFA's in general.

The only new study among healthy subjects that reported no difference in responsiveness to ADP used EPA ethyl esters as the source of omega-3 fatty acids (Ref. 179). Furthermore, the data were not shown in this brief report, so it is not clear if there was a trend toward an effect that might not have been statistically significant due to small number of subjects (eight per group). Those studies in healthy subjects reviewed in the proposed rule that did not find statistically significant differences in platelet responsiveness to ADP did have trends in the direction of reduced responsiveness (Refs. 24 and 54).

Other studies found no effect of fish oils on platelet aggregation in response to collagen (Refs. 179, 256 and 277). Each of these studies had a relatively small number of subjects, and there was a trend toward decreased sensitivity toward collagen at a high dose of omega-3 fatty acids in one study (Ref. 277). However, in the recent metabolic ward study (Ref. 256) there was no trend toward decreased sensitivity toward collagen or thrombin. These findings contrast with the results described above (Refs. 218, 241, 251, and 297) and with studies in healthy subjects described in the proposed rule (Refs. 2, 24, 54, 96, 143, and 166).

Studies reporting no effect of fish oils on PAF or AA-induced platelet aggregation (Refs. 179 and 218) may not have had sufficient power to find a statistically significant difference; where the data were reported there was a trend toward decreased sensitivity for both agents (Ref. 218).

iii. Platelet adhesion

A provocative study by Li and Steiner (Ref. 234) showed a 60-percent decrease in the extent to which platelets prepared from subjects fed fish oils adhered to substrates in a laminar flow chamber. The high flow rates used in this experiment showed that the change in adhesiveness of the platelets was due to changes on the platelet surface, and not due to a difference in the amount of material released from platelets that subsequently caused adhesion (i.e., AA). Also, a dose-response relationship was observed, and the time to return to pre-fish oil adhesion values was related to the amount consumed.

However, another study found no effect on fish oils on in vitro platelet adhesion to everted rabbit aorta, although there was a trend toward increased adhesion after 2 and 4 weeks of supplementation (Ref. 264). The reperfusion assay used in this study does not distinguish platelet membrane effects from effects mediated by substances released from platelets. Neither of these studies used a nonomega-3 PUFA control.

iv. Regulators of bleeding

Two recent studies in normal subjects have reported that omega-3 fatty acids have no effect on the clotting protein fibrinogen (Refs. 183 and 210), although in one of these studies a large supplement of vitamin E was associated with a decrease (Ref. 210). An uncontrolled study in normal subjects found a decrease in fibrinogen after fish oil supplementation (Ref. 278).

Studies on subjects at risk for CHD have reported no change (Ref. 203), a decrease (Refs. 276 and 277), and an increase in fibrinogen (Ref. 287). In agreement with its tentative conclusion in the proposed rule, FDA finds that the data on the effects of omega-3 fatty acids on fibrinogen level are ambiguous, because they do not distinguish effects due to PUFA's from effects specific to omega-3 fatty acids.

Plasminogen is an enzyme that dissolves clots. Plasminogen activator is a substance that increases clot dissolving; plasminogen activator is specifically inhibited by another substance, the PAI–1. Thus, a high level of PAI–1 decreases the capability to dissolve clots.

Three recent studies reported increased concentrations of PAI–1 after fish oil supplementation (Refs. 254, 278, and 287), which would appear inconsistent with a clot-dissolving effect of fish oil. Two of these investigators also found no change in the amount of plasminogen activator (t-PA) after supplemental fish oil (Refs. 254 and 287) including one who used a very specific immunologic assay (Ref. 254), suggesting that fish oils do not increase clot dissolution by increasing the amount of this protein. The third group, however, found an increase in the activity of tissue plasminogen activator (Ref. 277), which suggests that fish oils might increase clot dissolution by a different mechanism than affecting the amount of activator. Another group found no effect of cod liver oil on t-PA activity or fibrinolysis measured directly (Ref. 216). These reports are in contradiction to a report of increased fibrinolytic activity after a fish or fish plus fish oil diet (Ref. 183). FDA has not been able to find a reason for this rather marked contradiction. Therefore, in agreement with the conclusion in its proposed rule, FDA finds there is no clear relationship between omega-3 fatty acids and factors involved in dissolving blood clots, or clot dissolution activity.

Numerous investigators (Refs. 174, 191, 210, 220, 235, 241, and 279) have

recently reported that fish oils do not affect the concentration of Lp(a), a lipoprotein correlated with the risk of CHD. One investigator reported that very high levels of fish oils (9 g EPA plus DHA/day) gave a trend toward lower values, but the response may have been due to the PUFA's (Ref. 279). One study reported no effect overall of fish oils on Lp(a) among hypertriglyceridemics, but Lp(a) was reduced in those whose initial values were high (Ref. 174). On the basis of these reports and those reviewed in the proposed rule, FDA concludes that omega-3 fatty acids do not affect the risk of CHD by lowering Lp(a).

v. Blood pressure

Most of the studies not reviewed in the proposed rule that report data on blood pressure after consumption of fish oils have not found a significant change. One study of 50 elderly, healthy subjects reported that fish oils in combination with a salt-restricted diet decreased both systolic and diastolic blood pressure, but that fish oil alone had no effect (Ref. 190). There was a reduction in blood pressure during the run-in period, when the polyunsaturated fat placebo, sunflower oil, was fed.

Most studies on subjects with mild hypertension also have reported no change (Refs. 247, 277, and 289), including one large, randomized, placebo-controlled, multicenter trial of various behavioral changes and dietary supplements (Ref. 289). One study in hypertensives found reduced systolic and diastolic blood pressure comparable to reductions after the hypertension medication propranolol (Ref. 285), and in some cases the combined treatment of fish oil plus propranolol gave a greater decrease than either treatment alone. This study was controlled by olive oil (which is predominantly monounsaturated fatty acids), and therefore does not distinguish effects of omega-3 fatty acids from other PUFA's. Another double-blind randomized, placebo-controlled study in hypertensives whose blood pressures were maintained by medications found comparable blood pressure lowering compared to pretreatment values by fish oil or olive oil placebo (Ref. 299).

One uncontrolled study among hyperlipidemics also found reduced systolic and diastolic blood pressure (Ref. 263), but no effect was found in uncontrolled trials in subjects with end-stage renal disease (Ref. 207) or diabetics (Ref. 215). In a polyunsaturated fat (corn oil) controlled study on subjects with stable claudication (Ref. 203) fish oil and corn oil both reduced diastolic blood pressure comparably, but systolic blood pressure was only reduced by the corn oil treatment.

The results of these studies support the tentative conclusions reached in the proposed rule, that omega-3 fatty acids reduce blood pressure to a small degree in hypertensive people, but that it is not clear if there is any specific effect among normal subjects.

3. Other relevant information

a. Animal studies

Animal studies are especially important for studying effects of long-term consumption of omega-3 fatty acids, where there are few data from human intervention studies. The animal studies cited in the proposed rule related to the ability of omega-3 fatty acids to inhibit the development of atherosclerosis, an area not readily available for study in humans. A more complete discussion of the previously cited studies, with emphasis on those studies in nonhuman primates, is given in response to comment 47 of this document. Other recent animal studies cited in the comments or found during FDA's updated literature search that provide data on the development of atherosclerosis (where atherosclerosis is measured directly) are reviewed here. Also reviewed are studies on effects of omega-3 fatty acids during experimental ischemia, obviously not available for human study.

i. Atherosclerosis

One recent study in rabbits found less atherosclerosis in fish oil-supplemented animals, but there was no control for PUFA's, and the fish oil-treated animals also had reduced serum cholesterol (Ref. 192). Because humans do not have reduced serum cholesterol after fish oil consumption, these results are of questionable relevance to humans. Furthermore, the effect cannot be attributed specifically to omega-3 fatty acids rather than to polyunsaturated fats in general.

Fish oil feeding has also been associated with reduced binding of LDL to the blood vessel endothelium in monkeys (Ref. 193), and purified EPA ethyl ester was reported to reduce susceptibility of LDL to oxidation (Ref. 273), but these studies did not control for PUFA's. The antioxidant levels in the diets with respect to the amount of omega-3 fatty acids may be as important in determining whether or not there is any effect of omega-3 fatty acids on the oxidation of LDL.

Three recent papers describe effects of fish oils fed before surgical grafting of a vein into an artery, a procedure associated with an accelerated development of atherosclerosis. Two papers (Refs. 275 and 303) each used a polyunsaturated fat control and studied fish oil effects after vein allografts in animals treated with the immunosuppressant cyclosporin. In one study (Ref. 303), six groups of rabbits received one of three amounts of fish oil (giving 29, 87 and 174 mg EPA plus DHA/kg, respectively, similar amounts to those used in most human studies) or comparable amounts of safflower oil. In this study, safflower oil was more effective at reducing cholesterol than fish oil, and there was a trend toward more protection from atherosclerosis in the safflower oil-fed group. In the other study (Ref. 275), rats received, in addition to cyclosporin, either fish oil (containing 210 mg EPA plus DHA/kg), or safflower oil with aspirin, or safflower oil only. The fish oil group had remarkably less atherosclerosis than the other two groups. The contradictory results in these two studies, both of which used the same model of vein allografts with cyclosporin immunosuppression and the same polyunsaturated fat control, may be related to dose and species differences.

A third study of vein allografts in dogs (Ref. 274) found significantly less atherosclerosis in fish oil-fed animals either fed the fish oil alone or in combination with aspirin or a thromboxane synthetase inhibitor. Other animals were treated with aspirin only or a thromboxane synthetase inhibitor only. There was no difference among groups for blood lipids, platelet function or eicosanoid metabolism. This study suggests that mechanisms of atherosclerosis other than those involving blood lipids and platelet function may be affected by omega-3 fatty acids.

These animal models are most relevant to comparable surgical procedures or other invasive procedures (e.g., angioplasty) that would be expected to activate platelets in humans. Use of omega-3 fatty acids in these settings is a drug usage, but provides information on the extent to which omega-3 fatty acids may modify platelet response in vivo. The very different results of omega-3 fatty acids in modifying the response to vein allografts in immune-suppressed animals indicates that the actions of omega-3 fatty acids in these settings are not yet well established.

ii. Response to ischemia

One major line of research on omega-3 fatty acids in animals is experimental ischemia (deficiency of blood flow to

the heart). Force et al. (Ref. 199) found that rats fed a diet containing a high amount of fish oil (20 percent of the diet) for 6 to 12 weeks had much greater blood flow once the occlusion was removed than rats fed diets enriched in corn oil or lard. There were no differences among diet groups in the amount of tissue damaged by ischemia. Increased blood flow after ischemia has also been reported in a pig model (Ref. 221). This study did not control for polyunsaturated fat and used a lower amount of omega-3 fatty acids, and the differences in blood flow were not as pronounced as in the Force study. Another study found evidence of less tissue damage during reperfusion when rats had been fed a diet with 12 percent fish oil compared to other rats fed the same level of corn oil (Ref. 223). Another study in yet a third animal species (Ref. 230) showed that the functional capillary density was preserved during reperfusion in hamsters fed 5 percent fish oil for 4 weeks prior to experimental ischemia.

A reperfusion study in dogs determined the effects of fish oil on the duration of time needed for drug-induced reperfusion following an electrically induced blockage, and on the occurrence of spontaneous reocclusion in the reopened vessel (Ref. 182). High amounts of fish oil (one-third of total calories) for 3 weeks before the surgery resulted in a shorter time needed for the drug-induced reperfusion, but did not affect the time necessary for the electrically mediated occlusion to occur, the occurrence of second occlusion, or the time it took for the second occlusions to appear. This study did not have a polyunsaturated fat control, and even at the high intake only a modest effect of omega-3 fatty acids on platelet function was seen, that being primarily an enhancement of the effects of the fibrinolytic drug.

Another possible consequence of ischemia is arrhythmia, when the heart fails to maintain its normal rhythmic beating. The effects of fish oils on arrhythmia in monkeys are discussed in response to comment 39 of this document. Similarly, data have been reported for experimental ischemia in rats that show that both fish oil and sunflower oil reduced the occurrence of arrhythmia during occlusion and reperfusion compared to a saturated fat diet (Ref. 246). Another study, done on isolated, cultured rat heart cells (myocytes) showed that EPA, but not AA, prevented a known toxin (ouabain) from disturbing the rhythmic contractions and killing the cells (Ref. 212). The effective amount of EPA was so low that the mode of action was proposed to be due to production of an active metabolite, rather than due to direct effects of EPA on the cell membranes. This study suggests a specific effect of EPA in stabilizing the heart myocytes during stress. Prevention of arrhythmia by stabilization of these heart cells has been proposed as a mechanism by which omega-3 fatty acids may increase the chances of survival following a heart attack as reported in the Dart study (Ref. 16).

These studies indicate that, in various animal models, dietary fish oils promote greater reestablishment of blood flow in heart tissues following a transient block, as occurs in an acute heart attack. Importantly, the results are consistent across many animal species, and in some cases have been shown to be specific for omega-3 fatty acids rather than simply due to any PUFA. Finally, the experimental designs included coronary occlusions in otherwise healthy animals who were not suffering from heart disease, a model relevant for use of omega-3 fatty acids in reducing the risk of CHD rather than in therapy for persons with preexisting heart disease. The studies remain limited in that ischemia was produced by an acute blockage produced by mechanical or electrical means rather than by chronic dietary means, and the response to these different types of block may not be the same.

Other studies have attempted to learn the mechanism by which the platelet-vessel wall interactions are modified by omega-3 fatty acids. One study (Ref. 240) found that aortas from rats fed fish oil or corn oil did not contract as much in response to agents that cause contraction as aortas from rats fed beef tallow (saturated fat). This was true both before and after oxygen deprivation. The aortas from fish oil-fed rats were more responsive to one of three tested chemical relaxers than aortas from corn oil-fed or beef tallow-fed rats. Another study found that EPA potentiated the release of an EDRF (Ref. 181), but the effect was thought to be related to the unsaturation of the EPA, because the experiments were carried out in the presence of inhibitors of EPA metabolism.

One research group has recently shown that leukotrienes, chemicals produced from AA, are important in the tissue injury that accompanies reperfusion (Refs. 230 and 232). Since EPA competes with AA for the enzyme that makes leukotrienes from AA, EPA could potentially reduce the amount of leukotriene formed from AA. This same group has shown that leukotrienes promote the adhesion of leukocytes to the vessel wall (Ref. 231), and that feeding hamsters fish oil at 5 percent of the diet for 4 weeks greatly reduced (over 60 percent) the adhesion of leukocytes to the vessel wall (Ref. 233). The reduced adhesion could be relevant for both the conditions during which atherosclerosis develops (indeed, the stimulus used to elicit leukocyte adhesion was oxidized LDL, a candidate for promoting atherosclerosis in humans), and the acute response to coronary ischemia.

These animal data suggest mechanisms by which omega-3 fatty acids could affect the development of atherosclerosis or the response of heart tissue after a transient occlusion of its blood flow. Both modes of action could make important contributions to the risk of CHD and, therefore, merit additional study. The reperfusion studies and the myocyte toxicity study have demonstrated specificity of the effect as to omega-3 fatty acids. However, the increase in reperfusion volume is not sufficient to ensure a reduced risk of CHD death. Omega-3 fatty acids may not affect the extent of tissue damaged during an occlusion, or the tendency for a second, spontaneous occlusion. Additionally, omega-3 fatty acids may not affect tissue vulnerability during reperfusion. Those studies where CHD deaths or second occlusions have been recorded used large amounts of fish oils, and do not indicate whether amounts of omega-3 fatty acids found in the diet would have the same effects. Thus, there are many possible avenues suggested by these animal studies for beneficial effects of omega-3 fatty acids on the development of CHD, but there are also important limitations in the study designs and models used that prevent drawing conclusions from these data about the importance of omega-3 fatty acids in reducing the risk of human CHD.

b. Safety concerns

i. Diabetes

Three additional papers (Refs. 170, 222, and 304) and one major review (Ref. 238) on the effects of fish oils in diabetics were published after the time period reviewed in the proposal. All three new studies found increased LDL cholesterol after fish oil consumption in type II diabetics. However, effects on fasting glucose varied, with no change (Ref. 170), a transient increase (Ref. 222) or an increase (Ref. 304) reported. Although fasting insulin concentration was unchanged after fish oil (Refs. 170 and 304), postprandial insulin response usually, but not always (Ref. 170), has been reported as reduced (Refs. 238 and 304).

These effects of fish oils on blood glucose appear to depend on the amount of fish oils fed. One study found no change in fasting blood glucose levels among type II diabetics treated with 3.0 g/day EPA plus DHA for 2 weeks (Ref. 170). Two other studies that used 3 or 2.7 g/day EPA plus DHA for 6 and 8 weeks (Refs. 222 and 79) only found transient increases in blood glucose halfway through their respective supplementation periods. A fifth study (Ref. 12) that used 3.0 g/day EPA plus DHA for 3 weeks found comparable increases in fasting blood glucose when either fish oil or safflower oil was fed, so the increase cannot be attributed specifically to the omega-3 fatty acids. Similarly, Vessby and Boberg (Ref. 157) fed 3 g/day EPA plus DHA and did not find a difference in fasting glucose or glycosylated hemoglobin after fish oil supplementation compared to baseline; they did find a significant difference compared to the olive oil treatment that produced changes in the opposite direction from fish oil. Studies on type II diabetics that reported increased glucose used higher amounts (4.5 to 8 g/day) of omega-3 fatty acids (Refs. 52, 55, 128, and 304). Thus, FDA concludes that glycemic control among diabetics remains a valid safety concern, but notes that restriction of the amount of supplemental omega-3 fatty acids may suitably address this concern.

ii. Increase in LDL cholesterol

Many studies published after 1987 with data for LDL or apoB report increased LDL cholesterol or apoB after fish oils, in hypercholesterolemic or hypertriglyceridemic subjects (Refs. 1, 26, 32, 55, 60, 61, 63, 73, 75, 94, 114, 119, 120, 129, 146, and 166). Virtually all the studies with 10 or more subjects supplemented with 5 g/day EPA plus DHA or more found increased LDL. Some studies on normal subjects (all of which were reviewed in the proposed rule) also report increased LDL or apoB after fish oil consumption (Refs. 54, 127, and 156). Many studies that found no effect may not have had sufficient sample size to detect a difference due to treatment. FDA concludes that increased LDL cholesterol among some populations already at increased risk of CHD remains a valid safety concern, but because most reports of increased LDL are in studies where large amounts of fish oils are given, it is possible that restriction of the amount of supplemental omega-3 fatty acids and/or changes in the fatty acid composition of omega-3 fatty acid supplements may suitably address this concern.

III. Overall Summary and Conclusions

FDA concludes that there is some evidence that supports a relationship between omega-3 fatty acids and CHD, but that the totality of scientific evidence available at this time does not provide an adequate basis for a health claim. In some cases, there is not significant scientific agreement that the changes that are specific to omega-3 fatty acids will reduce the risk of CHD. In other cases, the data do not demonstrate that the effect is specifically due to the omega-3 fatty acids and not due to other dietary variables. For yet other cases, the data are ambiguous because effects of omega-3 fatty acids are not consistently observed, which suggests that other variables are important in determining whether or not an effect is seen. Therefore, the agency does not consider the evidence sufficiently strong to draw a firm conclusion about the relationship between omega-3 fatty acids and risk of CHD, and therefore is not authorizing the claim at this time.

In the course of developing this regulation, FDA has identified some areas where greater agreement is needed that the effects produced by omega-3 fatty acids are directly related to the risk of CHD. Many surrogate markers have been hypothesized, on the basis of limited evidence, to be related to specific diseases, including CHD, but few have withstood the continued scrutiny of scientific investigation. Also, some markers may have scientific validity, but may not be applicable for use in the general population, because of technical limitations. Thus, FDA asserts that only when a surrogate marker for a disease has been accepted as a risk factor for the general population, as indicated by a statement by an unbiased, nationally representative authoritative scientific or medical body, can the agency authorize a health claim based on the relationship of a nutrient to the surrogate marker of the disease. Examples of potential surrogate measures for which validation is needed are in vitro platelet aggregation, in vitro platelet adhesion, elevated fasting triglycerides postprandial triglycerides (recently considered at the NHLBI consensus development conference, Ref. 255), and subfractions of LDL and/or HDL.

In some cases additional research is needed to determine whether hypothesized subpopulations, e.g., those with high LDL:HDL ratio and high triglycerides, are at increased risk of disease. The pronounced triglyceride lowering effects of omega-3 fatty acids might well have a protective effect against CHD in such a subpopulation.

There are other areas where additional research is needed to show, for agreed endpoints, that the effects are consistently produced, or are specifically due to omega-3 fatty acids. These areas require additional data to establish that the effect of omega-3 fatty acids is specific, or to further define the conditions under which omega-3 fatty acids have their effects. For example, data are needed to show a reduction in MI or CHD mortality among individuals fed supplemental omega-3 fatty acids (specifically) compared to a group fed omega-6 PUFA's. The critical failing of some recent studies associating omega-3 fatty acids and CHD is that specificity was not obtained. Future studies should carefully control for known confounders, particularly dietary variables.

Finally, the available data suggest that some set of conditions or population may exist for which omega-3 fatty acids will increase HDL. Additional research should be able to define the conditions under which omega-3 fatty acids have this effect.

Interested parties may choose to petition the agency for approval of other health claims about omega-3 fatty acids. For example, additional data may be developed to support an omega-3 fatty acids/hypertension health claim petition. Because the blood pressure-lowering effect of omega-3 fatty acids appears most marked against a background of very low dietary intakes of omega-3 fatty acids, the role of omega-3 fatty acids in the total diet would need clarification before such a petition could be adequately supported. Similarly, limitations of the effects of omega-3 fatty acids on the magnitude and duration of change in blood pressure, the quantitative amounts of omega-3 fatty acids required for the effects, and characterization of the sensitive subpopulation would require discussion in a petition. A petition should also address apparent conflicting pieces of information, e.g., high blood pressure among populations that have high intakes of omega-3 fatty acids. Safety concerns raised in this final rule will, of course, require resolution prior to the authorization of any petitioned claim.

IV. Decision Not to Authorize a Health Claim Relating Ingestion of Omega-3 Fatty Acids to Reduced Risk of CHD

In evaluating the scientific evidence, FDA considered: (1) The strength of the association of omega-3 fatty acids with CHD or surrogate markers for CHD, (2) the consistency of findings among the

many studies, (3) the specificity of the outcome to omega-3 fatty acids, (4) the presence or absence of a dose-response relationship, and (5) the biologic plausibility of an association. FDA has determined that there is inadequate evidence to show that increased consumption of omega-3 fatty acids will reduce the risk of CHD.

FDA sought to determine whether there was significant scientific agreement among qualified experts that the totality of publicly available scientific evidence supported the claim that omega-3 fatty acids reduce the risk of heart disease. FDA reviewed the position taken in numerous Federal Government reports and other authoritative scientific reports and evaluated the publicly available scientific evidence that has become available since those reports were written. The decision to deny a health claim is based on the conclusions reached following review of the following sources of information: (1) "The Surgeon General's Report on Nutrition and Health;" (2) the National Research Council's "Diet and Health: Implications for Reducing Chronic Disease Risk," and (3) the National Cholesterol Education Program's Report of the Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults. Each of these reports concluded that there was inadequate evidence of a relationship between consumption of omega-3 fatty acids and CHD. FDA has reviewed again all of the relevant cross-sectional data from which the hypothesized relationship between omega-3 fatty acids and CHD originated, and all clinical intervention data published since these Federal Government and other authoritative reports were issued to determine whether the additional evidence is adequate to support a health claim for omega-3 fatty acids.

The LSRO report reached a different conclusion from the other authoritative reports by finding a relationship between omega-3 fatty acids and CHD. The report used only selected evidence, and often did not distinguish effects specifically due to omega-3 fatty acids from effects due to PUFA's in general. The description of international epidemiologic findings of a relationship between fish consumption and CHD, similarly, was not shown to be specific to omega-3 fatty acids. In some instances, FDA disagreed with the interpretation of the studies reviewed by LSRO, or with LSRO's conclusions. Finally, the LSRO report also based its conclusions about the usefulness of omega-3 fatty acids, in part, on changes in blood lipid parameters that are not generally agreed to be risk factors for CHD. Therefore, FDA finds numerous reasons for not accepting all of the findings of the LSRO report. FDA's conclusions regarding the relationship between omega-3 fatty acids and CHD rely instead on FDA's independent review of the publicly available scientific information, and are consistent with the Federal Government and other comprehensive and authoritative reports except for the LSRO report.

The surveys, cross-sectional studies, and nonintervention prospective studies do not provide adequate support for a relationship between consumption of omega-3 fatty acids and CHD. Only a few studies found an association between fish intake and CHD, while others have found no association; thus, there was no consistency of findings. None of the studies that reported a relationship distinguished fish consumption from other factors associated with fish consumption, and therefore none demonstrates specificity. Even in those studies that reported a relationship between fish consumption and CHD, it is not clear that the observed effects were due to the omega-3 fatty acids in fish. Also, the omega-3 fatty acid content of the fish diet associated with reduced CHD in these studies was so low that the importance of omega-3 fatty acids is questionable, thus weakening the biologic plausibility of the relationship.

The data from intervention studies also do not establish a relationship between omega-3 fatty acids and risk of CHD. The most compelling type of evidence to support a diet-disease relationship is a prospective, double-blind, placebo-controlled intervention study, with CHD morbidity and mortality as endpoints. To date, there is only one such trial (Ref. 16). The results of that study showed that increased consumption of fish does not reduce the risk of a second heart attack but may reduce the risk that the attack will be fatal. This study provides evidence for a protective effect of fish consumption against second heart attacks. However, as with the nonintervention study data, this study did not provide evidence to attribute the benefit to omega-3 fatty acid intake rather than some other factor associated with fish consumption (specificity).

Less persuasive than prospective studies in which CHD per se is measured, but still very useful, are prospective clinical trials in which surrogate markers for CHD are measured. Recent studies have not found beneficial effects from omega-3 fatty acids on total cholesterol or LDL cholesterol in normal, healthy persons, or among persons at risk for CHD. Numerous studies, including some large or multicenter studies, have reported these results, demonstrating consistency in the findings and providing the agency confidence that they were not spurious. The data on HDL cholesterol are ambiguous. There appear to be other factors in the dietary interventions besides the omega-3 fatty acids that determine whether or not supplementation with fish or fish oils raises HDL.

An increase in bleeding times and a decrease in platelet aggregation have been observed frequently, but not always, after supplemental omega-3 fatty acids in normal healthy individuals as well as in diseased persons. Additionally, there is evidence that platelet adhesion is reduced by omega-3 fatty acids. The effects of decreased platelet aggregation and platelet adhesion appear to be related to the intake of omega-3 fatty acids in a dose-response relationship. What has not been established, however, is that in vitro platelet aggregation or platelet adhesion are bona fide surrogate risk factors for CHD in the general population.

Omega-3 fatty acids have been shown to reduce blood pressure in hypertensive people to a small degree, which may bear on a relationship between omega-3 fatty acids and CHD. This effect was not of large magnitude, but it is specific to omega-3 fatty acids, it has been reported by a number of investigators, a dose response was found, and the effect is biologically plausible through at least two mechanisms. However, it has not been established that omega-3 fatty acids reduce blood pressure in normal subjects (lack of consistency, weak effect, absence of dose-response relationship). Additionally, it has not been demonstrated that the magnitude and duration of changes in blood pressure observed in short-term studies will persist during long-term consumption of omega-3 fatty acids, or that these changes result in a reduced risk of CHD.

Finally, the potential that omega-3 fatty acids may increase LDL cholesterol and/or apoB among diabetics and hyperlipidemics, and the potential that omega-3 fatty acids may worsen control of blood glucose in diabetics are significant safety concerns that must be addressed before a claim may be made that consumption of omega-3 fatty acids by the general population will reduce the risk of CHD.

In conclusion, there are numerous effects of omega-3 fatty acids that may

be related to the risk of CHD, e.g., reduction in fasting and postprandial triglycerides, reductions in platelet aggregation and adhesion, changes in the composition of lipoproteins. However, at this time these endpoints are not generally agreed to be closely related to the risk of CHD. In other areas, additional data are needed to show that effects related to fish consumption are specifically due to the omega-3 fatty acids in the fish, and to define the conditions under which omega-3 fatty acids consistently increase HDL. These avenues may provide a reasonable basis for a future petition for a health claim relating omega-3 fatty acids to the risk of CHD.

V. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

VII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.71 is amended by adding new paragraph (f) to read as follows:

§ 101.71 Health claims: claims not authorized.

* * * * *

(f) Omega-3 fatty acids and coronary heart disease.

Dated: October 30, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

Note: The following tables will not appear in the annual Code of Federal Regulations.

BILLING CODE 4160-01-F

TABLE 1

Epidemiologic Studies: Omega 3 Fatty Acids and CHD

Study	Study Design	Subjects	Methods	Results	Comments
Beswick et al. (Ref. 167).	Dietary counseling compared with survey data and platelet activity 6 months later. Men from Cardiff, Wales with history of myocardial infarction.	56 men, ages 36 to 71 (mean=58). 13 excluded for medication, 1 for inadequate blood sample. 18 smokers, 34 patients on cardiovascular medication, 19 on B blockers, 8 on antihypertensive drugs, and 24 on angina medication.	Questionnaire to estimate polyunsaturated to saturated fat ratio, percent calories from fat, and EPA intake. Platelet activity based on ADP added for aggregation of platelets in blood and plasma.	Significant inverse correlation between fat ratio and platelet activity. Nonsignificant trend for decreased platelet aggregation with increased EPA intake.	Study inconclusive on role of EPA in platelet activity. Small sample. In vitro assay not repeated for accuracy. Nutrient intake estimated. Health behaviors, medications, and other factors which may have influenced results not presented. Study population ill.
Bulliyya et al. (Ref. 185).	Dietary and serologic survey in Nellore and Chittor districts of India.	100 individuals in fish consuming populations and 109 individuals in nonfish consuming populations.	Dietary survey. Total serum and HDL-cholesterol, TG, and phospholipid measured. Clotting and bleeding times observed. Age, weight, pulse rate, blood pressure tabulated.	Total serum cholesterol was lower in the coastal village (152.7 mg/dL) than in the nonfish consuming village (214.9 mg/dL). HDL-cholesterol was higher in the coastal village.	Dietary survey methods not presented in paper. Dietary intake was presented as correlational data. The potential confounding effect of other components of diet on cholesterol level warrants explanation. Lower total cholesterol level in the fish eating population was observed.
Bjerregaard and Dyerberg, (Ref. 176).	Analysis of CHD mortality rates, Greenland.	All deaths due to CHD in Greenland from 1968 to 1983.	A register of deaths by cause was developed using information from death certificates, parish registers, and civil registration records. The register was computerized and brought under the management of the Danish Board of Health from 1975 to 1983.	Age standardized mortality rates per 10,000 person-years for CHD in men in Greenland settlements (5.3) were half those of men in Denmark (10.0). There was an increasing rate of CHD from settlements to towns in Greenland. The difference in rates of CHD in women were less apparent, with lower rates in Denmark than in towns in Greenland.	Genetic protection, exercise and confounding factors such as tobacco use cannot be eliminated as factors in this observation. These data support earlier observations of lower CHD rates in male Greenlanders versus Danes, but not for females. Note, the 50 percent difference is approximately the same as reported by Kromhout for comparing men eating no fish and those eating approximately 30 g/day.

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Bonaa et al. (Ref. 178).	Dietary and serologic survey of residents of Tromso, Norway.	156 subjects selected subjects from a survey population of 21,826 for an intervention trial.	Food consumption questionnaire, with separate questions for fatty and lean fish, also alcohol. Also, 2 unannounced 24-hour diet recalls. Analysis of covariance and multiple linear regression.	Fish consumption was inversely correlated with TG's, but no significant correlations between fish and cholesterol or apoprotein measures. EPA correlated with HDL until TG's were controlled. EPA correlated with TG even after HDL was controlled. DHA inversely correlated with HDL and $apoA_1$	Divergent relationships between EPA and HDL, and DHA and HDL, may explain discrepancies in the literature regarding the effect of various supplements on HDL.
Gerasimova et al. (Ref. 205).	Dietary and serologic survey of residents of Moscow and the Chukot peninsula.	Randomly selected men; Moscow n= 650 Chukot n= 261.	HDL by ultracentrifugation. A subsample was used for HDL phospholipids and apoproteins. 24-hour recall for dietary data.	Chukot residents had ↓ cholesterol, TG, LDL; ↑ HDL, ↑ consumption of omega-3 fatty acids, plasma lipid EPA.	Correlation between increased consumption of omega-3 fatty acids and serologic measures is consistent with the hypothesis of a relationship between omega-3 fatty acids and CHD, but many other dietary and behavioral factors could also be correlated and were not examined in this survey.
Innis et al. (Ref. 225).	Dietary and serologic survey.	Sample was selected as part of an unrelated dietary survey. 185 Canadian Inuit and 24 Vancouver residents.	Phospholipid fatty acid analyses.	Mean chain length and unsaturation index of the lipids in the two populations was very similar. The Inuit had greater EPA and lower AA than the Vancouver population. NS cholesterol	Observational data. Supports a dietary origin of phospholipids. Not directly relevant to CHD.

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Popeski et al. (Ref. 266).	Retrospective survey of pregnancy induced hypertension in Inuit women and diet survey of women in these communities.	Hypertension study: 300 medical records from Inuit women in 7 communities in the Northwest Territories. Diet survey 27 Inuit women in the 7 communities above.	Retrospective study: Blood pressure measurements 6 hours before delivery, incidence of pregnancy induced hypertension. Diet survey: Reported diet, hunter interviews, cord serum phospholipid from 16 infants born in 6 months.	Communities with higher marine oil consumption ha significantly lower diastolic pressure in their women in the last 6 hours of pregnancy. Pregnancy associated hypertension was 2.6 times more common in communities with low fish consumption.	Ecologic data. Generates hypothesis for a relationship between the consumption of fish and blood pressure during pregnancy. Prospective study or clinical trial of diet and pregnancy needed.
Seidelin et al. (Ref. 281).	Correlation study of adipose tissue fatty acids and extent of coronary artery stenosis.	40 consecutive autopsies from subjects age 52 to 90 years.	Coronary artery disease was quantified by semi automatic image analysis, Degree of stenosis was used to divide subjects into three groups for correlations. Umbilical adipose lipids were extracted with methanol-chloroform, trans-methylated esters by gas chromotagraphy.	No correlation between extent of stenosis and 16:0, 18:0, 18:2n-6, 16:1n-9 or 18:1n-9, but a significant inverse correlation with 22:6n-3. Stenosis correlated with extent of body weight.	Limited data are presented for a limited number of subjects, i.e., no data for other fatty acids of interest are presented, e.g., EPA, AA.
Van Houwelingen et al. (Ref. 294).	Sample of clinical parameters from 40 healthy men selected from cohort in longitudinal study, Zutphen, Holland.	Men in low (n=15) and high (n=25) fish consumption groups. Low consumption group ate an average of 2 g fish/day while high consumption group ate an average of 33 g fish/day.	Individuals in this study where interviewed 4 times in 25 years using cross-check dietary methods for habitual fish consumption. Of 79 men selected for the study, 40 completed it. Blood collected for fatty acid composition, PAI activity, collagen-induced platelet aggregation, ATP release, and TXB_2.	There was significantly higher serum phospholipid concentration of omega-3 fatty acids EPA and DHA acid and no significant difference in collagen-induced platelet aggregation, cutaneous bleeding time, ATP-release in whole blood or platelet number between the two groups.	Small sample reflects inconsistency of fish consumption over time. Dose of omega-3 in high fish consumption group lower than in most clinical trials.

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Van Houwelingen et al. (Ref. 293).	Sample of clinical parameters from 61 elderly male volunteers from longitudinal cohort. Zutphen, Holland.	61 healthy elderly male volunteers ages 67 to 82. Lowest quartile of fish consumption ate 0 g/day. Highest quartile ate 27 g/day.	Cross-check dietary history was taken to assess the habitual intake of polyunsaturated fatty acids. Blood was collected under controlled conditions for measurement of serum total lipids, phospholipids, TG's, and cholesterol esters.	Dietary history seemed to correlate with serum linoleic acid. The correlation between dietary history using the cross check method for fish consumption and serum level of fish-related fatty acids, however, seems less reliable.	The discrepancy between dietary history and serum level of fish-related fatty acid may be the result of large variation in the level of these fatty acids in the same foods.

TABLE 2

Intervention Trials of Omega-3 Fatty Acids and CHD

Study	Study Design	Subjects	Methods	Results	Comments
Agren et al. (Ref. 168).	Randomized parallel trial of fish, fish plus reduced fat (especially saturated fat) or usual diet (one fish meal per 2 weeks) for 15 weeks.	62 Normal, healthy female students.	Plasma lipids and lipoproteins at baseline, 7 and 15 weeks.	Controls: NS TG, cholesterol, $apoA_1$, apoB. Fish eaters: NS versus baseline TG, cholesterol, apoB; ↓ $apoA_1$; ↓ TG versus controls. Fish plus low fat: ↓ TG, cholesterol, $apoA_1$, apoB.	This study shows the importance of the balance of the diet, particularly regarding saturated fat, in determining the blood lipid response to omega-3 fatty acids. Changes were slight unless a low fat low saturated fat diet was used. Study would have been stronger with a control group eating a low fat low saturated fat diet matched with fish intake to the nonfish control.
Annuzzi et al. (Ref. 170).	Randomized double-blind crossover trial of 10 g fish oil/day (3.0 g EPA plus DHA, MaxEPA) versus olive, no wash out, 2 weeks each treatment.	Eight female NIDDM, without liver, kidney or any other disease known to influence lipid and/or carbohydrate metabolism.	One of the patients was treated by diet only; others on Glibenclamide (4) and metformin (3). The patients were under dietary control and they were in the metabolic ward.	↓ TG, VLDL; ↑ LDL; NS cholesterol, HDL FFA; NS LDL-TG, HDL-TG; NS fasting glucose, average glucose insulin response, sensitivity.	Duration period was very short and no fatty acid analysis on neither fish oil nor olive oil diet. There was no washout period between cross-over of the study.
Bairati et al. (Ref. 172).	Randomized, double-blind placebo-controlled trial of 15 g fish oil/day (MaxEPA, 4.5 g EPA plus DHA) versus olive oil from 3 weeks pre angioplasty to 6 months; concurrent aspirin.	119 Subjects undergoing first, successful, computer quantified percutaneous transluminal coronary angioplasty, evaluated also at 6 months.	Angiographic assessment, quantified by computer. diet by food frequency. Restenosis defined in four ways for analysis.	By three of four definitions of restenosis, and multivariate analysis to control for exclusions, fish oil reduced restenosis. NS ECG evidence of myocardial ischemia, but trend toward ↓ fish oil, also on exercise testing. Significant difference also according to dietary omega-3 fatty acids (highest, middle versus lowest tertile) although highest tertile intake was only 0.15 g/day, and dietary odds ratio comparable to fish oil odds ratio.	Comparable compliance. Olive oil control doesn't control for polyunsaturated fatty acids. The comparable magnitude of the effects of dietary omega-3 fatty acids and fish oil supplementation suggest long-term, low dose effects are as strong as short-term, larger amounts. No associations of restenosis with other dietary variables, total fat, classes of fat, cholesterol, or dietary seafood. Differences between groups use of blood pressure medications (see Bairati et al. Ref. 173)) was not discussed.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Bairati et al. (Ref. 173).	Randomized double-blind, placebo-controlled trial with 15 g/day MaxEPA (4.5 g EPA plus DHA) versus olive oil.	125 patients undergoing first percutaneous transluminal coronary angioplasty, evaluated also at 6 months.	Recumbent blood pressure, blood lipids by commercial kits.	Blood pressure increased in the olive oil control group, and was unchanged in the fish oil group, possibly because greater number of patients in the olive oil group discontinued concurrent blood pressure medications. Fish oil ↓ TG's, NS in cholesterol, LDL or HDL versus control, but the change from baseline was different between groups with ↑ LDL and HDL in fish oil.	Multiple linear regression analysis used to control use of blood pressure medications reduced differences in LDL and HDL to borderline significance (p = 0.06), and inclusion of TG resulted in NS change in HDL.
Beil et al. (Ref. 174).	Randomized double-blind trial with 10.5 g/day fish oil (3.15 g EPA plus DHA, MaxEPA) versus 5.25 g/day fish oil plus 5.25 g oleic acid (low fish oil) versus 10.5 g oleic acid (placebo) 6 weeks.	30 Patients with primary hyper-triglyceridemia. Patients off lipid lowering drugs for 6 weeks, no beta blockers, diuretics or hormones. Fat restricted diet (30 percent, polyunsaturated fat:saturated fat ratio 1.5:1, cholesterol <250 mg/day).	Lipids by standard methods, Lp(a) by commercial kit.	↓ TG in high fish oil group versus placebo; NS cholesterol, LDL, HDL apoB; NS Lp(a), post-hoc analysis shows ↓ Lp(a) in those initially greater than 10 mg/dL.	Although randomized, there were large differences in initial Lp(a) levels, with only 1 of 10 in the placebo group over 6 mg/dL versus 6 and 8 of 10 in the low and high fish oil groups, respectively. Therefore, on the basis of Lp(a) the randomization was inadequate. Oleic acid does not control for polyunsaturated fatty acids.
Bhathena et al. (Ref. 175).	Nonblinded, longitudinal design, 10 week run-in on placebo (15 g mixed fat); 10 weeks with 15 g fish oil (anchovy oil, 6.5 g EPA plus DHA); 8 weeks of 15 fish oil plus 200 mg vitamin E	40 healthy females, no history of metabolic disease, no medication, no smoking.	Diet for the placebo and test group was controlled, fish was eliminated from the menu. Forty percent of energy comes from dietary fat which was more than the level of current dietary guideline recommended.	Fish oil ↑ fasting glucose; ↓ TG, insulin, glucagon, GH, somatomedin-C; NS cholesterol, cortisol, dihydroepiandrosterone sulphate. Fish oil plus vitamin E gave no further change in glucose, TG, glucagon cortisol or cholesterol; but ↓ GH, insulin, increased somatomedin-C to placebo levels, and produced a ↓ in DHEA-S.	Unusual source and high level of omega-3 fatty acids. Study design doesn't allow conclusions about omega-3 fatty acid-specific effects.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Bonaa et al. (Ref. 178).	Randomized, double-blind placebo-controlled trial of 6 g/day Norsk Hydro (4.5 g ethyl esters of EPA plus DHA) versus corn oil, 6 month observational run in, 10-week intervention.	146 healthy subjects.	Fasting blood samples at beginning and end of intervention, standard, commercial assays for lipids and apoproteins. Multiple linear regression.	Fish oil ↓ TG; In both groups NS cholesterol, LDL, apoB, ↑ HDL; ↑ $apoA_1$ in corn oil group. In fish oil group ↑ phospholipid EPA correlated with HDL, but not in corn oil group, whereas in corn oil group DHA was inversely correlated to HDL.	No change in dietary fat, alcohol or protein. Both groups had a small, significant weight gain. The divergent results underscore the need for studies on individual omega-3 fatty acids, that may help explain inconsistencies in results of fish oil effects on HDL.
Bordet et al. (Ref. 179).	Randomized, dose-response study to 300, 900, 2700 mg EPA (ethyl ester, MND-21, Mochida, Japan) 4 weeks plus 4-week washout.	32 healthy females.	Bleeding times by Simplate II.	NS platelet aggregation sensitivity to ADP, collagen, PAF; ↑ sensitivity to ate NS bleeding time.	Differences from other studies may be due to absence of DHA, and need for longer studies to allow DHA incorporation.
Brown and Roberts (Ref. 183).	Randomized 3 X 3 crossover of fish (0.6 g EPA plus DHA/day) versus fish plus fish oil (2.0 g EPA plus DHA/day) versus control (fish free) 6 weeks each with 6-week washout.	12 healthy females.	Clotting times on 2 samples taken 4 days apart at the end of each diet treatment. Fibrinolytic activity in pooled samples from each individual assayed by euglobulin activity versus fibrin.	↓ leukocytes on fish, fish plus fish oil diets. Platelet count ↓ on fish oil; NS fibrinogen, ↑ fibrinolytic activity on both fish and fish plus fish oil.	The authors review other reports on fibrinolytic activity and note the inconsistency in findings.
Brown and Wahle, (Ref. 184).	Crossover trial of 15 g fish oil (MaxEPA, 4.5 g/day EPA plus DHA) with or without 400 IU vitamin E for 4 weeks each with 2-week washout between.	11 healthy females.	Thiobarbituric acid reactive substances, total tocopherol by fluorometric assay, whole blood aggregation by electrival impedance after collagen stimulus.	NS conjugated dienes, creatine kinase, or TBARS in the platelet poor plasma; ↑ total plasma TBARS on both, but less with added vitamin E; ↑ glucose on fish oil without vitamin E.	Small number of subjects; considerable variance in many measures with the exception of plasma TBARS. The interaction between glucose suggests a mechanism to address potential adverse effect in diabetics.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Clarke et al. (Ref. 189).	Noncontrolled supplementation, 1 g fish oil/day (0.3 g EPA plus DHA, MaxEPA) increasing in 1 g increments monthly to 5 g/day for months 5 and 6.	7 male and 4 female adolescents with FHL type II (5 type IIa, 6 type IIb).	Usual low cholesterol, low saturated fat diets, 2 received colstipol.	NS TG's, cholesterol, LDL, HDL. Increased nose bleeds during fish oil treatment versus before and after.	Numbers of observations at each time per subject not given for blood lipids measurements, so fish oil amounts for "after" treatment not clear. Platelet count and other biochemistries described as normal, but no data of effects of fish oil are described.
Cobiac et al. (Ref. 190)	Randomized double-blind placebo-controlled, 2 week run-in on restricted Na intake plus 8 to 1 g sunflower oil capsules and 8 to 600 mg slow release NaCl. Then 4 weeks on fish oil (8 g HIMEGA, 4.2 g EPA plus DHA) on either lo or normal Na, and crossover to alternate Na for 4 weeks.	50 Elderly, healthy subjects.	Blood pressure in sitting position.	↓ sys, dias blood pressure on Na restricted diet plus fish oil; NS on fish oil only; NS on sunflower oil (the run-in treatment).	Note that sodium restriction alone had no effect. 55 elderly subjects started the experiment but only 50 completed the study. No explanation was given why some subjects were dropped out. Dietary intake and compliance were not controlled. No fatty acid analysis of the diet and/or the control and test oils. No washout period in between cross-over.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Davidson et al. (Ref. 191).	Three experiments: 1. Dose response study with fish oil, (7.2, 5.4, 3.6 g EPA plus DHA/day, SuperEPA) for 6 weeks sequentially, 6-week washout between doses; highest dose crossover to olive oil 2. Crossover of MaxEPA versus SuperEPA at 4.8 g EPA plus DHA/day each, 6 weeks, 6-week washout 3. Uncontrolled supplementation of cases from a 4 year period, 148 subjects treated for 6 week periods with various fish oil.	1. 16 Type II-B hyperlipidemic patients. 2. 12 Hyper triglyceridemic type IV. 3. 148 Patients of different hyperlipidemias.	1. Stable AHA phase 1 diet for 3 months prior to and during study. 3. Stable on AHA phase I or Phase II diets.	1. ↓ TG, cholesterol on 7.2, 5.6 g EPA plus DHA/day, NS cholesterol on 3.6 g EPA plus DHA/day; NS HDL; cholesterol ↑ on olive oil. 2. SuperEPA ↓ cholesterol more than MaxEPA; MaxEPA ↑ LDL, HDL, HDL_2 versus SuperEPA; NS HDL_3. 3. Each MaxEPA, SuperEPA, Promega ↓ TG's, cholesterol; ↑ HDL in Type IIb on SuperEPA only; ↓ LDL in familial hypercholesterolemia after SuperEPA. NS Lp(a).	Olive oil control increased TG cholesterol versus run-in diet. Design doesn't control for polyunsaturated fatty acids. Larger decrease in cholesterol by SuperEPA may be due to its reduced content of saturated fatty acids. Capsule counts were used to assess compliance.
Eritsland et al. (Ref. 195).	Randomized to aspirin (300 mg/g) for 1 week, followed by 4 week on fish oil (Norsk, 85 percent ethyl esters of EPA plus DHA, 3.4 g/day) or 4 week on fish oil followed by 1 week on aspirin.	22 female patients with stable CHD.	4 week run-in. Beta blockers used by 9 patients, nitrates allowed. Usual diet.	↓ TG's by fish oil; ↓ cholesterol by fish oil plus aspirin; ↑ HDL in fish oil only.	2 minor bleeding episodes on aspirin, none on fish oil. No wash out between treatments, small number of subjects makes differences in response to fish oil only and fish oil plus aspirin questionable.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Fahrer et al. (Ref. 196).	Self selected to treatment of fish (1.5 to 2.0 g EPA plus DHA/day), fish oil (Sanomega S18, 3.1 g EPA plus DHA/day), normal diet for 2 months.	21 female, 21 male healthy volunteers.	No run-in, fish was pink salmon, tuna, herring, mackerel, pilchard. Fish consumption recorded in daily diary.	↓ TG's in both fish and fish oil groups; NS cholesterol, HDL; decrease in TG correlated with increase in EPA.	Baseline blood lipid values were comparable in the self selected groups.
Ferretti et al. (Ref. 197).	Nonblinded, longitudinal design, 10 week run-in on placebo (15 g mixed fat); 10 weeks with 15 g fish oil (anchovy oil, 6.5 g EPA plus DHA); 8 weeks of 15 fish oil plus 200 mg vitamin E.	40 nonsmoking females.	PGE-M by a stable isotope dilution method developed in the authors' laboratories.	Fish oil alone and fish oil supplemented with vitamin E produced comparable results on average, with the mean values µg PGE-M excreted per 24 hours in control, fish oil and fish oil plus vitamin E of 15.41 ± 2.12, 12.51 ± 1.78 and 12.77 ± 1.85, respectively. Paired t-test showed a significant ($p < 0.002$) reduction between baseline and fish oil treatment.	PGE-M is the sum of PGE_1 plus PGE_2, derived from AA. The EPA-derived PGE_3 was not measured. Dietary intake was well controlled. Prolonged use of fish oil supplementation was not recommended. The range of baseline values was from 3.8 to 60.9 µg/24 hours. There was no apparent relationship between initial values and magnitude of the change, and there were many individuals who had substantial differences for the two fish oil treatments. Thus, the significance of an average change of about 20 percent is not clear.
Force et al. (Ref. 200).	12 g fish oil (n= 8)(6 g EPA plus DHA, Promega) or 16 g fish oil (n= 6) (8 g EPA plus DHA), 6 weeks. After 6 weeks on fish oil only, concurrent increasing daily dosages of ASA (50, 100, 225, 1,300 mg) 2 weeks each.	14 females, 2 males, clinically stable but advanced CHD.	Gas chromatography-mass spectroscopy	Fish oil ↓ TXA_2 38 percent, with ASA ↓ 97 percent at each dose; fish oil and ASA each ↓ PGI_2 (ASA more than fish oil); fish oil ↑ PGI_3, but ASA did not increase PGI_3.	This is a study on the mechanism of action of fish oil. No concurrent placebo control. Dietary intake was not controlled.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Franceschini et al. (Ref. 202).	Uncontrolled supplementation study of 6 g/day fish oil (Norsk hydro, 2.8 g EPA plus 1.7 g DHA), 6 weeks.	5 Healthy subjects.	HDL subfractions assayed by nondenaturing polyacrylamide gel electrophoresis.	NS cholesterol, HDL, ↑ HDL_2, ↓ HDL_3, ↑ HDL_2/HDL_3 mass ratio.	Dietary intake was not controlled. Compliance was checked by plasma PL fatty acid composition. Small study.
Gans et al. (Ref. 203).	Randomized double-blind study (fish oil, source not specified, 1.8 g EPA plus 1.2 g DHA/day) versus corn oil, 4 months.	Stable claudication patients; 37 enrolled, 16 per group completed.	Supine blood pressure at rest and 1, 6, 10 min post exercise. Fibrinogen by commercial kit.	↓ Diastolic by both groups, ↓ systolic only in CO group; ↑ RBC deformability; NS cholesterol, LDL; fibrinogen; ↑ HDL, HDL_2; ↓ TG's; NS pain, walking distance.	Wide variation of age (18 to 80 years), Dietary intake was not controlled. Compliance was checked by plasma PL fatty acid composition. Blood pressure was lowered in both groups.
Gazso et al. (Ref. 204).	Randomized double-blind placebo-controlled Efamol-marine (1.2 g EPA) versus Efamol (v olive oil) 12 capsules/day 6 weeks.	17 normal healthy 6 males, 11 females 6-Efamol marine, 5-Efamol, 6-olive oil.	ic conversion, MDA, platelet aggregation to ADP.	↓ Platelet aggregation by Efamol-marine; ↓ MDA in all groups.	Groups differ in the endpoints at beginning of the experiment, so it is difficult to interpret changes. The MDA ↓ may be due to the vitamin E added.
Gerhard et al. (Ref. 206).	3-period crossover of three fish diets; Dover sole (2 g EPA plus DHA), Salmon (4 g EPA plus DHA), or sablefish (3.4 g EPA plus DHA), 18 d each with 3-week washout between.	21 normo-triglyceridemic females.	ApoB standardized to Centers for Disease Control standards. VLDL and LDL precipitated with magnesium phosphotungstate, HDL enzymatically in the supernatant.	Salmon, sablefish diets ↑ cholesterol, apoB, LDL. Sole ↓ HDL, ↑ LDL; Sablefish ↓ HDL.	Diets were comparable for total fat, saturated fat. Study design doesn't allow conclusions about omega-3 fatty acid-specific effects.
Goren et al. (Ref. 207).	Uncontrolled supplementation study, 150 to 200 mg/kg (EPAGIS) (0.86 to 2.3 g EPA plus DHA/day) 8 weeks.	16 Patients with end stage renal disease, 6 type IIb, 1 type IIa, 8 type IV.	Blood lipids before and after supplementation. cholesterol by microenzymatic method. Apoproteins by turbidity assays.	↓ TG; NS cholesterol, ↓ cholesterol/HDL in a subset of excessively hyperlipidemic subjects; NS blood pressure, platelet counts, $apoA_1$:apoB.	Fish oil dosage was adjusted to the body weight of chronic renal failure young patients (7 to 18 years).

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Green et al. (Ref. 209).	Randomized double-blind placebo-controlled crossover 15 g fish oil (EPAGIS, 4.3 g EPA plus DHA) versus corn:olive oil mix, 8 weeks each treatment with 4 week wash out.	27 Hyperlipidemic subjects, 15 type IIb, 12 type IV.	Cholesterol, HDL, TG by commercial kits. Apoproteins by immunoturbidity assay.	Overall NS cholesterol, LDL. Type IIb: ↓ TG, cholesterol; ↑ HDL; NS LDL. Type IV: ↓ TG; NS cholesterol, LDL, HDL. Both: NS platelet count, platelet aggregation, RBC deformability, apoB, $apoA_1$; ↓ blood viscosity.	Substantial amount of other omega-3 fatty acids in this supplement (0.50 g 18:3, 0.45 g 18:4 and 0.42 g 22:5) per day. Patients were on weight-maintenance diet but no cal percent or wt percent of each component was given. Compliance was shown on blood lipid analysis.
Haglund et al. (Ref. 210).	Double-blind crossover study 30 mL/day of low vitamin E fish oil (9.6 g EPA plus DHA/day, Eskimo-3 or Inuit-3) or same oil supplemented with 1.5 IU vitamin E, 3 week.	12 Normal healthy subjects.	Lipids, glucose, Lp(a), fibrinogen.	Both fish oil ↓ TG's; ↑ HDL, glucose; NS cholesterol, Lp(a), apoB, insulin. Low vitamin E fish oil ↑ MDA, fructosamine; ↓ vitamin E. High vitamin E fish oil ↓ TG's, fibrinogen.	High vitamin E produced some effects independently of the fish oil, underscoring the need the control for polyunsaturated fatty acids, and have adequate vitamin E in the test substances.
Hamazaki et al. (Ref. 215).	Uncontrolled supplementation study, 1.8 g EPA ethyl ester/day, (laboratory purified), 6 months.	16 Diabetics, 5 IDDM, 11 NIDDM.	Albumin by radioimmunoassay with a commercial kit. HbA_{1c} by high performance liquid chromatography.	NS TG, cholesterol, glucose, HbA_{1c}, systolic, diastolic blood pressure, blood viscosity; ↓ albumin excretion, hematocrit.	NS body weight. Compliance was checked by blood EPA level. Dietary intake was not controlled. In IDDM fasting glucose was reduced, and barely missed statistical significance. Study design doesn't allow conclusions about omega-3 fatty acid-specific effects.
Hansen et al. (Ref. 216).	Crossover trial of 25 mL cod liver oil/day (6.25 g EPA plus DHA), 8 weeks versus no supplement.	20 healthy female and 20 healthy male subjects.	Whole blood clot (produced by added thrombin) lysis time to complete lysis. t-PA by commercial ELISA kit. Fibrinogen by spectrophotometric assay.	NS fibrinogen, fibrinolytic activity, t-PA; ↓ TXB_2.	Study design doesn't allow conclusions about omega-3 fatty acid-specific effects.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Harats et al. (Ref. 217).	Parallel untreated controls versus 10 g MaxEPA/day (3 g EPA plus DHA), 4 weeks.	a. Smokers 6 MaxEPA, 5 controls. b. Smokers 3 control, 4 fish oil only, 4 fish oil plus 400 mg vitamin E smokers. c. Nonsmokers.	40 hour smoking abstinence and overnight fast prior to blood draw; 90 minutes 4 to 6 cigarettes smoked, for second blood draw.	↓ TG; NS cholesterol, HDL; fish oil ↑ TBARS in plasma presmoking ↑ TBARS after smoking.	TBARS in plasma, and LDL, more responsive to cigarettes than fish oils. Most, but not all of the increase due to fish oil alone could be blocked by the added vitamin E.
Harris et al. (Ref. 218).	Uncontrolled supplementation trial of fish oils plus aspirin; 325, 80, 80 mg aspirin for 3 days; 4 day wash out; 2 weeks on 4.5 g EPA plus DHA (SuperEPA); 325, 80 80 mg aspirin plus SuperEPA for 3 days.	8 healthy males.	Bleeding times by Simplate II. Platelet aggregation to AA, collagen, PAF and AA in combination with the other agonists.	Bleeding NS on fish oil; fish oil plus aspirin same as aspirin only; fish oil and fish oil plus aspirin NS on platelet sensitivity to AA, collagen, PAF, but fish oil ↓ extent of aggregation to collagen.	Medications were controlled but diet was not controlled. Short-term study with a small number of subjects may explain inconsistencies with other comparable studies. The study may not have had adequate statistical power to determine whether bleeding time increases of aspirin and fish oil are additive or greater than additive.
Harris and Windsor (Ref. 220).	Uncontrolled supplementation study on postprandial lipemia with of fish oil (2.2 g EPA plus DHA, Dale Alexander Omega-3), random assignment to capsules or emulsion for 4 weeks.	12 male and 4 female healthy normolipidemic subjects.	Bleeding times by Simplate. Background diets had 32 to 36 percent fat with 12 to 14 percent as saturated, 12 to 13 percent as monounsaturated, and 6 percent as polyunsaturated. Test meal provided 1 g fat/kg (61 percent of total calories: 32 percent of calories from saturated fatty acids; 13 percent from monounsaturated fatty acids, 7 percent from omega-3 fatty acids. Two hour blood samples through 10 hours post meal.	↓ TG's VLDL; NS cholesterol, LDL, apoB, $apoA_1$, HDL_1, vitamin E, Lp(a); ↑ HDL, HDL_2. ↑ Bleeding time; NS RBC deformability. Postprandial lipemia reduced about 40 percent.	No medications. No difference between capsules and emulsion in test meal, possibly because most fat was from other diet components.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Harris et al. (Ref. 219).	Randomized dose-response, 1.25 to 5 g EPA plus DHA/day (Promega) 6 months.	28 Hyperlipidemic patients.	Blood lipids, Simplate II for bleeding times.	↓ TG in dose-related manner 1 month and 6 months, except lowest dose NS at 6 months, ↓ VLDL on all but lowest dose; NS cholesterol, LDL, HDL, HDL_2, (except 2.5 g/day at 6 months ↑ LDL, HDL). ↑ Bleeding times on 2.5, 5 g/g RBC deformability largely unaffected.	Discrepancies among studies, methodologies were discussed. Irregularities may be due in part to small sample size. 4-week washout returned most values to pretreatment levels.
Hendra et al. (Ref. 222).	Randomized, double-blind, placebo-controlled trial of 10 g/day MaxEPA (3 g EPA plus DHA) versus olive oil, 6 weeks.	80 Noninsulin-dependent diabetic subjects.	Fibrinogen by Clauss, HDL by precipitation, LDL by calculation.	Transient ↑ glucose; NS HbA_1. ↓ TG; NS cholesterol, HDL; ↑ LDL (versus baseline). ↓ Spontaneous platelet aggregation, but NS responses to induced aggregation. ↓ blood pressure in both treatments.	Large, carefully controlled study in an at-risk population. Olive oil control doesn't allow conclusions about omega-3 fatty acid-specific effects.
Homma et al. (Ref. 224).	Uncontrolled supplementation test of 2.7 g/day purified EPA ethyl ester (source not specified), 12 weeks.	15 Outpatients.	Ad libitum diets. Blood samples after 12 hour fast. Plasma lipids by ultracentrifugation every 4 weeks.	↓ cholesterol, TG, apoB, small dense LDL; ↑ large light LDL, lipid transfer protein activity; NS HDL, HDL_2, HDL_3, $apoA_1$, apoC, apoE.	Authors state the relative atherogenicity of large light LDL and small dense LDL is controversial.
Jensen et al. (Ref. 226).	Sequential dose-response with 1, 3, 6 g EPA plus DHA (Shaklee EPA), 4 weeks each with 3-week washout between.	14 healthy males and 4 healthy females.	1 Month run-in on fish free diet, otherwise diet not controlled. Bleeding times by Simplate II. Lipids by auto laboratory method.	↓ TG, VLDL on 6 g dose; ↑ HDL and HDL/LDL ratio on 6 g dose, but baseline HDL changed; NS cholesterol, LDL.	Changes in baseline HDL not shown.
Kremer et al. (Ref. 228).	Randomized double-blind placebo (olive oil) controlled trial of 3.25 or 6.5 g EPA plus DHA/day (ethyl esters, Pharmacaps), 24 weeks.	49 With rheumatoid arthritis completed the study.	IL-1 by bioassay.	↓ IL-1 38 percent 41 percent and 55 percent in olive oil, low and high fish oil groups, respectively; NS IL-2 in both fish oil groups.	Actual doses were adjusted per kg body weight.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Li and Steiner (Ref. 234).	Dose-response, parallel design: 4.8, 9.6, or 14.4 g EPA plus DHA/day, (source not specified), 3 weeks.	5 Normal healthy subjects each dose.	Platelet adhesion measured ex vivo in laminal flow chamber, using purified substrates.	↓ Platelet adhesion to collagen I and fibrinogen, near maximal response at 3 g EPA/day; speed of return to baseline values in the washout was directly related to dose.	This procedure reduces formation of thrombi, dilutes platelet derived factors. Measures direct interaction of platelets with surface matrix. Study design doesn't allow conclusions about omega-3 fatty acid-specific effects.
Lindgren et al. (Ref. 235).	Metabolic ward crossover of salmon versus prudent diet (30 percent fat). 20 day run-in, 40 days each diet. Salmon diet provided 2.1 percent of calories as omega-3 fatty acids, (approximately 5 g/day EPA plus DHA).	9 normolipidemic females.	Plasma proteins measured by competitive ELISA except $apoA_1$, by radioimmunodiffusion.	NS cholesterol, LDL, HDL_{2a}, HDL_{3a}, apoB, apoE, Lp(a); ↓ TG, HDL_{3a} HDL_{3b}, $apoA_1$, $apoA_2$; ↑ HDL, HDL_{2b}.	Carefully designed metabolic ward study, using practical level of omega-3 fatty acids, and Fat (saturated fatty acids and omega-6 polyunsaturated fatty acids) carefully controlled. Details on effects of lipoprotein subfractions. Two assay methods for Lp(a) gave same result.
Malle et al. (Ref. 241).	Uncontrolled supplementation with fish oil, (6.7 g EPA plus DHA/day, EPAX-5000), 6 weeks and 4-week washout.	Normolipemic subjects with very high (8) and very low, i.e., undetectable Lp(a) levels (7).	4 week run-in. Normal diets. Platelet aggregation to collagen, thrombin.	↓ TG, platelet aggregation; NS cholesterol, LDL, HDL, Lp(a).	Comparable lipid and platelet responses for the low Lp(a) and high Lp(a) groups.
Marckmann et al. (Ref. 244).	observational, sequential diets of fish (3.4 g/day EPA plus DHA, 10 d) uncontrolled (18 d), and meat (10 d).	12 healthy females.	Clauss fibrinogen assay, t-PA and PAI-1 antigens by ELISA.	NS cholesterol, HDL, TG, fibrinogen; TG ↓ on both diets; ↓ PAI-1 and t-PA antigen, PAI activity and ↑ t-PA activity on meat, but NS on fish.	Since both diets produced changes with respect to the initial diets (that were uncontrolled) it is difficult to ascribe any change to the omega-3 fatty acids. However, the changes on the meat diet are more in line with reduced CHD risk than the lack of change on the fish diet.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Meland et al (Ref. 247).	Double-blind, randomized multi-center placebo (corn oil- olive oil mix) controlled trial, 20 mL MaxEPA/day (6.8 g EPA plus DHA), 6 weeks.	40 females mild hypertension.	Calibrated instruments at 8 centers. Time of day for measurements was controlled.	NS blood pressure, cholesterol; ↓ TG's on fish oil; ↓ cholesterol/HDL ratio in both groups.	Power to detect a 5 mm blood pressure difference was 96 percent; a 10 percent cholesterol difference was 61 percent. Cholesterol/HDL ratio decrease in placebo was nearly more than that after fish oil ($p<0.07$). 11 of 14 subjects on fish oil guessed their assignment correctly.
Meydani et al (Ref. 248).	Uncontrolled supplementation study 2.4 g/day EPA plus DHA (Promega), 3 months.	25 males.	Blood at 1, 2, 3 months.	↓ TG's; ↑ lipid peroxides.	6 IU vitamin E may not be adequate.
Molvig et al. (Ref. 250).	Randomized, double-blind Placebo-controlled trial of 1.6, 3.2 g EPA plus DHA (Pikasol) versus fatty acid blend, 7 weeks.	25 Healthy subjects and 8 IDDM subjects.	Isolated monocyte cell cultures. TNF and IL-1 by commercial ELISA kits.	↓ IL-1B immunoreactivity on high dose only; NS after low dose. NS TNF-α; ↓ proliferative response.	Placebo had 20 percent polyunsaturated, 38 percent monounsaturated fatty acids. Spontaneous and LPS-stimulated leucotriene B_4 and PGE_2 secretion did not differ among groups at baseline or after 7 weeks of treatment. IL-1 returned to baseline with 3-week washout.
Mori et al. (Ref. 251).	Matched (age, weight) and randomized to 15 g MaxEPA/day (4.5 g EPA plus DHA) or olive oil, 4 weeks.	32 females with peripheral vascular disease.	No aspirin for 14 days prestudy platelet aggregation to PAF, collagen.	↑ cholesterol, LDL, HDL_2; ↓ TG by fish oil, (but olive oil ↓ cholesterol, LDL); ↓ platelet aggregation by fish oil, but olive oil ↑ aggregation.	Compliance by capsule count. Changes in control make interpretation difficult. Olive oil does not control for polyunsaturated fatty acids.
Mori et al. (Ref. 252).	Matched groups randomly assigned to 15 g/day MaxEPA (4.5 g EPA plus DHA), olive oil, or olive oil plus cholesterol.	27 normolipidemic insulin-dependent female diabetics.	HDL by heparin, manganese chloride precipitation, followed by separate precipitation of subfractions. LDL by calculation.	NS cholesterol, LDL, HDL; ↑ HDL_2, ↓ HDL_3, TG.	Study design doesn't allow conclusions about omega-3 fatty acid-specific effects.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Mueller et al. (Ref. 253).	Randomized double-blind crossover trial of 8 g EPA plus DHA (Promega) versus olive oil, 21 d.	12 Healthy adults.	Bleeding times by Simplate II before and after administration of 325 mg aspirin. Excludes subjects with platelet or coagulation disorders, thrombocytopenia, ethanol.	Fish oil-NS bleeding time versus baseline but ↑ versus olive oil both before ($p < 0.02$) and after (NS) aspirin. ↓ TG on fish oil, platelet count, WBC count; NS cholesterol, LDL, HDL.	Trend toward ↑ HDL versus baseline, but olive oil in same direction, some order effects confound results.
Muller et al. (Ref. 253a).	Multicenter observational trial of 135 g canned mackerel paste (4.7 g/day EPA plus DHA) or meat paste.	84 healthy females.	Published methods for facror X, antithrombin III, alpha-antiplasmin, plasminogen. Fibrinogen by Clauss.	NS fibrinogen, other blood coagulation measures (only ↑ factor X), or fibrinolysis measures; meat ↓ plasminogen.	Compliance by lithium excretion. Study design doesn't allow conclusions about omega-3 fatty acid-specific effects.
Mullertz et al. (Ref. 254).	Uncontrolled supplementation, 0.55 g EPA plus DHA/day (Pikasol), 21 days.	7 Healthy adults.	Normal diets, PAI-1 and u-PA by ELISA kits.	↓ α-Tocopherol; NS cholesterol, TG's; ↑ PAI-1; NS t-PA, u-PA.	Suggests that differences reported for PAI-1 are due to the assay used, with the double antibody assay used in this study, and the monoclonal antibody used by Emeis et al. providing specificity. Concludes that fish oil decreases fibrinolytic activity.
Nelson et al. (Ref. 256).	Metabolic ward crossover of salmon, prudent diet (30 percent fat). 20 day run-in, 40 days each diet. Salmon diet gave 2.1 percent of calories as omega-3 fatty acids, (approximately 5 g/day EPA plus DHA).	9 normolipidemic females.	Platelet aggregation to ADP, AA, collagen, thrombin: threshold and maximum response. Bleeding time by Simplate II.	NS bleeding time; salmon diet ↓ platelet counts NS platelet response to collagen, thrombin but ↓ sensitivity to ADP.	Carefully designed metabolic ward study, using practical level of omega-3 fatty acids, and Fat (saturated fatty acids and omega-6 polyunsaturated fatty acids) carefully controlled.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Nikkila (Ref. 258).	Randomized, double-blind, placebo (corn oil) controlled, crossover, 2.4 g EPA plus DHA/day as ethyl ester (EPA X 6000EE, Almarin), two 4-week periods with a 4-week washout between, followed by open study of 3.6 g EPA plus DHA/day for 4 weeks.	32 females with CHD, increased TG and decreased HDL, 62 percent were overweight.	Lipid lowering diet for 4 weeks prior to study.	NS cholesterol, LDL, HDL, HDL/cholesterol ratio, $apoA_1$, apoB; ↓ TG's; During open phase those with severe hypertriglyceridemia had ↑ HDL/cholesterol.	HDL inversely related to TG in study group pretreatment.
Nye et al. (Ref. 259).	Randomized, fish oil and its placebo were double-blind 1. Aspirin 300 mg plus dipyridamole 75 mg.' 2. 3.6 g EPA plus DHA (MaxEPA). 3. Olive oil, up to 1 year.	79 females, 29 males post PTCA referred for angina, none had grafts.	Angiography (blind) at one year or before in those with anginal symptoms; restenosis defined as a loss of 50 percent or more of the gain produced by PTCA.	NS angina (trend toward less in A/D and fish oil groups D restenosis by EPA (11 percent versus 30 percent for olive oil) MaxEPA not different in any regard versus A/D NS in any blood lipids in a subset (n= 42).	No deaths in any group through 1 year, 93 percent follow-up rate. Results suggest that MaxEPA is as useful or moreso than aspirin/dipyridamole.
Oh et al. (Ref. 261).	Randomized crossover of 4 normal eggs versus 4 omega-3 fatty acid-enriched eggs/day (4.5 g EPA plus DHA/day), 2 week run-in, 4 weeks each treatment.	9 female and 3 male healthy volunteers.	Recumbent blood pressure; VLDL by untracentrifugation, HDL by manganese-heparin precipitation.	Omega-3 fatty acid-enriched eggs did not ↑ cholesterol, but regular eggs did. Omega-3 fatty acid-enriched eggs ↓ TG in one group.	One of the groups used butter to prepare eggs, changing the P:S ratio. Pooled data were not given despite absence of order effects for most variables. ↓ LDL in one group; NS HDL in either treatment. Systolic blood pressure ↓ in both groups, diastolic only in one.
Olivieri et al. (Ref. 263).	Uncontrolled supplementation trial of 20 mL fish oil/day (3.0 g EPA plus DHA, source not specified), 8 weeks.	20 hyperlipidemic 16 female, 4 male.	No hypolipidemic drugs for 15 days pre trial. blood pressure by blinded nurse.	↓ Systolic diastolic blood pressure, TG; NS cholesterol, HDL, vitamin E; ↑ glutathione peroxidase activity in RBCs and platelets, ↓ MDA.	Design doesn't allow conclusions about omega-3 fatty acid-specific effects.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Owens and Cave, (Ref. 264).	Observational study, 15 g/day MaxEPA (4.5 g EPA plus DHA) 4 weeks.	6 normal females.	Simplate II for bleeding time. Platelet adhesion in Baumgartner chamber using everted rabbit aorta. Prothrombin time, WBC and platelet count by automated methods.	NS WBC, prothrombin time, platelet adhesion, bleeding time.	Trend toward increased adhesion with duration of feeding. Assay method measures platelet changes, but does not assay vessel wall changes. Study design doesn't allow conclusions about omega-3 fatty acid-specific effects.
Rapp et al. (Ref. 268).	Uncontrolled supplementation study of MaxEPA at 6 percent of calories (16 to 21.3 g EPA plus DHA/day), 6 to 120 days.	11 patients, 9 female, 2 male with obstructive atherosclerosis scheduled for peripheral vascular surgery.	Excludes subjects with habitual fish intake. 15 endarterectomy specimens. Control specimens from 18 nonfish consuming subjects undergoing vascular reconstruction.	Fish oil increased content of omega-3 fatty acids in atherosclerotic lesion linearly with duration of feeding, although plasma enrichment of omega-3 fatty acids plateaued by 2 to 3 weeks; ↓ cholesterol; NS TG's, platelet counts, bleeding times.	Shows incorporation of omega-3 fatty acids into plaque, especially DHA. Relevance to CHD not known. Not a specific effect of omega-3 fatty acids, but would be expected to polyunsaturated fatty acids. High amount of omega-3 fatty acids.
Saynor and Gillott (Ref. 276).	Uncontrolled long-term supplementation with 20 mL/day MaxEPA during year 1, 10 mL/day thereafter.	365 During 1 month to 40 at 84 months. 47 percent had survived a heart attack, 49 percent had angina.	Total cholesterol by enzymatic assay. HDL after precipitation.	↓ TG; ↓ cholesterol only for initial high cholesterol; ↑ HDL for total group; NS LDL; ↓ fibrinogen.	Large attrition makes it difficult to ascribe changes to fish oil (responders to treatment are more likely to stay in the study). Lack of blinding also may have contributed to bias. Some data were presented for all subjects only, other data only for subsets. Estimates of deviation from mean values not shown. Lack of control prevents conclusions regarding effects to omega-3 fatty acids.
Schmidt et al. (Ref. 277).	Dose-response study 1.3, 4, 9 g EPA plus DHA/day (Pikasol), 3 periods of 6 weeks/amount. Randomized to increasing or decreasing dose. 6-week washouts.	10 healthy females.	Simplate II for bleeding times; t-PA, PAI by commercial kits; fibrinogen by thrombin clotting time.	NS cholesterol, LDL, platelet aggregation; ↑ HDL, bleeding time on 4 and 9 g/day, PAI and t-PA antigen after 9 g/day; ↓ TG, fibrinogen.	Design doesn't allow conclusions about omega-3 fatty acid-specific effects.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Schmidt et al. (Ref. 278)	Uncontrolled supplementation with 4 g EPA plus DHA/day (Pikasol), 6 weeks.	10 Untreated hypertensives.	Supine blood pressure.	NS cholesterol, LDL, HDL, TG, platelet aggregation to collagen, ADP, systolic, diastolic blood pressure, bleeding time; ↓ cholesterol/HDL ratio, fibrinogen, monocyte chemotaxis.	Design doesn't allow conclusions about omega-3 fatty acid-specific effects. Absence of significant change in plasma TG despite 25 percent decrease suggests inadequate sample size. Before and after compared by Pratt's test.
Schmidt et al. (Ref. 279).	Uncontrolled supplementation with 1.3 to 9.0 g EPA plus DHA/day (Pikasol, MaxEPA or cod liver oil), most for 6 weeks, angina subjects for 12 weeks.	Various at-risk subjects with angina (14), IDDM (10), hyperlipidemia (17), hypertension (10), and healthy subjects (46).	Normal diets. Lp(a) by two-site immunoradiometric test kit.	NS Lp(a) in any group.	Reports Lp(a) data for subjects from 5 previous Schmidt reports (Refs. 133 through 135), and the current refs above. Design doesn't allow conclusions about omega-3 fatty acid-specific effects.
Shapiro et al. (Ref. 283).	Uncontrolled supplementation with 18 g MaxEPA/day (5.4 g EPA plus DHA/day), 6 weeks, 10-week washout.	10 normolipidemic, healthy females.	3 Samples per time point, 2 to 3 days apart.	↑ cholesterol, LDL, HDL, vitamin E, retinol versus presupplementation and washout; ↓ TG versus washout.	Multiple samples per treatment reduces day-to-day fluctuations, magnitude of changes: Cholesterol 6 percent; LDL 9 percent; HDL 11 percent versus average of pretreatment and washout values.
Singer et al. (Ref. 285).	Randomized to propranolol (P), or fish oil (2.9 g EPA plus DHA/day, source not specified), for 36 weeks, or (P) only (12 weeks) then P plus fish oil (12 weeks) then P plus olive oil placebo (12 weeks). Each followed by 4-week washout.	47 female patients with mild essential hypertension.	Two baseline blood pressure measures 4 weeks apart, blood pressure measured in triplicate at fixed time and post 2 hours of rest each 12 weeks.	P ↓ systolic, diastolic blood pressure, recumbent and upright; fish oil ↓ systolic, diastolic blood pressure in recumbent and upright; Some additive effects of P plus fish oil.	Olive oil control doesn't control for polyunsaturated fatty acids. Study duration and multiple measures (each 12 weeks) shows blood pressure lowering effect is persistent.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Sirtori et al. (Ref. 286).	Randomized, three-arm crossover of 6 g fish oil (Norsk Hydro, 4.5 g EPA plus DHA ethys esters) versus olive oil (middle arm for each sequence) versus corn oil for 6 weeks each. 1 month run-in and 4 week wash-out between each arm with low saturated fat diet.	12 Type IIa hyperlipidemics.	Lipids by enzymatic assays, apoproteins by immunoturbidity assay. Platelet aggregation versus AA. TXB_2 by radioimmunoassay. Superoxide by spectrophotometry.	Fish oil ↓ cholesterol, LDL, ↑ HDL; Olive oil ↓ LDL, ↑ HDL; Corn oil ↓ HDL, apoB. Platelet aggregation ↓ by all three oils. Fish oil ↓ superoxide in monocytes.	Excellent design. Divergent results from another recent study with comparable design (Bonaa et al. (Ref. 178) that used the same amount and form of fish oil supplement and same control (corn oil), suggesting that responses to supplemental oils may be different for different sub-populations. Absence of change in platelet aggregation may also be a population specific finding.
Spannagl et al. (Ref. 287).	Uncontrolled supplementation with 8.1 g EPA plus DHA/day (PGE-technology), 4 weeks.	13 (3 male 10 female) near normoglycemic type I diabetics.	Fibrinogen by turbidity assay. t-PA, PAI by test kits.	NS clotting tests, t-PA; ↑ PAI, fibrinogen; ↓ TG.	Design doesn't allow conclusions about omega-3 fatty acid-specific effects. Fairly high amount of omega-3 fatty acids in this nonnormal population.
Trials of Hypertension Prevention Collaborative Research Group (Ref. 289).	Randomized life style interventions and double-blind, placebo-controlled nutritional supplement interventions including 3.0 g omega-3 fatty acids/day (source not specified), 6 months.	2182 female and male with diastolic blood pressure 80 to 89 mm Hg.	Sitting blood pressure after 5 minute rest. Measurements for baseline, 3 and 6 months were made in triplicate on 3 different days. On the fish oil arm there were 161 active and 157 control subjects.	NS systolic, diastolic blood pressure.	Large, multicenter design with many internal comparisons.
Vandongen et al. (Ref. 291).	2 week run-in, observational trial of 15 g/day MaxEPA (4.5 g EPA plus DHA) versus no supplement.	22 female insulin-dependent diabetics.	Double precipitation for HDL subfractions.	↑ cholesterol, LDL, HDL, HDL_2; ↓ TG, HDL_3.	Study design doesn't allow conclusions about omega-3 fatty acid-specific effects.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Virella et al. (Ref. 295).	Double-blind placebo (olive oil) controlled study of 2.4 g EPA (DHA not given) 6 weeks.	6 Normal subjects.	Blood samples at baseline, 3, 6, 14, 20, 28. Humoral immune response.	↓ TG in 3/4 on fish oil; variable in vivo response to tetanus toxoid booster; ↓ in vitro response to tetanus toxoid, ↓ IL-2 release.	Small number of subjects limits conclusions. Increase in bleeding reported in 2/4.
Vohwinkel et al. (Ref. 296).	Randomized, double-blind crossover of 6 g EPA plus DHA/day (source not specified) versus olive oil, 3 weeks.	48 Healthy subjects.	Glucose tolerance tests to 100 g oligosaccharides.	↑ Fasting glucose, insulin at 4 hours post load. Response of glucose to load affected differently by fish oil, depending on initial insulin response; among low responders fish oil increased insulin response and decreased glucose; among high insulin responders, fish oil reduced insulin response and lowered glucose response.	Complex results according to insulin responsiveness. Olive oil does;t control for effects of polyunsaturated fatty acids.
Wander and Patton, (Ref. 297).	3-period crossover of three fish diets; Dover sole (2 g EPA plus DHA), Salmon (4 g EPA plus DHA), or sablefish (3.4 g EPA plus DHA), 18 day each with 3-week washout between.	23 normo-triglyceridemic females.	Bleeding time by Simplate. Platelet aggregation versus collagen, ADP. TXB_2 by radioimmunoassay.	Salmon ↑ bleeding time. Sablefish ↓ platelet aggregation to collagen; Both sablefish and salmon ↓ aggregaton to ADP, ↓ TXB_2.	Diets were comparable for total fat, saturated fat. Study design doesn't allow conclusions about omega-3 fatty acid-specific effects.
Weintraub et al. (Ref. 298).	Metabolic ward study. Crossover to 3 isocaloric diets:saturated fat; omega-6 fatty acids and omega-3 fatty acids (3.4 g/day EPA plus DHA), 25 days each with 5 to 7 day wash-out.	8 normolipidemic females.	Vitamin A fat load test in fasted subjects; HDL by precipitation, LDL by calculation. Lipolysis assay using human milk lipoprotein lipase.	Omega-3 diet ↓ cholesterol, TG, LDL, HDL, platelet count versus saturated fat. Omega-6 diet ↓ cholesterol, TG, LDL NS fasting glucose, postprandial insulin. Both omega-3 and omega-6 reduced postprandial lipemia versus saturated fat. NS in lipemia between omega-6 and omega-3.	Excellent design studies both chronic and acute fat effects. Many postprandial fat effects were larger on the omega-3 than the omega-6 diets, but not statistically significant.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Wing et al. (Ref. 299).	Double-blind, placebo (olive oil) controlled crossover trial of 15 g fish oil (Lipitac), 4.5 g EPA plus DHA, 8 weeks each.	20 Treated hypertensives maintained on blood pressure medications.	Supine and standing blood pressure. HDL after manganese chloride/heparin precipitation.	Blood pressure lower comparable on olive oil and fish oil. ↓ TG in fish oil; NS HDL on either treatment.	Study design doesn't allow conclusions about omega-3 fatty acid-specific effects.
Wojenski et al. (Ref. 300).	Sequential treatments with ethyl oleate (placebo), 6 g Res-Q1000 (3.6 g EPA plus DHA/day), or 4.0 g ethyl EPA. Washouts between phases of 5 weeks, 4 months, respectively, and 8 weeks posttreatment.	9 healthy female volunteers.	Bleeding time by Simplate II; HDL by hospital automated method, platelet aggregation to ADP, collagen. TXB, by radioimmunoassay. Fibrinogen binding by ^{125}I-Fibrinogen versus saline.	Bleeding time ↑ on ethyl EPA; Platelet count ↓ on Res-Q1000 and ethyl EPA; Ethyl EPA ↓ cholesterol, TG, platelet aggregation; NS fibrinogen binding.	No aspirin or ibuprofen. Evidence for a greater effect by the ethyl ester than for a comparable amount of omega-3 fatty acids in a mixed TG supplement.
Wolmarans et al. (Ref. 301).	Crossover comparison of red meat to fish, (6.1 g EPA plus DHA/day) 3 week baseline, 6 week treatment, 6 week posttreatment and 3-month washout.	Healthy subjects, 12 females, 16 males.	Habitual diet.	Fish diet ↓ cholesterol, LDL, VLDL; ↑ HDL.	NS total fat but ↓ saturated fat on fish diet. EPA was 1.91 g/day versus 0.06 g/day in baseline and 0.01 g/day on meat; total omega-3 fatty acids were 6.1 g/day on fish, and 0.9 g/day otherwise.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Zambon et al. (Ref. 304).	Randomized crossover trial of fish oil 15 g/day SuperEPA (8 g EPA plus DHA ethyl esters), with and without glyburide 8 weeks on fish oil, 4 weeks on and 4 weeks off glyburide. Baseline treatment was glyburide alone, 4 weeks.	10 females with NIDDM.	Regular diets. Insulin by radioimmunoassay. Automated glucose analysis. Cholesterol by enzymatic methods.	Fish oil ↑ fasting glucose, NS fasting insulin, ↓ postprandial insulin. Fish oil ↑ LDL, NS cholesterol, HDL	High amount of omega-3 fatty acids may produce effects on glucose metabolism not seen with lower amounts. Effects are consistent with other reports, but absence of polyunsaturated fat control limits inferences about specificity of the effects.

Abbreviations used: apoA, apoprotein A (a protein in high-density liporpotein) apoE, apoprotein E (a protein in many lipoproteins, most notable VLDL and HDL); ASA, acetylsalicylic acid; ATP, adenosine triphosphate; CDC, Centers for Disease Control; CHD, coronary heart disease; ELISA, enzyme-linked immunosorbant assay; MDA, malondialdehyde; NIDDM, noninsulin dependent diabetes mellitus; NS, not statisticalluy significantly different; PGE-M, prostaglandin-M; TBARS, thiobarbituric acid reactive substances; TG's, triglycerides; TXB, thromboxane.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 91N-0096]
RIN 0905-AB67

Food Labeling: Health Claims and Label Statements; Dietary Saturated Fat and Cholesterol and Coronary Heart Disease

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing its decision to authorize the use on the label or labeling of certain foods of health claims relating to an association between dietary lipids (specifically, saturated fat and cholesterol) and cardiovascular disease (specifically, coronary heart disease (CHD)). The agency has concluded that, based on the totality of the scientific evidence, there is significant scientific agreement among qualified experts that diets low in saturated fat and cholesterol may reduce the risk of heart disease. Therefore, FDA has concluded that claims on foods relating the reduction in dietary saturated fat and cholesterol to reduced risk of CHD are justified. This action is in response to provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) that bear on health claims and has been developed in accordance with the final rule on general requirements for health claims, which is published elsewhere in this issue of the **Federal Register**.

EFFECTIVE DATE: May 8, 1993.

FOR FURTHER INFORMATION CONTACT: Paddy Wiesenfeld, Center for Food Safety and Applied Nutrition (HFS-465), Food and Drug Administration, 8301 Muirkirk Rd., Beltsville, MD 20708, 301-344-5825.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 27, 1991 (56 FR 60727), FDA proposed to authorize the use in food labeling of health claims relating diets low in saturated fat and cholesterol to decreased risk of CHD. The proposed rule was issued in response to provisions of the 1990 amendments (Pub. L. 101-535) that bear on health claims and in accordance with the proposed general requirements for health claims for food (56 FR 60537, November 27, 1991). As amended by the 1990 amendments, the Federal Food, Drug, and Cosmetic Act (the act) provides that a food is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition unless the claim is made in accordance with section 403(r)(3) or (r)(5)(D) of the act (21 U.S.C. 343(r)(3) or (r)(5)(D)).

Section 3(b)(1)(A) of the 1990 amendments specifically requires that the agency determine whether claims respecting 10 nutrient/disease relationships meet the requirements of section 403(r)(3) or (r)(5)(D) of the act. The relationship between dietary lipids and cardiovascular disease is one of the claims required to be evaluated. In the **Federal Register** of March 28, 1991 (56 FR 12932), FDA published a notice requesting scientific data and information on the 10 specific topic areas identified. Relevant scientific studies and data received in response to this request were considered as part of the agency's review of the scientific literature on lipids and cardiovascular disease. Comments received in response to the notice and not specifically addressed in the proposed rule are summarized and addressed in this document.

Because of the extremely large volume of scientific literature on this topic, FDA limited its scientific review to those aspects of the relationship for which the strongest scientific evidence and agreement already existed: dietary intakes of total saturated fats and cholesterol relative to risk of CHD. In addition to evaluating the scientific evidence relating saturated fat and cholesterol to cardiovascular disease, the proposed rule identified qualifying and disqualifying criteria for foods, specified mandatory and optional information for health claims statements, and provided model health claims. FDA also discussed potential safety issues associated with reducing current dietary intakes of saturated fat, cholesterol, and total fat.

FDA requested written comments in response to the proposed rule and solicited comments on several issues in particular. The agency asked how to restrict the use of these health claims to foods that are appropriately included as part of healthy diets, and whether there is a need for consumer summaries.

On January 30 and 31, 1992, FDA held public hearings on all aspects of the proposed rules published in response to the 1990 amendments, including health claims for dietary saturated fat and cholesterol and heart disease (57 FR 239).

In response to its proposed health claim on lipids and cardiovascular disease, the agency received approximately 100 comments from consumers, consumer advocacy groups, State health departments, organizations of health professionals, the food industry, and Government agencies. A number of comments were received that were more appropriately answered in other documents, and these were forwarded to the appropriate docket for response.

II. Comments on the Relationship Between Dietary Saturated Fats and Cholesterol and CHD

The majority of comments supported FDA's conclusion, noting that the scientific evidence that dietary saturated fat and cholesterol increase the risk of CHD is very strong and well accepted in the scientific community. Many of these comments provided little or no detail on their reasoning. One detailed comment that supported the saturated fat and cholesterol/heart disease relationship was the report of the Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology (FASEB), which evaluated recent scientific publications on this topic. The FASEB draft report was summarized by FDA in the November 27, 1991, proposal (Ref. 78). The final report was submitted to the docket as a comment (Ref. 196). The conclusions of the final LSRO report concur with previous dietary guideline recommendations that reducing intakes of saturated fat and cholesterol would lower total blood and low-density lipoprotein-cholesterol (LDL-cholesterol) levels and, thus, lower risks of CHD in the U.S. population.

A number of comments suggested modification and revision in various provisions of the proposal. A summary of the suggested changes and the agency's responses follows.

1. The agency received a number of comments focusing exclusively on dietary cholesterol as a risk factor for heart disease. Some comments suggested that the scientific evidence does not support a relationship between dietary cholesterol and blood cholesterol levels and suggested that the nutrient/disease linkage is primarily with saturated fat. The comments noted that most dietary cholesterol is not absorbed, and that individual responses to dietary cholesterol are highly variable. Conversely, many comments noted the compelling nature of the scientific evidence linking dietary cholesterol to risk of heart disease. The 1992 LSRO review of the science on this topic (Ref. 196) not only strongly supported the relationship between dietary cholesterol and increased blood

cholesterol levels but suggested that newer evidence increased the importance of dietary cholesterol as a risk factor for heart disease.

FDA agrees with those comments that suggested that there is adequate scientific evidence and significant scientific agreement that diets high in cholesterol increase the risk of heart disease. This conclusion is consistent with current dietary guidance and nutrition policy statements from the Federal Government (Refs. 29, 36, 136, and 150), the National Academy of Sciences (Ref. 20), and the recent LSRO report (Ref. 196). None of the comments that argued against such a link submitted either data or compelling logic to convince FDA that this conclusion is not correct. FDA recognize that there is some scientific disagreement about the relative importance of dietary cholesterol versus saturated fat intakes (56 FR 60730). However, there are strong and consistent data that support that saturated fat and cholesterol have independent effects on the risk of heart disease. Because the data support an independent effect for dietary cholesterol and for saturated fat, the relative importance of dietary cholesterol versus saturated fat on blood cholesterol levels and risk of heart disease really is irrelevant to the agency's conclusion that a health claim on both nutrients is appropriate. FDA recognizes that individual responses to dietary cholesterol are less consistent than to saturated fat. However, recent authoritative reviews (Refs. 20, 29, 31 through 36, 63, 71, 74, 98, 99, 129, 130, 136, 141, 150, 151, and 223) have concluded that the majority of persons in the United States will benefit from recommended dietary changes in cholesterol intake, even though the magnitude of the benefit varies among individuals.

2. Several comments stated that FDA did not address the issue of a beneficial role for dietary *cis*-monounsaturated fatty acids (MUFA's), a major source of dietary fat in the United States, in reducing the risk of heart disease. In this context, one comment noted that the Keys equation, which was used in several studies for predicting or explaining changes in blood total cholesterol based on dietary intakes of saturated and polyunsaturated fatty acids (PUFA's), was inadequate as a basis for evaluating the role of dietary lipids in reducing risk of heart disease, because it does not include a term for the amount of MUFA's. The comment further stated that, in light of newer data on possible beneficial effects of MUFA's, this equation may no longer adequately reflect the predictive value of changes in fat intakes to changes in blood cholesterol levels in the U.S. population.

The LSRO report (Ref. 196) evaluated the potential usefulness of oleic acid, the major *cis*-monounsaturated fatty acid, as a replacement for saturated fat in the American diet. The report concluded that recent research results are consistent with the conclusions that substitution of oleic acid for saturated fatty acids (SFA's) in the diet is safe and without adverse effects on blood LDL-cholesterol levels. The report stated that substitution of *cis*-monounsaturated fats for saturated fats can allow Americans to maintain customary intakes of total dietary fat without the negative effects of the more cholesterol-raising SFA's (i.e., lauric, myristic, and palmitic fatty acids). The LSRO report noted, however, that a diet high in monounsaturated fats (i.e., oleic acid) may contribute to development of obesity, a risk factor for heart disease.

FDA is aware of the recent and ongoing research efforts on the possible beneficial role of *cis*-forms of MUFA's in helping Americans to find a practical means of reducing saturated fat intake without changing total dietary fat intakes (Refs. 6, 37, 53, 57, 89, 93, 139, 144, 158, 159, 175, 180, 188, 192, 196, and 219). FDA, however, considers this issue outside the scope of this rule. In the proposed rule, the agency noted that, because of the extremely large volume of scientific research on lipids and cardiovascular disease and because of the extremely limited time constraints of the 1990 amendments, it had limited its science review to an evaluation of the relationship of saturated fat and cholesterol intakes to risk of CHD. Therefore, in both the proposed and final rules, FDA has limited the health claim to saturated fats and cholesterol.

FDA notes that the rapidly expanding science base may now, or in the future, be adequate to support that *cis*-monounsaturated fatty acids have a beneficial role in reducing blood total and LDL-cholesterol levels. However, because the question of whether this nutrient/disease relationship is appropriate for a health claim is outside the scope of this rulemaking, the question should be the subject of a petition for a health claim in accordance with the provisions of the final rule on general requirements for health claims published elsewhere in this issue of the **Federal Register**.

3. One comment suggested that novel fats that affect a surrogate marker for the disease, such as lowering of blood LDL-cholesterol, should be allowed to carry a health claim.

FDA is aware that a large amount of research and development is being done on novel fats. Novel fats are those fats that are not commonly found in the food supply. Some examples of novel fats include those fats modified by rearrangement of fatty acids in triglyceride or by the addition of a cyclic or aromatic ring to a fatty acid. (The issue of "bioavailability" of novel fats is addressed elsewhere in this issue of the **Federal Register** in the final rules on mandatory nutrition labeling, nutrient content claims, and health claims.)

FDA did not have any scientific evidence on the possible effects of specific novel fats on risk of heart disease, or on other validated surrogate markers for heart disease, in developing this final rule. Therefore, FDA has not dealt with this issue in this final rule.

III. Qualifying Nutrients

The qualifying levels for saturated fat, cholesterol, and total fat are the maximum level at which these nutrients may be present in a food if it is to qualify to bear a claim. The levels of saturated fat, cholesterol, and total fat in a food must be less than those specified in the qualifying levels for the food to be eligible.

A. Saturated Fat and Cholesterol

In the proposed rule, FDA tentatively provided that, to bear a claim associating a diet low in saturated fat and cholesterol with reduced rate of coronary heart disease, the food must be "low saturated fat," "low cholesterol," and "low fat," as those terms are defined in new § 101.62. FDA also proposed to require that the food contain 1 g or less of saturated fat per 100 g of food.

4. A number of comments recommended that claims include information about the amount of saturated fat and cholesterol beyond the information contained on the nutrition panel. Some comments recommended the use of an index or "cholesterol-saturated fat index" (CSI) that integrates known relative effects of saturated fat and cholesterol intakes in predicting increased changes in total and LDL-cholesterol levels (Refs. 202 and 203). These comments pointed out that the CSI consists of a single score or number by which it would be possible to determine the relative cholesterol-raising propensity of a given food. The comments suggested that the CSI for a given food would be calculated from the experimentally-derived formula: (1.01 × g saturated fat) + (0.05 × mg cholesterol).

One comment included a detailed listing of CSI's for a wide variety of foods, including milk with 1-percent fat, which had a CSI of 2, and butter, which had a CSI of 37.

FDA agrees with the concept that consumers should have label information presented in a manner that enables them to evaluate an individual food relative to total dietary goals. However, the agency has not included any requirement for use of a CSI index in the final rule. The comments did not provide data to show that consumers would find use of a CSI index more helpful than the nutrition information currently required on food labeling. FDA is concerned that consumers might place undue emphasis on the CSI index in purchasing decisions and not concentrate on consuming healthful diets, which include a variety of foods.

FDA considers that a consistent approach to nutrition information on food labels will be less confusing to consumers than the use of a CSI index. FDA's general approach is to provide information that allows a consumer to construct a diet that is consistent with the particular health claim and with general dietary recommendations. The use of a CSI index, however, would be inconsistent with that approach because it would likely lead the consumer to place more emphasis on the specific food than on the entire diet. In addition, the larger scientific community has not generally agreed on a particular symbol or approach, such as the CSI index, for helping consumers to identify foods that will help lower their risk of heart disease.

Thus, FDA is retaining its proposed approach with respect to the label information that must appear on foods that qualify for a health claim on lipids and heart disease.

5. A few comments suggested that foods that contain eggs or egg products should be eligible to bear the authorized health claim.

The agency agrees that a food containing eggs or egg products should not be denied a health claim for saturated fat and cholesterol and heart disease, provided that the food is "low saturated fat," "low cholesterol," and "low total fat" and meets the other qualifying requirements for a health claim on this topic. The qualifying criterion for cholesterol is based on the final concentration of cholesterol in the food product and not on the cholesterol content of ingredients. Therefore, if eggs and egg products used as ingredients do not cause a food to exceed the definition of "low cholesterol," the food may qualify for a health claim.

6. Other comments suggested that the qualifying level for the saturated fat and cholesterol content of a serving of food be made less restrictive so that a larger number of wholesome foods can qualify for a health claim. Some of the comments stated that the permissible level of 1 g of saturated fat for a serving of food should be increased io 2 g. A few comments proposed that "foods that contain 20 milligrams or less of cholesterol per serving and 2 grams or less of saturated fat should be allowed to make a health claim." Other comments asserted that the saturated fat and cholesterol/heart disease health claims should be allowed on foods that qualify for the comparative claim, "reduced cholesterol." Some comments also objected to the per 100 g density criterion for qualifying levels of saturated fat and cholesterol, suggesting that it unfairly discriminates against foods that have a useful dietary role in reducing the risk of heart disease but that, because their servings sizes are less than 100 g, exceed the qualifying criterion on a per 100-g density basis.

Based on the large number of comments that the agency received, FDA has reassessed the qualifying levels for saturated fat, total fat, and cholesterol, including the density criterion. (See the final rule on general requirements for nutrient content claims published in this issue of the **Federal Register** for a more detailed discussion. FDA incorporates that discussion by cross reference. Based on this reanalysis and on the comments received, FDA has been persuaded that the second qualifying criterion based on per 100 g is too restrictive for "low fat" and "low cholesterol" claims. (The proposed definition for "low cholesterol" did not include a per 100-g criterion.) The agency has concluded that this criterion should be modified to more directly reflect the nutrient dence foods with small serving sizes that it was designed to address. Therefore, FDA has modified the density criterion from a per 100-g basis to a per 50-g basis for foods that have a reference amount customarily consumed of 30 g or of 2 tablespoons or less. With this modification, a larger number of wholesome foods may qualify for a health claim, including more brands of breakfast cereals and cereal grain products (Ref. 222).

The agency disagrees that "reduced cholesterol" and other comparative claims should be the basis for qualifying levels of nutrients. Many foods, even after meeting the requirements for "reduced" claims, contain significant amounts of saturated fat or cholesterol. When making substitute choices among similar types of foods (e.g., deciding upon which brand of vegetable oil to purchase), comparison claims are very useful in helping consumers to make a choice. However, when putting foods together within a total dietary context, the absolute amount of nutrient present in a food is important.

7. Some comments noted that FDA's proposed definition of saturated fat (i.e., the sum of lauric, myristic, palmitic, and stearic acids) is not consistent with the most recent evidence on cholesterol-raising fatty acids. The comments suggested that the cholesterol-raising characteristics of SFA's are due almost entirely to three SFA's: lauric, myristic and palmitic fatty acids. Conversely, stearic acid, which is a significant source of SFA's in the U.S. diet, has relatively little effect on blood cholesterol levels. The comments further note that this variability in cholesterol-raising potential opens new opportunities to replace cholesterol-raising saturates with other saturates that are not cholesterol-raisers (i.e., stearic acid).

The agency agrees that specific SFA's vary in their potential for an adverse effect on blood cholesterol levels and on other atherosclerotic risk factors. In the proposed rule (56 FR 60727 at 60734), FDA acknowledged that lauric, myristic, and palmitic SFA's have the greatest effect on blood cholesterol levels, and that, in this respect, stearic acid is relatively neutral. FDA disagrees, however, that the definition of saturated fat should be limited only to the sum of lauric, myristic, and palmitic fatty acids. In the final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**, and in response to comments, FDA has changed the definition of saturated fat to include the sum of all fatty acids containing no double bonds. This definition will apply to all references to saturated fat on the food label. Also, as noted in the preamble to the final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**, this definition for saturated fat is consistent with dietary guidelines for diets to reduce risk of heart disease (i.e., consume less than 10 percent of calories as saturated fat; therefore, all four saturated fat (lauric, myristic, palmitic and stearic) plus less abundant saturated fats are included in the new definition.) Furthermore, FDA has noted that elevated blood cholesterol is not the only risk factor for cardiovascular disease (56 FR 60727 at 60734). Saturated fats have been implicated as possibly increasing the risk of cardiovascular disease through mechanisms other than adverse effects

on blood total and LDL-cholesterol (Ref. 20).

B. Total Dietary Fat as a Qualifying Criterion

In the proposal (56 FR 60727 at 60739), FDA proposed to prohibit health claims relating diets low in saturated fat or cholesterol to lower blood cholesterol levels and reduced risk of CHD unless the food also meets requirements for a "low" claim relative to total fat content (i.e., 3 g or less of fat per label serving size, per reference amount customarily consumed, and per 100 g). FDA notes that, while total fat is not as strongly or directly linked to increased risk of CHD as it may have significant indirect effects.

8. A number of comments supported the agency's position that a food must not only be low in saturated fat and low in cholesterol but must also be low in total fat, and that decreasing total fat intakes will generally aid in decreasing intakes of saturated fat and cholesterol. However, several comments opposed the additional "low fat" qualifying criterion, suggesting that foods recommended by public health authorities (such as fish, chicken, and lean beef and vegetable oils that are low in saturated fat and cholesterol) would not qualify for a health claim and that this would appear inconsistent with efforts to encourage an overall healthful diet.

FDA agrees that total fats are an appropriate qualifying criterion, and this provision is retained in new § 101.75(c)(2)(ii). (In the November 1991 proposed rules, FDA combined the regulations for lipids and cardiovasuclar disease (proposed § 101.73(a)) and lipids and cancer (proposed § 101.73(b)) into one section. In these final regulations, FDA has separated the two health claims into individual sections. New § 101.75 covers dietary saturated fat and cholesterol and coronary heart disease. New § 101.73 covers dietary fat and cancer.) FDA has retained this criterion because low fat foods generally help individuals in reducing their intake of saturated fat and cholesterol. In addition, excess calories, of which fat contributes more per g than the other energy nutrients, is associated with two health-related conditions (obesity and diabetes) that are risk factors for heart disease. These provisions now read in new § 101.75(c)(2)(ii): "The food shall meet all the requirements for a 'low saturated fat,' 'low cholesterol,' and 'low fat' food; * * *."

FDA agrees that lean meats, fish, and poultry, when eaten in moderation and prepared with little or no added fat, can play an important role in helping consumers to meet dietary guidelines. Meats, fish, and poultry play an important role in the U.S. dietary pattern, serving as entrees as well as rich sources of protein, bioavailable sources of many minerals, and rich sources of several vitamins. As proposed, the qualifying criteria virtually prohibit this category of foods from bearing health claims. As a result, the proposed criteria may inadvertantly interfere with the dietary guidance goals of encouraging consumption of a variety of foods and of increased use of lean meats, fish, and poultry instead of higher fat cuts.

In the final rule on general requirements for nutrient content claims published elsewhere in this issue of the **Federal Register**, FDA is defining the term "extra lean" as a claim for game meats and fish. Although this definition is not as stringent as the definition for "low fat," "low saturated fat," and "low cholesterol," it is consistent with the U.S. Department of Agriculture (USDA) definition for "extra lean" for meats and poultry.

The agency is persuaded that, to be consistent with the dietary guidence goals discussed above, health claims should be allowed on "extra lean" cuts of meat, fish, and poultry. FDA is therefore providing for saturated fat and cholesterol/CHD claims on "extra lean" game meats and fish that meet these requirements. This provision is added in new § 101.75(c)(2)(ii) which reads: "* * * except that fish and game meats (i.e., deer, bison, rabbit, quail, geese, and ostrich) may meet the requirements for 'extra lean' in § 101.62."

FDA disagrees with the comment suggesting that foods consisting entirely of fats and oils, but low in saturated fat and cholesterol, should qualify for heart disease health claims. Low fat diets are recommended in all Federal Government and National Academy of Sciences' dietary guidelines for reducing the risk of heart disease. Labeling of foods that are 100-percent fat with a message implying they are "heart healthy" is clearly inconsistent with dietary guidelines. FDA believes that the use of content claims is a more appropriate method for helping consumers make purchasing decisions about those oil products that they choose to include in their total daily diet than allowing those foods to bear health claims.

9. One comment suggested that total fat should be the basis for both the cancer and the heart disease health claims because these two diseases generally are considered together under a single dietary guidance goal for moderation in intakes of total fat and saturated fat.

The agency agrees that public health dietary guidelines generally focus on the reduction in total fat as a major, single goal when referring to both heart disease and cancer risks. However, health claims are specific for a nutrient-disease relationship. Heart disease and cancer relate to dietary factors through different mechanisms.

In the instance of CHD, dietary saturated fat and cholesterol are the major dietary risk factors because they increase blood LDL-cholesterol levels, which increase the risk of heart disease. As noted in the proposed rule (56 FR 60727 at 60739) and discussed above, total fat consumption affects risk of heart disease indirectly, through its effects on obesity and on facilitating dietary reductions in saturated fat and cholesterol. In contrast to the association between dietary fat and heart disease, the observed association between dietary fat and cancer has not been attributed to a specific type of lipid but has generally been linked to total fat intakes (see the final rule on dietary lipids and cancer published else where in this issue of the **Federal Register**.

Health claims must reflect current scientific understanding and agreement as to the basis of a diet-disease relationship. Thus, total fat is not listed as a causal dietary fat in the health claim. Instead, it is addressed as an additional criterion that must be met by a food before it may carry a health claim relating dietary saturated fat and cholesterol to risk of heart disease, because of the strong indirect effect of fat on heart disease risk. Of course, food labels may also include the claim "low fat" in addition to a health claim in accordance with the requirements for such claims, as discussed in the final rule on general requirements for nutrient content claims elsewhere in this issue of the **Federal Register**.

C. Other Qualifying Criteria

10. Some comments recommended that consumption of foods that alter other risk factors for CHD be included as qualifying nutrients relative to the fat/heart disease claim. For example, because foods high in salt or excess calories from sugars may be related to hypertension or obesity, respectively, the comments requested that limits be placed on the amount of salt or sugars that a food bearing this health claim may contain.

FDA recognizes that both hypertension and obesity are risk factors for heart disease and (see the final rule on sodium and hypertension, published elsewhere in this issue of the **Federal**

Register. As stated in the dietary guidelines, salt and sugars should be used in moderation. However, FDA believes that the arguments for making sugars content a qualifying criterion are considerably less compelling than those for total fat.

FDA has not established a Daily Reference Value for sugars because, other than dental caries, no public health concerns related to sugar have been substantiated (see final rule on Reference Daily Intakes and Daily Reference Values published elsewhere in this issue of the **Federal Register**). A cause-and-effect relationship between sugars intake and obesity is also not well established (Refs. 224 and 225). Conversely, the relationship of fat to obesity is based in part on the fact that fat is a more concentrated source of calories than sugars (9 calories per g versus 4 calories per g). Furthermore, new research suggests that, on a calorie-by-calorie comparison, fat calories may be more likely to be laid down as adipose (fat) tissue in the body than carbohydrate calories (including sugar) (Ref. 20).

Additionally, since saturated fat and cholesterol constitute part of the total fat content of foods, most dietary guidelines suggest that it is generally easier to reduce the target nutrients if total fat also is reduced (Refs. 20, 29, 33, 35, 36, 136, 150, and 151). High total fat intakes are also associated with the risk of cancer (see the final rule on dietary lipids and cancer, published elsewhere in this issue of the **Federal Register**. For these reasons, all current dietary guidelines include reduction of total fat as well as saturated fat and cholesterol when recommending dietary changes to reduce the risk of heart disease. Similar recommendations are not made for sugars (Refs. 20, 35, 136, and 151).

Thus, FDA concludes that the arguments to make sugars content a qualifying or disqualifying criterion are not convincing based on available data. FDA recognizes that all food nutrients, including sugars, have an appropriate role in the diet.

In the case of salt (and sodium), the issue is more difficult. FDA has found that sodium is a risk factor for hypertension (see the final rule on health claims for sodium and hypertension published elsewhere in this issue of the **Federal Register**). Furthermore, hypertension is considered to be a risk factor for cardiovascular disease, particularly for strokes and, to a lesser degree, for heart disease (Refs. 20 and 30 through 36). In choosing qualifying criteria for authorized health claims, FDA has tried to limit the number of qualifying nutrients to those nutrients that are most strongly linked to the nutrient/disease relationship, based on the current science. In the case of total fat, FDA concluded that it is appropriate to include it as a qualifying criterion because saturated fat is a subcomponent of total fat and because dietary guidelines consistently recommend moderate intakes of saturated fat, cholesterol, and total fat.

Sodium is a disqualifying nutrient for the dietary saturated fat and cholesterol/heart disease health claim, as for all health claims (i.e., as finalized, any health claim is prohibited on a food if the food contains 480 mg or more of sodium per reference amount customarily consumed, per label serving, or, if the reference amount is 30 g or less or 2 tablespoons or less per 50 g of food). The suggestion to make sodium a qualifying, rather than a disqualifying nutrient for this claim is less compelling than the argument for total fat. The link of salt to heart disease is not as direct as the link between saturated fat and cholesterol to heart disease. Dietary guidelines generally deal with sodium and fat separately. If sodium were changed from a disqualifying to a qualifying nutrient, that is, if foods were required to be low in sodium to be eligible for a saturated fat/cholesterol and heart disease claim, the number of foods that could bear such a claim would be greatly reduced. Foods excluded would include many foods in the following food categories that are generally found to be useful in meeting healthful diets: vegetable products, whole wheat breads, cereals, legume products, and some dairy products (Ref. 222). By retaining sodium as a disqualifying nutrient, not only will a much broader range of useful foods be allowed to qualify for a fat/heart disease claim, but foods in these and other food categories that contain large amounts of sodium will be disqualified. Examples of foods that will be excluded because their sodium content exceeds the disqualifying levels are certain vegetable products such as sauerkraut and some juices, many soups, and some sauces.

11. Several comments recommended that the agency drop the qualifying requirement for saturated fat in proposed § 101.73(a)(3)(iii), in which FDA proposed that the saturated fat content of the food must be less than 1 g per 100 g of food. One comment suggested that the agency instead require that the food be low in saturated fat or have "not more that 7 percent of calories from saturated fat."

The agency was persuaded by the comments that the additional density requirement (per 100 g) for saturated fat is not necessary. The agency was originally concerned that if it used only the definition for "low saturated fat" in the nutrient content claim proposal; the claim could appear on certain fats and oils. However, the agency has recognized that the requirement that a food meet the "low fat" criteria will prohibit foods that are 100 percent fat, such as oils, from bearing that health claim. The agency therefore has dropped the additional qualifying requirement for saturated fat that was in proposed § 101.73(a)(3)(iii). The agency has determined that the food or food product must meet the following qualifying criteria: "low in saturated fat, low in cholesterol, and low in total fat," as described in the rule on nutrient content claims published elsewhere in this issue of the **Federal Register** and stated in new § 101.75(c)(2)(ii).

IV. Safety Issues

In the proposed rule (56 FR 60727 at 60735), FDA noted that reductions in dietary intakes of saturated fat and cholesterol could result in higher intakes of other dietary components (e.g., monounsaturated and polyunsaturated fats, simple and complex carbohydrates, and commercially generated fats), because calories lost from decreased intakes of saturated fats would likely be "made up" by other energy-yielding nutrients. The availability of saturated fat and cholesterol/heart disease health claims will likely motivate manufacturers to alter the amount and type of fats added to foods, resulting in changes in composition of the U.S. food supply. As FDA discusses more thoroughly in the preamble of the final rule on general requirements for health claims, which appears elsewhere in this issue of the **Federal Register**, changes in consumption patterns may affect whether a food ingredient is safe and lawful under the act. Manufacturers should therefore assure themselves that such consumption changes will not affect the lawful status of the foods containing these ingredients. The agency, in its proposed rule (56 FR 60727 at 60735 to 60737), identified several areas of possible concern regarding changing American dietary patterns.

A. Trans-fatty Acids

One area of potential concern identified in the proposed rule is the potential for increased consumption of *trans*-fatty acids because of substitution of these fats for SFA's in foods. *Trans*-fatty acids (generally isomers of *cis*-monounsaturated fatty acids) are primarily constituents of commercially

hydrogenated or hardened natural vegetable oils used in formulating margarine, shortenings, and salad and cooking oils.

12. A number of comments were received, some agreeing and some disagreeing, on the agency's public health concern that *trans*-fatty acids may have cholesterol-raising characteristics, and, therefore, may increase the risk of heart disease. These concerns were raised in response to the published results of the Mensink and Katan study (Ref. 95). This study assessed the effects of a diet enriched in *trans*-fatty acid on blood lipids in 34 healthy women and 25 healthy men. The study results suggested that compared to an isocaloric diet enriched in oleic acid (a monounsaturated fat), the *trans*-fatty acid diet significantly increased LDL-cholesterol and significantly decreased high-density lipoprotein cholesterol (HDL-cholesterol) levels (two risk factors for heart disease (Refs. 1, 31, 33, 35, 48, 49, 74, 84, 112, 113, and 187)). (An evaluation of study design, results, and public health implications is found in the proposed rule (56 FR 60727 at 60736)).

In addition, the potential adverse health effects of *trans*-monounsaturated fatty acids were evaluated in the final version of the 1992 LSRO report on Lipids and Cardiovascular Disease (Ref. 196). This report states that:

> * * *until recently there was the general belief that *trans*-monounsaturates are "neutral" with respect to serum cholesterol levels. However, the recent findings of Mensink and Katan (1990) strongly suggest that these fatty acids have an adverse effect on serum lipoprotein levels, especially raising LDL-cholesterol levels. Still it hardly seems prudent to alter general dietary recommendations on the basis of a single study, albeit an excellent piece of investigation. Further carefully controlled studies thus appear to be in order before definitive recommendations can be made about *trans*-fatty acids for the American diet.

Other comments stated that "*trans*-fatty acids in foods may increase the risk of CHD equal to or greater than saturated fatty acids." Another comment suggested that "*trans*-fatty acids may increase the risk of coronary heart disease by a mechanism other than by increasing blood cholesterol." Another comment referred to *trans*-fatty acids as "deadly *trans*-fat pollution." Another comment suggested that the agency require a "warning" label for foods containing significant amounts of *trans*-fatty acids. Several comments suggested that *trans*-fatty acids should be included in the declaration of total SFA's content because they may have "cholesterol-raising" effects.

One comment on *trans*-fatty acids provided data that suggested that the *trans*-fatty acid content of some foods such as French fries was much higher than reported in commonly used food composition tables (i.e., that a medium serving of French fries from a fast food restaurant contained 7 g of *trans*-fatty acids, the upper daily limit of consumption suggested in several authoritative reports). Another comment criticized these data suggesting that proper sampling of the class of analyzed food had not been done.

One comment suggested that *cis*- and *trans*-monounsaturated fatty acids have similar metabolic actions. No data were provided in support of this comment, although it pointed out that the 1985 FASEB report on *trans*-fatty acid (Ref. 74) concluded that *trans*-fatty acids did not increase the risk of heart disease. One comment was concerned with the negative tone of the discussion on *trans*-fatty acids and suggested that the cited 1991 study by Mensink and Katan (Ref. 95) on adverse effects of *trans*-fatty acids was limited by its short duration (3 weeks), study population (healthy students), and processing techniques used to generate the hydrogenated *trans*-fatty acid isomers used in the test diets (varying catalyst and time) (Ref. 200). The comment expressed concern that the *trans*-fatty acids used in the test diets differed from those most commonly found in the U.S. food supply (i.e., different positional isomers), and that the *trans*-fatty acids may have been consumed in larger quantities in the test diets than they are generally consumed in the United States. The comment further suggested that a combination of these factors may have created a situation in which the study results suggesting that the consumption of diets enriched in *trans*-fatty acids increase blood LDL-cholesterol levels and decreased blood high density lipoprotein HDL-cholesterol; a blood cholesterol component for which low levels are associated with increased CHD risk (Refs. 1,47 through 49, 74, 75, 112, 113, and 187) were not necessarily applicable to the U.S. population. One comment referred to the report of Nestel (Ref. 177), which compared the effect of edible vegetable oil blends containing hydrogenated fatty acids on serum lipids. (The diets and study design are described in Table 1 of this document.) The results of this study showed that low saturated fat test diets containing *trans*-fatty acids from different oil sources lowered blood total cholesterol and LDL-cholesterol levels significantly as compared to control diets high in saturated fat.

Among the other comments on the study by Mensink and Katan (Ref. 95, 56 FR 60737 at 60736), was a referral to a published article written by Mensink and Katan (Ref. 201) which addressed criticisms of their 1990 study by noting that another study of longer duration (16 weeks), conducted in the same laboratory, found a similar effect on blood cholesterol levels, even after only 2 weeks on the diets (Ref. 201). One comment suggested a need for further research in the area of *trans*-fatty acids and blood cholesterol levels before policy decisions are made.

The agency agrees in general with the conclusions of the 1992 LSRO report that, while the available evidence to date is suggestive that *trans*-monounsaturated fatty acids may have LDL-cholesterol-raising characteristics, there is insufficient evidence upon which to make policy decisions at this time. FDA also notes that the requirement that foods be "low" in total fat before making a fat/heart disease health claim limits a manufacturer's ability to increase *trans*-fatty acid levels in foods, since any substitution of *trans*-fatty acids for SFA's must be done within the 3 g per reference serving size, or per 50 g, limit for total fat. This approach is unlikely to result in significantly increased levels of *trans*-fatty acids in foods qualifying for a health claim. The agency may reconsider the relationship of *trans*-fatty acid to heart disease claims at a later date if new data become available to confirm and strengthen the initial findings of an adverse effect of *trans*-fatty acids on blood LDL- and HDL-cholesterol levels. Results from well-designed scientific studies on the effect of *trans*-fatty acids at, or, slightly above, current U.S. consumption levels on blood lipids levels and on other risk factors for cardiovascular disease will aid the agency in reaching future decisions.

B. PUFA's

In the proposed rule, FDA expressed concerns about possible safety problems associated with consumption of diets enriched in polyunsaturated fats because of the substitution of these fats for SFA's (56 FR 60737 at 60736). Among concerns that FDA raised were potential adverse effects on cell membrane fluidity (a possible risk factor for cardiovascular disease (Ref. 20); decreasing levels of blood HDL-cholesterol; increase in formation of lipid hydroperoxides (oxidized LDL-cholesterol has a high atherogenic potential, Ref. 132); increasing blood

triglyceride levels (a possible risk factor for heart disease (Ref. 187); and increasing the risk of some types of cancer (see the proposed rule on dietary lipids and cancer at 56 FR 60764, November 27, 1991).

13. Many comments raised issues concerning the question of the safety of PUFA's in foods and supplements. Comments suggested that safety issues related to PUFA's included increased risk of cancer, coronary thrombosis, and osteoporosis in humans. A few comments also stated that PUFA's may adversely affect immune function. Conversely, others disagreed with the statement in the proposal that PUFA's may increase predisposition to or frequency of certain types of cancer because none of the dietary consensus documents of the Federal Government identified PUFA's as a risk factor for cancer in humans. One comment disagreed that diets enriched in PUFA's may decrease HDL-cholesterol levels but did agree with the description of results from the study by Wardlaw in Table 2 of the proposed rule (56 FR 60727 at 60764 (Ref. 144)) that, "High concentrations of PUFA's may have pharmacological effects on lowering HDL-cholesterol, however, diets containing 35 percent of calories from fat and a polyunsaturated:saturated fatty acid (P:S) ratio of less than 1.5 are not likely to lower HDL-cholesterol significantly." One comment suggested that diets high in PUFA's (greater than 10 percent of calories) cannot be achieved by the American public, so the potential safety concerns were overly emphasized.

The LSRO report on "Lipids and Cardiovascular Disease," submitted as a comment to the record, separated the evaluation of PUFA's into two categories: omega-6 polyunsaturates and omega-3 polyunsaturates (Ref. 196). Relative to linoleic acid (one of the major types of omega-6 fatty acids in the U.S. diet and an essential fatty acid), the report noted that while:

> * * * higher intakes may slightly reduce LDL-cholesterol * * * a higher consumption may increase risk for some cancers, promote LDL oxidation with the arterial wall, and possibly raise the risk for coronary thrombosis * * *. A reasonable recommendation may be to avoid both excessively low intakes of linoleic acid (below 4 percent of calories) and higher intakes (above 7 percent of calories).

Relative to the second type of PUFA's, the omega-3 fatty acids, the LSRO report noted that:

> Recommendations for increasing omega-3 fatty acids for the purpose of preventing common chronic diseases must be made with caution and only after more conclusive data are available * * *. Since these fatty acids are biologically active, they deserve intense investigation, but not premature recommendations for their consumption by the general public.

FDA agrees with the concern that high levels of intake of PUFA's have the potential for adverse effects in some persons. However, when consumed in amounts similar to current intakes, little or no risk is anticipated (Refs. 20, 29, 31, 33, 35, 74, 78, 136, and 196). Indeed, adequate intakes of essential fatty acids are needed to prevent nutrient deficiencies. By requiring that a food be low in total fat as a qualifying criterion, FDA has made it unlikely that excessively high intakes of PUFA's will be encouraged through the use of a health claim, because there is little room for manipulation of different fats within this range for total fat. Given current levels of intake of essential fatty acids by the U.S. population, deficiencies are not anticipated (56 FR 60727 at 60738; also, see document on dietary lipids and cancer published elsewhere in this issue of the **Federal Register**.

C. Other Safety Issues

14. One comment expressed concern about foods that qualify for a health claim for lipids and cardiovascular disease but that contain a nutrient that may increase the risk of cardiovascular disease or another disease or disorder. As an example, the comment suggested skim milk, which contains no or low fat and cholesterol but does contain casein. The comment suggested that casein has been reported to have atherosclerotic properties in some animals, but no data were provided to support this comment.

The basic concept of this comment, that the use of foods bearing health claims should not unduly increase the risk of disease because of the level of nutrients other than the nutrient that is the subject of the claim, is mandated by section 403(r)(3)(A)(ii) of the act. The preamble of the final rule concerning the general requirements for health claims, which appears elsewhere in this issue of the **Federal Register**, contains an extensive discussion of the agency's implementation of that section of the act through disqualifying nutrient levels.

FDA, however, disagrees with the specifics of this comment, i.e., that casein should be considered a negative component that would disqualify a food from bearing a fat/heart disease claim. FDA is aware of early research suggesting that casein has possible adverse effects on risk of heart disease (Ref. 20). However, these observations have never gained wide acceptance by the scientific community, and casein (a rich source of protein) is not considered to significantly contribute to the risk of heart disease.

V. Miscellaneous Issues

The proposal contained a number of additional provisions addressing both mandatory and optional aspects of claims about lipids and cardiovascular disease in proposed § 101.73(a)(4) and (a)(5). Proposed § 101.73(a)(4)(i) provided that a claim must state that a diet low in saturated fat and cholesterol will reduce high blood cholesterol and, thus, the risk of coronary heart disease. Proposed § 101.73(a)(4)(ii) provided that health claims must include the caveat that "some but not all individuals" would benefit from these dietary changes. Also the terminology for heart disease, blood lipid levels, and dietary fats were described in proposed § 101.73(a)(4)(iii)(A), (a)(4)(iii)(B), and (a)(4)(iii)(C). Furthermore, information on the multifactorial nature of the disease and other risk factors was included as a specific requirement in proposed § 101.73(a)(4)(iv), and optional information on the need for medical guidance and on the prevalence of heart disease in the U.S. population was provided in proposed § 101.73(a)(5)(i) and (a)(5)(ii), respectively. Many of these provisions are addressed in the following comments.

15. Some comments questioned the applicability of a claim relating diets low in saturated fat and cholesterol to reduced risk of heart disease in the general U.S. population. These comments asserted that only about 25 percent of the population may be responsive to reduction in dietary cholesterol and saturated fat. Thus, the comments argued, it would be misleading to imply that all persons would benefit. Conversely, the LSRO report concluded that "all people in the United States * * * will potentially benefit * * * from reductions in dietary saturated fat" (Ref. 196). Relative to dietary cholesterol, the LSRO report noted that "* * * avoidance of high intakes of dietary cholesterol for the whole population is prudent." Another comment suggested that the agency prescribe the term "most" individuals, persons, or people in referring to those people who may benefit from these dietary changes rather than "most but not all people."

As discussed in the proposed rule (56 FR 60727 at 60740), FDA recognizes that the beneficial effects from reduction of intakes of saturated fat and cholesterol are highly variable among individuals, particularly in terms of magnitude of effect. For this reason, FDA proposed to require that health claims make clear that the effects described in the claim

are likely to be realized by "some but not all persons" (proposed § 101.73(a)(4)(ii)). At the same time, FDA does not wish to imply that a health claim on dietary lipids and heart disease in accordance with this rule is not useful information for the general population. Current dietary guidelines and the LSRO report cited above conclude that, even if responses among individuals are variable in magnitude, the majority of the population, including persons with normal blood cholesterol levels, will benefit from these dietary goals (Refs. 20, 29 through 36, 74, 136, and 151). Given the strong scientific agreement that the majority of persons in the U.S. will benefit from a reduction in intake of saturated fat and cholesterol, FDA has concluded that the proposed term "some persons but not all" is too conservative. FDA has thus not included any requirement for indicating that the nutrient/disease relationship is limited to "some persons but not all" in the final rule. Therefore, new § 101.75(c)(2)(i)(A) reads: "The claim states that diets low in saturated fat and cholesterol 'may' or 'might' reduce the risk of heart disease;".

16. Several comments recommended that the agency require that health claims include a statement on seeking medical advice for persons with multiple risk factors for heart disease. These comments suggested that the majority of the population at risk of cardiovascular disease may require medical advice and may need a combination of medication and diet and lifestyle changes. For these persons, adopting a diet low in saturated fat and cholesterol may not substitute for aggressive medical intervention.

FDA agrees that persons with blood LDL-cholesterol levels in the moderate to high risk ranges and with multiple risk factors for heart disease should seek medical advice. However, as noted above, dietary goals for intakes of saturated fat and cholesterol have been recommended for the general population as well as for persons with elevated blood cholesterol levels because of findings of benefit across the entire range of blood cholesterol levels (Refs. 31 and 33). FDA is concerned, therefore, that to require a statement that persons seek medical advice and guidance as part of the health claim might give the erroneous impression to consumers that there is no benefit for them in making the recommended dietary changes unless they have been identified as high risk patients. For this reason, FDA is not persuaded to change the status of information on medical advice from an optional to a mandatory requirement. Thus, the agency is retaining this provision as an optional statement in new § 101.75(d)(7), which states:

> The claim may state that individuals with elevated blood total- or LDL-cholesterol should consult their physicians for medical advice and treatment. If the claim defines high or normal blood total- or LDL-cholesterol levels, then the claim shall state that individuals with high blood cholesterol should consult their physicians for medical advice and treatment.

17. The agency proposed in § 101.73(a)(4)(iv) that the health claim may state that CHD is a multifactorial disease and listed major risk factors for the disease that may be used in the claim. This provision was worded so as to suggest that providing the above information was optional. However, this provision was included among the specific requirements in § 101.73(a)(4).

The agency received comments that both supported and opposed FDA requiring that any health claim describe CHD as a multifactorial disease. Several comments suggested that the multifactorial nature of the disease should be referred to indirectly, while other comments suggested that these multiple factors should be required to be identified in the health claim. Some comments identified a number of modifiable dietary risk factors for cardiovascular disease not included among those listed the proposed health claims such as: sodium (56 FR 60825), fiber (56 FR 60582), and antioxidant vitamins (56 FR 60624). Other comments recommended that the agency require that the most important risk factors for CHD, elevated LDL-cholesterol, high blood pressure, and cigarette smoking, be listed.

FDA recognizes that its proposal was inadvertantly ambiguous about whether the fact that CHD is a multifactorial disease would be a required element of the health claim on dietary lipids and this disease. As pointed out in the proposal (56 FR 60726 at 60740), given the multiple dietary, genetic, and lifestyle risk factors for this disease, consumers would be misled if they were to think that dietary factors are the only risk factors. Given this fact, FDA has concluded that the multifactorial nature of the disease should be a required element (§ 101.75(c)(2)(i)(E)).

The issue that is raised as a result is how the significant risk factors should be presented. FDA is concerned that encouraging an unrestricted listing of risk factors for heart disease could result in the listing on food labels of risk factors with relatively little importance or minimal scientific support or could be used to bypass other label requirements. For example, some comments listed several nutrient risk factors for heart disease, including sodium intake. While FDA is authorizing the use of sodium/hypertension health claims, the agency has not been presented with evidence that sodium intake is a risk factor for heart disease. A claim characterizing the relationship between sodium and heart disease is a health claim and would misbrand a food under section 403(r)(1)(B) of the act unless it is specifically authorized by the agency. Thus, the comments suggested that some would use a list of factors as a backdoor means of making unauthorized health claims. As a result, FDA concludes that only the significant risk factors should appear as part of a health claim. For example, those factors that identify the populations that are at risk, where the general population is not at risk, are appropriate for inclusion in the claim. Listing risk factors that are not significant would be false or misleading and could, as explained above, misbrand the food under section 403(r)(1)(B) of the act.

While FDA has decided that the fact that coronary heart disease is multifactorial should be a mandatory element of nutrition labeling, it has also decided that the specific risk factors need not be. As discussed below in conjunction with model health claims, FDA has received numerous comments that the shorter health claims are, the more likely it is that they will be used and understood. Therefore, given the information that it is requiring, FDA has decided, that on balance, it is not necessary to include the significant risk factors as mandatory elements of a claim.

The listing of risk factors provided in proposed § 101.73(a)(4)(iv) represented scientific consensus as to the most significant factors for heart disease. In this final rule, FDA has redesignated the list of risk factors in proposed § 101.73(a)(4)(iv) as new § 101.75(d)(1). This section provides a list of the factors that, based on general scientific agreement, are the major factors for heart disease. The agency has also provided that any list of risk factors included as part of a health claim may include one or more of these factors but must be limited to the factors on this list. Thus, new § 101.73(d)(1) states that:

> The claim may identify one or more of the following risk factors in addition to saturated fat and cholesterol about which there is general scientific agreement that they are major risk factors for this disease: a family history of coronary heart disease, elevated blood LDL-cholesterol, excess body weight, high blood pressure, cigarette smoking, and long-term physical inactivity.

18. Other comments pointed out that, while excessive intake of some nutrients such as fat may be harmful, there are also minimum intake levels which are essential. Some of the comments suggested that the agency identify minimum thresholds levels for SFA's, MUFA's, PUFA's, total fat, and other dietary nutrients below which intakes should not drop. The comments expressed concern that intakes below these levels would increase risk of nutrient deficiencies.

FDA recognizes that there are intake levels for nutrients below which there may be a risk of nutrient deficiencies that could present a risk of adverse effects. FDA disagrees, however, that these levels should be included in the health claim on dietary saturated fat/cholesterol and heart disease. In the proposed rule for a health claim on lipids and cardiovascular disease and as stated in the proposed rule on dietary lipids and cancer, FDA noted that:

> The requirement of linoleic acid to avoid essential fatty acid deficiency is 1 to 2 percent of total calorie intake. Currently, the average linoleic acid consumption in the U.S. ranges between 5 and 10 percent of total calorie intake, and deficiencies of essential fatty acids are rare in the U.S. Thus, a reduction of total fat consumption from the current 36 to 37 percent of total calorie intake to about 30 percent is not likely to cause essential fatty acid deficiencies in the general population.

(56 FR 60764 at 60712)

Furthermore, as previously noted in the response to comment 14 of this document, the reduction of saturated fat intakes to meet dietary goals for reduction in risk of heart disease is likely to result in increased intakes of PUFA—the source of the essential fatty acid, linoleic acid. Thus, FDA concludes, as was also concluded in several authoritative reports (Refs. 20, 29, 35, 136, and 150), that there is little likelihood of nutritional deficiencies resulting from changes in U.S. dietary patterns in response to health claims relative to saturated fat/cholesterol and heart disease.

19. One comment suggested that health claims not be allowed on foods that have been modified to meet the "low fat," "low saturated fat" or "low cholesterol" requirements unless the foods are nutritionally equivalent to the unmodified versions of those foods. FDA rejects this comment. The issue of the effects of a failure to maintain nutritional equivalency are fully addressed by § 101.3(e) of FDA's regulations, and in the final rule on standardized foods named by use of a nutrient content claim and a traditional standardized term, published elsewhere in this issue of the Federal Register. As long as a food meets the requirements of those regulations, § 101.14, and § 101.75, it may bear a health claim on the relationship of saturated fat and cholesterol and coronary heart disease.

20. One comment asked the agency to reconsider its position that health claims are inappropriate for foods intended to be consumed by infants and toddlers of less than 2 years of age; second, to reconsider the amount of total fat, saturated fat and cholesterol that meet requirements for health for infants and toddlers; third, to reconsider the age when infants and toddlers should start to consume "low fat" diets. The comment recommended that low saturated fat, low cholesterol, and low fat diets should be extended to even earlier ages, and that the percent of calories from fat for infants and toddlers should be less than 30 percent to reduce obesity, a risk factor for heart disease. The comment did not submit scientific data to support the proposition that a reduction in heart disease would occur if infants and toddlers consumed low fat diets (*i.e.*, less than 25 percent of calories) earlier than 2 years of age.

FDA disagrees with the comment. In the 1990 amendments, Congress indicated that, if FDA's decision on a health claim petition deviated from recommendations of the Federal Government, those differences should be justified (section 403(r)(4)(C) of the act). The agency based its conclusions on the report from the National Cholesterol Education Program (NCEP) on population strategies for healthy children and adolescents (56 FR 60727 at 60731 (Ref. 34)). This report stated that general dietary recommendations for diets low in saturated fat, cholesterol, and total fat should be extended to cover toddlers and children 2 years and older. FDA has seen no compelling evidence to counter the conclusions of the NCEP report.

21. Several comments supported the agency's proposed limitation in proposed § 101.73(a)(4)(iii) on interchangeable terms for the disease, for lipids levels, and for the nutrients involved. Another comment suggested that the term "low density lipoprotein cholesterol" or the term "LDL-cholesterol" be used in place of the term "total blood cholesterol."

FDA agrees that the term "LDL-cholesterol" is more precise than the term "blood total cholesterol," but disagrees that it should be used in place of the term "total blood cholesterol" in § 101.75(d)(2) of the final rule. FDA, in proposing the term "total blood cholesterol" was using language commonly used in dietary guidance materials at the time of the proposal. Since the publication of the proposal, the National Heart, Lung and Blood Institute (NHLBI) of the National Institutes of Health (NIH) held a consensus conference on Triglycerides, High Density Lipoprotein, and Coronary Heart Disease in February 1992 (Ref. 187). As a result of that conference, a consensus panel draft report was published reconfirming that high levels of blood LDL-cholesterol are associated with high risk of CHD. The consensus conference panel draft report also concluded that low levels of another blood cholesterol component, HDL-cholesterol, in conjunction with high levels of LDL-cholesterol, were associated with a higher risk of heart disease. These two different cholesterol transport components of blood cholesterol when considered in combination are better predictors of risk than when considered independently.

The agency believes that the term "blood total cholesterol" should be retained to minimize consumer confusion, since that term is used in dietary guidance materials and many consumers know their blood total cholesterol levels. However, the agency believes that consumers will eventually learn that high LDL-cholesterol levels are strongly associated with risk of heart disease and are reduced by diets low in saturated fat and cholesterol in most people. The agency has therefore specified in new § 101.75(d)(2) that the term "LDL-cholesterol" may optionally be used in addition to the term "blood cholesterol," and states: "The claim may indicate that the relationship of saturated fat and cholesterol to heart disease is through the intermediate link of "blood cholesterol" or, "blood total- and LDL-cholesterol."

In other respects, the agency is carrying forward the terminology from the proposal in new § 101.75(c)(2)(i)(B), the agency is limiting the terms used to specify the disease to heart disease or coronary heart disease. This provision is consistent with proposed § 101.73(a)(4)(iii)(A). Furthermore, in new § 101.75(c)(2)(i)(C), the agency retains the limitations on specifying the nutrient in proposed § 101.73(a)(4)(iii)(C). However, § 101.75(c)(2)(i)(C) states that: "In specifying the nutrient, the claim uses the terms 'saturated fat' and 'cholesterol,' and lists both;".

22. One comment requested that health claims relating to lipids and cardiovascular disease be allowed for fruits and vegetables, which are naturally low in saturated fat, total fat, and cholesterol.

FDA agrees that fruits and vegetables should be allowed to bear appropriate health claims. The agency notes that because most fruits and vegetables are naturally low in saturated fat and do not contain cholesterol, they will meet the qualifying criterion of new § 101.62 for "low saturated fat," "low cholesterol," and "low total fat," and thus will qualify under § 101.75(c) to bear this claim.

FDA advises that it has made a couple of additional minor changes in § 101.75. The agency has added § 101.75(a)(1), which, consistent with other regulations that the agency is adopting that authorize health claims, defines some of the terms in the regulation. These definitions are consistent with generally accepted science and with the discussion in the proposal. In addition in § 101.75(d)(5), FDA has added the National Institutes of Health and "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 29) in recognition that both are sources of information on the number of Americans with heart disease.

VI. Model Health Claims

23. Several comments suggested that the model health claims should be reduced in length. Some suggested that health claims should follow examples established by the Surgeon General's office, keeping the health claim in a precise, easily understandable text. One manufacturer submitted model health claims and examples of labeling. One comment submitted an example of a possible health claim: "Eating a healthful diet low in fat, saturated fat and cholesterol can help reduce the risk of heart disease." Another comment suggested that the health claim should state: "This ———— can be part of a total diet low in saturated fat and cholesterol, which can reduce risk of heart disease. Use in place of more saturated fats as part of a diet low in total fat. Contains ———— grams of saturated fat, ———— grams of total fat per serving." Another comment recommended an additional statement to be added to the health claim: "In vitro and animal data are often useful for formulating research hypotheses, but can be inappropriate and unreliable for making public policy."

FDA agrees with the comments that, to the extent possible, the model health claims should be shortened and made more understandable. They are more likely to be used by manufacturers if they take up as small an amount of label space as possible. Consumers will be more likely to read messages if they are stated simply and succinctly. However, section 403(r)(3)(B)(iii) of the act requires that health claim regulations ensure that claims accurately represent the nutrient/disease relationship and its significance and enable consumers to understand the information and its significance in the context of the total daily diet. Thus, there are constraints on FDA's authority to permit claims to be abbreviated.

The issue of shorter health claims has been discussed in detail in the preamble to the final rule on general requirements for health claims published elsewhere in this issue of the **Federal Register**. As noted in comment 15 of this document, FDA has dropped the phrase "in some but not all." Additionally, FDA is making reference to the blood cholesterol linkage between dietary saturated fat and cholesterol and risk of heart disease optional. FDA reasons that this amount of detail is not necessary to motivate consumers to implement recommended dietary changes and contributes to wordiness. Thus, the minimum requirements can now be met with a statement as simple as "While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease." Additional provisions that were included in the proposed rule have been deleted or made optional to simplify health claims. Other model health claims are provided in new § 101.75(e). As discussed earlier in this preamble, FDA does, however, believe it is important for each model health claim to acknowledge that many factors affect heart disease.

Other changes incorporated into the final regulation include reorganization of paragraphs and clarification of requirements. The final regulation requires claims to use the word "may" or "might" rather than "can" or other words when describing the possible effect of a diet low in fat and cholesterol on risk of heart disease (§ 101.75(c)(2)(i)(A)). Although FDA recognizes that it cannot require preclearance of claims, it considers this and other restrictions on word choices to be necessary so that claims will accurately reflect the state of the science. All changes in the final regulation are a logical outgrowth of the proposal.

24. A few comments suggested that the agency amend the language of the health claim to include "very-low fat, low-cholesterol diets begin to reverse CHD in some patients." Accompanying the comments were six scientific publications describing six clinical trials. The comments thus suggested tighter criteria for the qualifying levels of fat and cholesterol, e.g., "very low," and a replacement of "may reduce the risk of" with a stronger statement about a "reversal" of CHD. In addition, the suggested claim would target one segment of the general population which is at increased risk for heart disease. The comments submitted a number of publications to justify use of the term "reversal" of heart disease.

FDA does not agree that the submitted publications justify the statement that heart disease may be reversed by very low fat, low saturated fat, and low cholesterol diets. Three of the randomized, controlled trials were previously reviewed (in Table 2 of the proposal) by the agency (56 FR 60727 at 60754 through 60755 and 60763) (Refs. 12, 14, and 106). The fourth was conducted in 1984 (Ref. 197) and therefore evaluated by Government and other public health authoritative reports, and the two remaining studies did not provide adequate information to be able to attribute beneficial results to specific dietary components (Refs. 198 and 199). Thus, while FDA finds these results very interesting and considers the studies to suggest a decrease in progression of heart disease from the combination of medical interventions used in these studies, FDA has concluded that these results are not applicable to health claims for several reasons. First, the treatment modality used to obtain results was primarily drugs that lower both blood lipids and blood pressure, in combination with dietary changes. Secondly, the treatment changes were quite severe, and their implementation in the general population is unlikely to be a reasonable goal. Finally, subjects were persons with serious preexisting CHD and under close medical supervision.

25. An association of medical professionals provided a number of references that suggest serum cholesterol goals for patients with noninsulin-dependent diabetes mellitus and patients with hyperlipidemia. The comment asked that the health claim be required to specifically identify and target this group of individuals as high-risk populations.

FDA disagrees that specific dietary advice and goals for persons with diseases such as noninsulin-dependent diabetes mellitus and hyperlipidemia should be required to be included as part of health claim messages. These are serious health conditions and require medical supervision. Health claims are intended for the general population. Foods bearing claims for conditions requiring medical supervision are more appropriately regulated as foods for special dietary use, as medical foods, or as drugs, depending upon the specifics of the food and the claims made for it.

VII. Consumer Summary

FDA also proposed to make available consumer summaries to provide additional information on the health claim. Comments from consumers, health care professionals, public health associations, and the food industry supported the use and availability of consumer summaries. FDA did not receive any comments that did not support the use of consumer summaries for this health claim regulation. Comments were received, however, for other health claim regulations suggesting that there was no need for consumer summaries.

As discussed in the final rule on general requirements for health claims published elsewhere in this issue of the Federal Register, consumer summaries are not required, although their use remains an option. For this reason, the proposed consumer summary has not been included in this final rule.

VIII. Summary of Updated Science Review

To ensure that significant new evidence had not become available subsequent to the proposal, FDA updated its review of the scientific evidence with human studies that were directly relevant to the proposed rule or that became available after publication of its proposal (Table).

A. Relationship of Dietary Saturated Fat and Cholesterol to Blood Cholesterol and, Therefore, to Risk of Heart Disease.

1. Saturated Fat

In the proposed rule (56 FR 60727 at 60728), FDA accepted the conclusions of consensus documents that serum cholesterol levels are a valid intermediate predictor of risk of heart disease (Refs. 20, 29 through 36, 74, 136, 150, and 151). FDA limited its evaluation of the nutrient/disease relationship to diets low in saturated fat and cholesterol and reduced risk of CHD. FDA additionally proposed that health claims should be prohibited on foods that are not low in fat because of strong indirect links between high fat diets and risk of heart disease.

A recent study supports the applicability of dietary modifications to children. A longitudinal study in 108 healthy Hispanic preschool children (Ref. 183) compared children in the highest tertile (a tertile is a comparison based on thirds, i.e., highest, middle and lowest tertile) of total fat and saturated fat consumption (36.2 percent and 14.6 percent of calories as fat and saturated fat, respectively) to children in the lowest tertile (30 percent and 11 percent of calories as fat and saturated fat). Higher total fat and saturated fat intakes were associated with higher blood total and LDL- cholesterol levels (Table).

Several new clinical trials provide additional support that reductions in intakes of dietary saturated fat and cholesterol reduce serum total and LDL-cholesterol levels, even though serum triglyceride and HDL-cholesterol levels do not change significantly.

Deneke et al. (Ref. 162) compared the effects on blood cholesterol levels in 10 men, mean age 66, (Table) of isocaloric, liquid diets differing in type and amount of SFA. In the self controlled, cross-over study, the saturated fat was derived from either butter (25 percent SFA), beef (18 percent SFA), cocoa butter (23 percent SFA) or olive oil (8 percent SFA). These fat diets also differed in the amount of stearic acid: 4, 7.6, 13 and 1.2 percent, respectively. Diets enriched in saturated fat from butter, beef, or cocoa butter, significantly increased total cholesterol and LDL-cholesterol compared to diets containing less saturated fat. The higher concentration of stearic acid in both beef and cocoa butter diets did not negate the effect of saturated fat on blood cholesterol levels. Under the conditions of the study design, stearic acid was neutral in its ability to change blood cholesterol levels. This study should be repeated using more subjects, including healthy subjects, and with solid foods to provide nutritional data that is more applicable to the general public.

In another dietary intervention study, the effects of a low fat, low saturated fat, no cholesterol diet on serum cholesterol was reported (Ref. 184). Five familial hypercholesterolemic (FH) patients and four healthy control individuals consumed a diet that was very low fat (8.2 percent of calories), and high carbohydrate (90.5 percent of calories) for 1 month, following 1 month on a basal diet, and after 3 months on a wash-out diet (see Table). Both normal controls and FH patients responded similarly, with a significant decrease in total and LDL-cholesterol. HDL-cholesterol decreased nonsignificantly, but serum triglycerides increased significantly. One difference in response by FH patients and controls to the diets was observed in cholesterol synthesis. Cholesterol synthesis fell 24 percent (8.4 to 6.4 mg/kg/day) in controls and 58 percent (11.4 to 4.8 mg/kg/day) in FH patients.

Another dietary intervention study compared the effects of diets supplemented with saturated fat or linoleic acid on blood cholesterol levels (Ref. 180). This study of free-living subjects was conducted in 12 mildly hypercholesterolemic individuals (5 men and 7 women) ages 27 to 74 years, in a randomized, cross-over design that provided 2 weeks on the basal diet and 3 weeks on each of the test diets. Total fat composition of the diets is shown in the Table. The test diets contained an additional 17.3 percent SFA or 14.8 percent of PUFA (in the form of linoleic acid). The saturated fat-enriched diet significantly increased total cholesterol and LDL-cholesterol compared to the baseline diet. The linoleic-supplemented diet, which has a similar concentration of saturated fat as the basal diet, produced significantly lowered total cholesterol, 19 mg/decaliter (dL) (0.5 millimoles/Liter (mmol/L)) less compared to the basal diet and 39 mg/dL (1.0 mmol/L) less compared to the saturated fat-enriched diet. This study should be repeated using more subjects including healthy subjects and with solid foods to provide nutritional data that are more applicable to the general public. The study does suggest the possibility of more flexibility in dietary options available for the general public.

The effect of a "Western" diet rich in saturated fat and cholesterol (total fat, saturated fat and cholesterol: 43 percent, 21 percent, of calories, 1,020 mg/day, respectively) on blood cholesterol levels was measured in free-living subjects who normally consume a low fat, low saturated fat, Tarahumara diet (less than 20 percent of calories from total fat, 7 percent from saturated fat and less than 50 mg/day) (Ref. 176). The study included 12 adults (5 women) and one 12-year-old boy. After consumption of the "Western" diet for 5 weeks, total cholesterol, LDL-cholesterol, HDL-cholesterol and triglycerides increased significantly in all subjects. Total cholesterol increased from 121 mg/dL at baseline to 159 mg/dL, and LDL-cholesterol went from 72 to 100 mg/dL. The "Western" diet as described by the study design contains a higher level of total fat, saturated fat, and cholesterol than consumed by the U.S. general population.

2. Dietary Cholesterol

In another recent study, the effect of dietary cholesterol (in the form of eggs) on serum cholesterol levels was measured in seventy 18 to 19 year old, free-living, healthy males (Ref. 190). A baseline diet containing 3 eggs per week was consumed by all subjects for 3 months (diet composition contained in the Table: total fat was 40 percent of approximately 3,350 calories per day). The subjects were divided into three groups of approximately equal numbers:

one group continued on the baseline diet, group 2 was supplemented with 7 eggs per week, and the third group was supplemented with 14 eggs per week for an additional 5 months. No significant differences were reported in total cholesterol, LDL-cholesterol, or triglycerides between groups.

The authors proposed several suggestions to explain these results. They stated that the relatively high levels of total fat compounded with a low content PUFA compared to SFA content may have canceled the potential serum cholesterol-raising effects of dietary cholesterol. Secondly, they suggested that the subjects may have adapted to the diet by decreasing cholesterol synthesis or by increasing the rate of cholesterol eliminated from the body.

Meta-analysis was used to examine the effects of dietary cholesterol on serum cholesterol from 76 studies that had reported completely controlled diets (Ref. 221). This meta-analysis, unlike previously reported studies, included baseline together with added dietary cholesterol data, PUFA and SFA content of the diet, and weighted the number of subjects in each trial. The diets used in the trials included formula diets, semipurified diets, and diets based on customary food. The baseline dietary cholesterol was a statistically stronger predictor of change in blood cholesterol than added dietary cholesterol. Thus when baseline dietary cholesterol was high, added dietary cholesterol resulted in diminished increases in total blood cholesterol. Therefore, when one to two eggs are added to a diet that already contain 350 to 400 mg/day of cholesterol, little increase in blood cholesterol would be expected.

B. Estimates of Change in Blood Cholesterol by Following Low Fat, Saturated Fat and Cholesterol Dietary Guidelines

In the following group of studies, the effectiveness of diets reduced in total fat, SFA, and cholesterol to levels suggested by national nutritional guidelines and health organizations were evaluated.

A diet referred to as "US74" (fat content was 38 percent of total calories, SFA 18 percent, MUFA's 14 percent, PUFA 4 percent, and cholesterol 600 mg/day) (Table, Ref. 168) was compared to the diet recommended by U.S. public health authorities (fat 30 percent and SFA, MUFA, and PUFA 10 percent of total calories, respectively, and cholesterol 300 mg/day and referred to as modified diet ("MOD" diet)) on total blood cholesterol levels. The study included 5 free-living women of Chinese origin and 14 of Caucasian origin, in a cross-over, randomized order design with each test diet lasting 3 weeks. Throughout the intervention study, the Chinese women had consistently higher total cholesterol, LDL-cholesterol, HDL-cholesterol and triglyceride levels than Caucasians, regardless of diet selected. Caucasian women showed a significant decrease in total cholesterol and LDL-cholesterol only when the US74 diet was compared to the MOD diet. Consumption of the US74 diet increased total cholesterol and very-low density lipoprotein-cholesterol (VLDL-cholesterol) in Chinese women compared to a self selected diet (in which fat was 34 percent of total calories and SFA was about 12 percent, MUFA was 13 percent (based on g of oleic acid/day), PUFA was 8 percent (based on g of linoleic acid/day), and cholesterol was 360 mg/day).

The second study evaluated the effectiveness of the American Heart Association (AHA) Step-1 diet in lowering blood cholesterol in free-living subjects (Ref. 154). (The AHA Step-1 diet contains 10 percent or less saturated fat; 30 percent or less of total calories from fat; and less than 300 mg/day cholesterol.) Forty-nine men and 38 women completed the 18 week dietitian-instructed study (they were hypercholesterolemic, total cholesterol 243 mg/dL. and LDL-cholesterol 169 mg/dL; and mean age of 50 years, Table). Modest, but significant, decreases were observed in total-cholesterol and LDL-cholesterol after 6 weeks. No further reductions in total- or LDL-cholesterol were observed at 12 or 18 weeks, and there was a tendency to return to or exceed baseline cholesterol levels. The authors suggested that since most of the participants knew they were hypercholesterolemic before the study, they may have already been following a self-developed, low saturated fat, low fat, low cholesterol diet. This conclusion was derived from analysis of self-administered food frequency questionnaires and 4-day food records, including 1 weekend day collected on baseline diet and AHA Step-1 diets.

The third study compared the effectiveness of the AHA Step-3 diet with a typical American diet. It pointed out additional considerations in implementing dietary changes to reduce blood cholesterol and CHD risk in women. In the study, 19 free-living premenopausal women consumed a typical American diet for 28 days prior to 5 months of the AHA Step-3 diet (Table, Ref. 161). In brief, self-reported dietary fat, saturated fat, and cholesterol for the American versus AHA Step-3 diet was 37 percent versus 21 percent; 15.7 percent versus 4.7 percent; and 271 versus 96 mg/day, respectively. Total cholesterol, LDL-cholesterol, and HDL-cholesterol decreased in these women consuming the AHA Step-3 diet. However, only after subdividing the women by body mass index were there significant decreases in total cholesterol. LDL-cholesterol, and HDL-cholesterol. Lean women, as determined by body mass index, had significant decreases in blood cholesterol, while moderate or grossly obese women did not. The authors suggest that results from this study with free-living individuals may imply that obese women may be more sensitive to dietary carbohydrates and therefore not as responsive to a diet low in total fat, saturated fat, and cholesterol and enriched in carbohydrate (43.8 versus 59.4 percent). Secondly, alternative diets that replace SFA by means other than carbohydrate exchange may be more effective in these individuals.

In a fourth study, the effectiveness of intensive dietary instruction on reduction of serum cholesterol level was evaluated as part of the Heart Tune Program (Ref. 169). Hypercholesterolemic patients (30 women and 19 men) attended 4 consecutive classes on heart disease, properties and definitions of fat, healthy food selections, and meal preparations for 2 1/2 hours per week. At baseline, the total and LDL-cholesterol levels of participants in the study were 268 mg/dL (6.95 mmol/L) and 180 mg/dL (4.68 mmol/L), respectively. After 4 weeks of enrollment in the program, there was a significant reduction in both total cholesterol and LDL-cholesterol to 240 mg/dL (6.30 mmol/L) and 161 mg/dL (4.16 mmol/L), respectively.

Additional confirmation and estimation of benefits associated with a reduction in serum cholesterol levels that are predictive of heart disease was provided using a computer model (Ref. 170). Subjects for the computer model system included both men and women with blood cholesterol levels ranging from 200 mg/dl (5.2 mol/L) to 300 mg/dL (7.8 mmol/L) at baseline. Data for the study incorporated updated estimates from both America (Framingham Heart Study) and Canada (Canadian Health Survey). Results suggested that, by reducing serum cholesterol levels by 5 to 33 percent, life expectancy could be lengthened by 0.03 to 3.16 years.

In summary, the updated literature review was consistent with and generally supported the tentative conclusions reached in the proposed rule (56 FR 60727 at 60735). That is,

diets low in saturated fat and cholesterol reduce blood cholesterol levels, particularly LDL-cholesterol levels.

C. Safety Issues

1. Trans-fatty Acids

One area identified in the proposed rule as a potential concern was the possibility of increased intake of *trans*-fatty acids as a result of changes in the fat composition of the U.S. food supply. One study that has been widely cited within the scientific community is the study by Mensink and Katan (Ref. 95).

Studies that examined the effects of *trans*-fatty acids on serum cholesterol levels are limited and report conflicting results and conclusions. One *trans*-fatty acid study discussed and evaluated in Table 2 of the proposed rule (56 FR 60727 at 60761, Ref. 95), reported that consumption of a diet enriched in *trans*-fatty acids (11 percent of total calories or 33 g/day) significantly increased total cholesterol and LDL-cholesterol and significantly reduced HDL-cholesterol levels in healthy subjects. The level of *trans*-fatty acids used was much higher than the level reported available for consumption by the U.S. population (3 to 4 percent of calories or 7 to 10 g/day).

In a recent study by Zock and Katan (Ref. 193), healthy, free-living, normolipidemic individuals (26 males and 30 females) consumed diets that compared the effect of C–18 fatty acids (saturated, trans-monoene, and unsaturated form) on serum lipids. Each diet, which did not differ in nutrient content, lasted for 3 weeks and was eaten as solid foods. In this multiple, cross-over design study, the *trans*-fatty acid level was set at 7.7 percent of total calories or 24 g/day. Both stearate and *trans*-fatty acid-enriched diets increased total cholesterol and LDL-cholesterol levels significantly, relative to the linoleate diet (a polyunsaturated fat). In addition, both stearate and *trans*-fatty acids significantly reduced HDL-cholesterol relative to linoleate. Lower HDL-cholesterol levels were observed in 46 of 56 subjects on the *trans*-fatty acid enriched diet. The authors concluded that, if the data from this study are combined with those from the previous study (Refs. 95 and 193), the results suggested that for every 1 percent of energy derived from *trans*-fatty acids, LDL-cholesterol would increase by 1.2 mg/dL and HDL-cholesterol would be lowered by 0.6 mg/dL relative to an equivalent amount of oleic or linoleate. The authors concluded that the current U.S. *trans*-fatty acid consumption level of about 3 to 4 percent of total calories may increase LDL-cholesterol by 4 mg/dL and decrease of HDL-cholesterol by 2 mg/dL.

2. Unsaturated Fatty Acids

In the following group of studies, the effect of diets reduced in total fat, SFA, and cholesterol to levels suggested by national nutritional guidelines and health organizations was evaluated with respect to the possibility of increased intake of unsaturated fatty acids, especially PUFA's. This issue was raised in the proposal as a result of possible changes in the fat composition of the U.S. food supply (56 FR 60727 at 60735).

In a randomized, blinded, controlled dietary intervention study, the effect of diets enriched in vegetable oils on serum cholesterol levels in 31 free-living mildly hypercholesterolemic men (Ref. 192) was reported. Two conditions were examined: Test diets, in which the saturated fat content was 7 percent (test) versus 15 percent in the control diets, were enriched in either MUFA (22 percent MUFA-test versus 14 percent-control) or PUFA (22 percent PUFA-test versus 9 percent PUFA-control) (refer to the Table). Total and LDL-cholesterol levels were reduced significantly by consumption of diets reduced in saturated fat and enriched (22 percent of calories) in either MUFA or PUFA (total cholesterol: -15 (PUFA) and -12 (MUFA) percent, and LDL-cholesterol: -20 (PUFA) and -12 (MUFA) percent, respectively).

3. PUFA-Enriched Diets Versus MUFA-Enriched Diets

A recent study by Mata et al. (Ref. 175) compared the long-term effects of PUFA-enriched diets versus MUFA-enriched diets, on blood cholesterol levels in 46 free-living, healthy men (mean age 33 years) and 32 women (mean age 42). The two diets were similar in all respects other than the content of the test unsaturated fatty acids (the PUFA-enriched diet content contained total fat 37 percent; SFA 12.5 percent; PUFA 13 percent; and MUFA 10 percent; while the MUFA-enriched diet had the same amount of total and saturated fat but 3.4 percent PUFA and 20 percent MUFA) (see Table). This controlled, solid food study, was conducted in two phases: phase 1, PUFA-enriched diets (for 16 weeks) followed by a second phase, the MUFA-enriched diet, which lasted for 28 weeks. The MUFA-enriched diet had no effect on blood total cholesterol in men but increased it in women. The MUFA-enriched diet increased HDL-cholesterol levels compared to the PUFA-enriched diet. HDL-cholesterol levels increased in both men (17 percent) and women (30 percent). No significant changes occurred in LDL-cholesterol or total triglycerides.

In summary, the updated literature review reveals relatively few new studies pertaining to possible unintended safety effects from reducing dietary intakes of saturated fat and cholesterol. Possible adverse effects on LDL-cholesterol and HDL-cholesterol from the consumption of large quantities of *trans*-fatty acids are supported by recent scientific reports. Most results are consistent with those of earlier reviews (Refs. 20, 30 through 36, 136, 150, and 151) and with comments received in response to the proposed rule.

Overall, the updated literature review provided no convincing evidence to suggest that the agency's tentative conclusions as to the relationship of saturated fat and cholesterol to risk of heart disease, as described in the proposal, required modification.

IX. Conclusions

FDA has responded to all comments received in response to the proposed saturated fat and cholesterol and CHD health claim regulation. In addition, the agency has reviewed all additional scientific studies received in comments or independently identified. The agency has determined that the new studies strengthen the tentative conclusions reached in the proposed regulation. After considering the comments and the new scientific studies, the agency concludes that there is significant scientific agreement based on the totality of publicly available scientific evidence that a claim that diets low in saturated fat and cholesterol may reduce the risk of CHD is supported by that evidence. Therefore, FDA is authorizing a claim.

The agency has decided that the regulations for the authorized health claims are most useful if they follow a consistent format and require only information that the agency considers essential. Therefore, the agency has made a number of editorial changes in the proposed codified material of the saturated fat and cholesterol and CHD health claim to make it more consistent with other authorized claims.

X. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XI. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

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List of Subjects in 21 CFR Part 101

Food Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. New § 101.75 is added to subpart E to read as follows:

§ 101.75 Health claims: dietary saturated fat and cholesterol and risk of coronary heart disease.

(a) *Relationship between dietary saturated fat and cholesterol and risk of coronary heart disease.* (1) Cardiovascular disease means diseases of the heart and circulatory system. Coronary heart disease is the most common and serious form of cardiovascular disease and refers to diseases of the heart muscle and supporting blood vessels. High blood total- and low density lipoprotein (LDL)- cholesterol levels are major modifiable risk factors in the development of coronary heart disease. High coronary heart disease rates occur among people with high blood cholesterol levels of 240 milligrams/decaliter (mg/dL) (6.21 millimoles per liter (mmol/L)) or above and LDL-cholesterol levels of 160 mg/dL (4.13 mmol/L) or above. Borderline high risk blood cholesterol levels range from 200 to 239 mg/dL (5.17 to 6.18 mmol/L) and 130 to 159 mg/dL (3.36 to 4.11 mmol/L) of LDL-cholesterol. Dietary lipids (fats) include fatty acids and cholesterol. Total fat, commonly referred to as fat, is composed of saturated fat (fatty acids containing no double bonds), and monounsaturated and polyunsaturated fat (fatty acids containing one or more double bonds).

(2) The scientific evidence establishes that diets high in saturated fat and cholesterol are associated with increased levels of blood total- and LDL-cholesterol and, thus, with increased risk of coronary heart disease. Diets low in saturated fat and cholesterol are associated with decreased levels of blood total- and LDL-cholesterol, and thus, with decreased risk of developing coronary heart disease.

(b) *Significance of the relationship between dietary saturated fat and cholesterol and risk of coronary heart disease.* (1) Coronary heart disease is a major public health concern in the United States, primarily because it accounts for more deaths than any other disease or group of diseases. Early management of risk factors for coronary heart disease is a major public health goal that can assist in reducing risk of coronary heart disease. There is a continuum of mortality risk from coronary heart disease that increases with increasing levels of blood LDL-cholesterol. Individuals with high blood LDL-cholesterol are at greatest risk. A larger number of individuals with more moderately elevated cholesterol also have increased risk of coronary events;

such individuals comprise a substantial proportion of the adult U.S. population. The scientific evidence indicates that reducing saturated fat and cholesterol intakes lowers blood LDL-cholesterol and risk of heart disease in most individuals. There is also evidence that reducing saturated fat and cholesterol intakes in persons with blood cholesterol levels in the normal range also reduces risk of heart disease.

(2) Other risk factors for coronary heart disease include a family history of heart disease, high blood pressure, diabetes, cigarette smoking, obesity (body weight 30 percent greater than ideal body weight), and lack of regular physical exercise.

(3) Intakes of saturated fat exceed recommended levels in many people in the United States. Intakes of cholesterol are, on average, at or above recommended levels. One of the major public health recommendations relative to coronary heart disease risk is to consume less than 10 percent of calories from saturated fat, and an average of 30 percent or less of total calories from all fat. Recommended daily cholesterol intakes are 300 mg or less per day.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met.

(2) Specific requirements. (i) *Nature of the claim.* A health claim associating diets low in saturated fat and cholesterol with reduced risk of coronary heart disease may be made on the label or labeling of a food described in paragraph (c)(2)(ii) of this section provided that:

(A) The claim states that diets low in saturated fat and cholesterol "may" or "might" reduce the risk of heart disease;

(B) In specifying the disease, the claim uses the terms "heart disease" or "coronary heart disease;"

(C) In specifying the nutrient, the claim uses the terms "saturated fat" and "cholesterol" and lists both;

(D) The claim does not attribute any degree of risk reduction for coronary heart disease to diets low in dietary saturated fat and cholesterol; and

(E) The claim states that coronary heart disease risk depends on many factors.

(ii) *Nature of the food.* The food shall meet all of the nutrient content requirements of § 101.62 for a "low saturated fat," "low cholesterol," and "low fat" food; except that fish and game meats (i.e., deer, bison, rabbit, quail, wild turkey, geese, and ostrich) may meet the requirements for "extra lean" in § 101.62.

(d) *Optional information.* (1) The claim may identify one or more of the following risk factors in addition to saturated fat and cholesterol about which there is general scientific agreement that they are major risk factors for this disease: A family history of coronary heart disease, elevated blood total and LDL-cholesterol, excess body weight, high blood pressure, cigarette smoking, diabetes, and physical inactivity.

(2) The claim may indicate that the relationship of saturated fat and cholesterol to heart disease is through the intermediate link of "blood cholesterol" or "blood total- and LDL cholesterol."

(3) The claim may include information from paragraphs (a) and (b) of this section, which summarize the relationship between dietary saturated fat and cholesterol and risk of coronary heart disease, and the significance of the relationship.

(4) In specifying the nutrients, the claim may include the term "total fat" in addition to the terms "saturated fat" and "cholesterol".

(5) The claim may include information on the number of people in the United States who have coronary heart disease. The sources of this information shall be identified, and it shall be current information from the National Center for Health Statistics, the National Institutes of Health, or "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Health and Human Services (DHHS) and U.S. Department of Agriculture (USDA), Government Printing Office.

(6) The claim may indicate that it is consistent with "Nutrition and Your Health: Dietary Guidelines for Americans," DHHS and USDA, Government Printing Office.

(7) The claim may state that individuals with elevated blood total- or LDL-cholesterol should consult their physicians for medical advice and treatment. If the claim defines high or normal blood total- or LDL-cholesterol levels, then the claim shall state that individuals with high blood cholesterol should consult their physicians for medical advice and treatment.

(e) *Model health claims.* The following are model health claims that may be used in food labeling to describe the relationship between dietary saturated fat and cholesterol and risk of heart disease:

(1) While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease;

(2) Development of heart disease depends upon many factors, but its risk may be reduced by diets low in saturated fat and cholesterol and healthy lifestyles;

(3) Development of heart disease depends upon many factors, including a family history of the disease, high blood LDL-cholesterol, diabetes, high blood pressure, being overweight, cigarette smoking, lack of exercise, and the type of dietary pattern. A healthful diet low in saturated fat, total fat, and cholesterol, as part of a healthy lifestyle, may lower blood cholesterol levels and may reduce the risk of heart disease;

(4) Many factors, such as a family history of the disease, increased blood- and LDL-cholesterol levels, high blood pressure, cigarette smoking, diabetes, and being overweight, contribute to developing heart disease. A diet low in saturated fat, cholesterol, and total fat may help reduce the risk of heart disease; and

(5) Diets low in saturated fat, cholesterol, and total fat may reduce the risk of heart disease. Heart disease is dependent upon many factors, including diet, a family history of the disease, elevated blood LDL-cholesterol levels, and physical inactivity.

Dated: November 3, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

Note: The following table will not appear in the annual Code of Federal Regulations.

BILLING CODE 4160-01-F

TABLE

Dietary Saturated Fat and Cholesterol and Coronary Heart Disease

Study	Study Design	Subjects	Methods	Results	Comments
Nestel P. et al (Ref. 177)	Double blind, controlled, cross-over clinical trial of free-living subjects. Purpose: comparison of diets differing in concentration of SFA and PUFA (edible oil blends, containing hydrogenated oils and therefore trans fatty acids) on blood lipid levels. Trans fatty acid content was 4% of total calories. Study site: Australia	Twenty-six mildly hypercholesterolemic free-living men (5 to 7.5 mmol/L or 193 to 290 mg/dL), ages 20 to 65 years	Dietary instruction, food records for 3 consecutive days, total of 12 days. 14 weeks diet study: 2 weeks run-in; 4 weeks control diet and 4 weeks each test diet Composition of Diets: % of calories Control / Test 1 / Test 2 Fat 42 / 42 / 42 PUFA 6 / 10 / 11 MUFA 15 / 16 / 16 SFA 17 / 13 / 12 Chol (mg) 214 / 175 / 164 Test blend 1 contained 50% sunflower oil and a mixture of partially hydrogenated cottonseed and soybean oil. Test blend 2 contained 50% sunflower oil and partially hydrogenated canola and palm olein.	Total cholesterol (TC) and LDL-C were significantly reduced by consumption of diets containing oil blend 1 and 2 compared to controls. HDL-C and triglycerides (TG) were not significantly altered by consumption of test (oil blend diets) 1 and 2 compared to control diet. Results: (lipids in mg/dL) Control / Test 1 / Test 2 TC 221 / 216 / 212 LDL-C 154 / 150 / 147 HDL-C 42 / 42 / 42 When about 8% of energy from palmitic acid was exchanged for oleic acid, both LDL and HDL-cholesterol increased significantly. Therefore palmitic acid was either neutral or hypercholesterolemic dependent on the initial LDL receptor activity (subjects were hypercholesterolemic (>220 mg/dL) by malfunction in LDL-receptor activity).	Study suggests that edible oil blends that are lower in SFA (36 versus 21%) and higher in PUFA (21 versus 35%) than currently available in the market, can lower TC and LDL-C even when part of a diet in which fat is 42% of calories. Results of study were different than predicted by Keys equation. When trans fatty acid were treated as if they were SFA, then the Keys equation predicted closely the results observed.
Walden C. et al (Ref. 191)	Recruitment and design of dietary intervention study. Purpose: compare effectiveness of diets equivalent to NCEP Step I and Step II diets in lowering blood cholesterol on two different types of hyperlipidemia in free-living subjects. Study site: Washington State area.	320 hypercholesterolemic (HC) and 211 combined hyperlipidemia (CHL) men.	Initial dietary instruction provided, 8 weeks diet classes, 4 day food records maintained, evaluated at 6 month intervals. Four diet regiments compared: differing % fat, and amount of cholesterol. PUFA to SFA content held constant (ratio 1.0) % of Calories I / II / III / IV Fat 30 / 25 / 20 / 15 SFA 10 / 7 / 7 Chol (mg) 300 / 200 / 100 / 100	Out of 8,372 men screened for study, 47.7% were in the 60th percentile for elevated cholesterol and LDL-C, and elevated triglycerids (TG). Baseline lipid profiles for those classified as HC and CHL were similar. Fat was 36% of calories and cholesterol ranged from 279 to 316 mg/day in baseline diets.	Demonstrates the need for dietary intervention since a significant number of these industrial workers had elevated TC and LDL-C.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Bonanome A. et al (Ref. 159)	Self-controlled clinical trial in Italy in free-living subjects. Purpose: compare effects of carbohydrate and MUFA diets on blood cholesterol level. Clinical, hospital out- patients	NIDDM patients whose diabetes was under control. 10 men and 9 women, average age 55 years. Free-living	Dietary counseling, 2 months on each diet. Three phases: carbo-MUFA-carb: isocaloric diets; MUFA from olive oil. % of calories Carb / MUFA Fat 25 / 40 MUFA 10 / 25 PUFA 5 / 5 Chol (mg) <300 / <300 Carb 60 / 45	Baseline glucose, insulin and lipid parameters showed NIDDM under control. No statistically significant difference in TC, LDL-C or HDL-C found between carbo and MUFA enriched diets. Slight increase in TC and HDL on MUFA diet. Plasma LDL-C, TG and HDL-C did not change significantly by changing from one dietary phase to another. Results: serum lipids (mg/dL) Carb / MUFA TC 239 / 251 LDL-C 163 / 166 HDL-C 42 / 51	Study suggests that it is possible to substitute SFA calories with either carbohydrate or MUFA and obtain similar results on blood cholesterol levels. This is especially important for NIDDM patients, because they were still able to maintain glycemic control on either diet.
Denke M. et al (Ref. 162)	Cross-over, controlled clinical trial. Purpose: compare effects on blood cholesterol of diets differing in type and amount of SFA. Study site: Texas Medical Center	Ten men, mean age 66 years; 5 of whom smoked, baseline TC 6 mmol/L (232 mg/dL); TG 1.5 mmol/L; free-living	Liquid diets: 3 weeks each diet. Cross-over 1 week ad libitum diet. Random order of diets. All diets: fat 40% of calories, 40% carbo., chol 120 ug/kcal, PUFA <8%. Fat / % SFA / % stearic Butter 25 / 4 Beef 18 / 7.6 Cocoa 23 / 13 Olive 8 / 1.2	High concentration of stearic in beef fat did not negate its cholesterol-raising properties. Cocoa butter not significantly less hypercholesterolemic than beef fat. Results: serum lipids (mg/dL) TC / LDL-C / HDL-C Butter 219 / 164 / 34 Beef 211 / 156 / 36 Cocoa 198 / 147 / 34 Olive 188 / 140 / 34	Possible differences due to liquid diet, comparisons to solid food diets would be helpful. The authors suggested that base line drops in TC and LDL-C (even on butter diets) was due to regression toward mean and/or hospitalization.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Bierenbaum M. L. et al (Ref. 158)	Controlled clinical trial in free-living subjects. Purpose: measure effects of canola oil (enriched in PUFA) on serum lipids. Study sites: New Jersey /New York, hospitals	Thirty-six free-living hypercholesterolemic and/or hypertriglyceridimic patients. Twelve men and 15 women, average age 60.7 years. Four had diabetes, 14 post-CVD event, 2 post-MI Baseline lipids (mg/dL) TC 254 LDL-C 173 HDL-C 47 TG 214	Dietary instruction. 4 months on diet. 24-hour food diary prior to and during study. Diet: % of calories Basal / Test Fat 39% / 39% SFA 19% / 30 ml/day MUFA 11% / canola oil PUFA 9% / exchanged Chol (mg/day) 390 / for basal dietary oil	Dietary adherence monitored by measuring w-3 fatty acid in RBC membranes before and after 4 months on diet. Both 18:3(w-3) 22:6(w-3) significantly increased from 1.4 to 39.8% and 0.7 to 10.2% respectively, while 18.0 decreased from 25 to 3.2%. No significant changes in total chol, HDL-C, TG, or BP. LDL-C was lowered significantly by the PUFA enriched diet. Blood lipid results (mg/dL) TC 248 LDL-C 160 HDL-C 51 TG 226 Serum a-tocopherol and B-carotene significantly decreased and retinol unchanged after 4 months on diet. Bleeding times increased significantly.	Dietary data not adequately described. Two types of hyperlipidemic may respond to differently to dietary changes. Response not necessarily equivalent to normal subjects. Study suggests a need for increased supplementation of antioxidant vitamins when increasing concentration of PUFA in the diet. One subfraction of HDL (HDL-2) decreased on PUFA enriched diet.
Garcia P. A. et al (Ref. 160)	Cross-over, controlled clinical trial in free-living subjects. Random order of diet treatment sequences. Purpose: measure effects of diets differing in fatty acid composition (SFA and PUFA) on serum lipids. Study site: Iowa and Nebraska	Twenty women; 10 from Nebraska, 10 from Iowa; 5 were Chinese and 14 Caucasian; average age 23 years; free-living. Baseline lipids (mg/dL): CA / CH TC 154 / 166 LDL-C 86 / 97 HDL-C 44 / 47 CA = caucasian CH = chinese	Dietary records self recorded: 28-day/diet total 70-day study. 3 diets: self selected (SS), two experimental diets: US74 and modified fat (MOD). Meals provided and food records maintained through study for US74 and MOD diets. Test Diet Composition US74 / MOD Fat (%) 40% / 30% PUFA 4 / 10 MUFA 14 / 10 SFA 14 / 10 Chol (mg) 600 / 300	Chinese women had consistently higher TC, LDL-C, HDL-C and TG levels that Caucasian women regardless of diet selected. Caucasian women only showed significant decrease in TC, LDL-C, VLDL-C when effect of US74 to MOD diet compared. US74 diet increased TC, VLDL-C in Chinese women compared to self selected diet. Cross over diet effect on HDL levels of both groups of women. Blood lipids (mg/dL) US74: CA / CH MOD: CA / CH TC 163 / 195 / 139 / 159 LDL-C 89 / 104 / 75 / 85 HDL-C 46 / 51 / 44 / 49	Uneven numbers of subjects in each racial group. The Caucasian group from Iowa was significantly physically larger than the mixed racial group from Nebraska. Significant effects of experimental diets may have been masked by residual diet effects.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Wardlaw G. M. et al (Ref. 144)	Two-phase, randomized, blinded, free-living, controlled clinical trial. Purpose: measure effects of diets enriched in PUFA and MUFA, low in SFA on blood lipids while maintaining % energy from fat at 30%. Study site: Ohio	Thirty-one men completed the study. One criteria for selection of subjects was blood chol >5.16 mmol/L (199 mg/dL). Average age of free-living subjects was 33 years.	Baseline (BL) diet 3 weeks (phase 1), Test diets Mono (enriched MUFA) and Poly (enriched in PUFA), 8 weeks each (phase 2). All meals provided for study. Diets Composition (% of Calories) BL / MONO / POLY Fat 39 / 40 / 39 SFA 15 / 7 / 7 MUFA 14 / 22 / 9 PUFA 9 / 11 / 22 Chol (mg) 360 / 320 / 320	TC fell from baseline significantly: -15% POLY and -9% MONO: LDL fell significantly from baseline by -20% POLY and -12% MONO enriched diets: apo B fell significantly from baseline by -21% POLY and -24% MONO enriched diets. Neither vegetable oil based diets resulted in a significant change in TG, HDL-C, HDL-2, or HDL-3, apo AI when compared baseline diet. Blood lipid results (mg/dL) BL / MUFA / PUFA TC 208 / 189 / 178 LDL-C 143 / 123 / 116 HDL-C 42 / 39 / 42	Results indicate that consumption of diets low in SFA reduces blood cholesterol. Study also suggests that diets enriched in UFA do not necessarily decrease blood levels of HDL and/or increase TG. Study showed that when dietary energy from fat is 39% of calories (therefore higher than recommended by public health authorities), but the SFA content of the diet is reduced, it is possible to still achieve a reduction in blood cholesterol levels.
Reaven P. et al (Ref. 101)	Controlled dietary intervention clinical trial in free-living subjects. Purpose: compare effect of diets enriched in MUFA (18:1) with PUFA (18:2) on blood cholesterol levels and oxidative potential on LDL-C. Random diet assignment Study site: California university	Nine healthy volunteers, age 18 to 43 years. Gender not stated. Baseline lipids (mg/dL): olea. / linolea. TC 166 / 147 LDL-C 95 / 69 HDL-C 46 / 62	Liquid diets (fat content less than 1%) to which test oils are added. Test oil one: Trisun 80 = >85% 18:1 (oleic acid). Test oil 2 sunflower oil, >60% 18:2 (linoleic acid). 5-week/diet. Diets enriched in (% of calories) Oleate / Linoleate Fat 39.2 / 39.2 SFA <2 / <8 MUFA 34 / 9.6 PUFA 6 / 27 Chol 0 / 0 Fatty acid content for sunflower oil was not given by authors, and was as estimated here by using data from another publication, in order to evaluate study results.	No significant decrease in TC or LDL-C by either diet. HDL-C decreased significantly in linoleate (PUFA) supplement group. Blood lipid results (mg/dL) oleate / linoleate TC 147 / 113 LDL-C 77 / 58 HDL-C 46 / 49 Other results: Antioxidant (vitamin E) conc not significantly reduced by either diet. The amount and rate of formation of conjugated dienes (measure of degree of unsaturation) greater in linoleate group. No significant increase in TBAR (a measure of oxidization in LDL-C). However, significant increase in LDL-C degradation (measure of atherosclerotic potential) by macrophages in linoleate group.	Complete fatty acid analysis of oils used not provided in paper, especially important in case of Trisun 80. Preliminary study can not at this time apply results to general public health advise.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Cole T. G. et al (Ref. 161)	Dietary, clinical intervention trial. Purpose: effect of AHA Phase 3 diet (very low fat and cholesterol) diet on blood cholesterol levels Study site: Chicago	Nineteen free-living premenopausal women, mean age 32. Selection based on TC at or > than 50th percentile. Healthy subjects. Six women were classified as grossly obese by body mass index (BMI > 30). Mean BMI for all subjects 28.2. Baseline lipids (mmol/L & mg/dL) TC 5.24 205 LDL-C 3.45 133 HDL-C 1.36 52	Stabilization diet: 28 days on typical American diet. 5 months on AHA Phase 3 diet. % of calories AMER / AHA 3 Fat 37 / 21.4 Carb 43.8 / 59.4 Prot 19.2 / 19.2 SFA 15.7 / 4.7 MUFA 11.7 / 6.4 PUFA 6.7 / 8.4 Chol (mg/day) 271 / 96 meals provided on site	TC, LDL-C, HDL-C and HDL-2 decreased when all women were considered as a group. HDL-3, TG and VLDL-TG increased when all women considered as a group. Blood lipid results (all subjects in mg/dL) AMER / AHA 3 TC 202 / 189 LDL-C 133 / 121 HDL-C 52 / 49 When women were divided into 3 groups based on BMI, leanest women had a significant decrease in TC, LDL-C and HDL-C. Blood lipid (mg/dL) response grouped by BMI <24 / <30 / >30 TC 169 / 202 / 199 LDL-C 106 / 130 / 128 HDL-C 49 / 57 / 40 Moderately and grossly obese women were nonresponders.	Results suggest that obesity, at least in women (n=6 BMI>30) had an influence on responsiveness to low-fat, low-cholesterol diet. Authors suggest that obese women may be carbohydrate-sensitive and therefore less responsive to low fat, low SFA diet.
Kwon, Jon-Sook et al (Ref. 172)	Controlled dietary, intervention study in free-living subjects. Purpose: study the effects of diets enriched in UFA from vegetable oils on platelet phospholipid (PL) fatty acid composition and function. Two phase diet design: phase 1, a 3-week baseline or control diet; followed by phase 2, an-8 week experimental diet. Study site: Ohio.	Thirty-four healthy males ages 21 to 50 years. All subjects had chol concentrations of 4.8 to 7.8 mmol/L (185 to 301 mg/dL) on self selected diet. All subjects consumed baseline diet. Sixteen assigned to diet enriched in PUFA and 14 assigned to diet enriched in MUFA.	Three diets: Baseline enriched in SFA, Canola enriched in MUFA and Safflower oil enriched in PUFA. Meals provided, eaten on site and dietitian monitored. % of Calories Base / MUFA / PUFA FAT 38.8 / 39.9 / 39.3 SFA 15.4 / 7.2 / 7.4 MUFA 13.8 / 22.8 / 8.1 PUFA 8.6 / 10.7 / 22.2	Compared to SFA enriched diet, platelet PL fatty acid composition was altered. MUFA enriched diet (canola) raised conc of oleic (MUFA) and linolenic (PUFA); there was a significant decrease in oleic and increase in linoleic with the PUFA enriched diet (safflower). Both vegetable oil diets produced increase in SFA (lauric and palmitic), a decrease in stearic acid of PL fatty acids of platelet compared to SFA diet. Both vegetable oil diets significantly increased platelet aggregation time compared to platelet from SFA diet. Data: Diet Aggregation. MUFA ↑ PUFA ↑ SFA ↓	Authors discussed the possible mechanism by which UFA from vegetable oils may platelet aggregation time. The authors suggest that vegetable oils: canola oil, may alter platelet aggregation by PG metabolism and membrane fluidity and safflower oil by membrane fluidity. The authors also suggested that the increased conc of 2 SFA (palmitic and stearic) in PL of platelet may not be prothrombic.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
McMurry P. et al (Ref. 176)	Dietary intervention study. Purpose: to measure the effects of an "industrialized, western, or affluent" diet on blood lipids levels of subjects who normally consume low fat, low SFA high fiber diets, the Tarahumara Indians Two phase design: phase 1, 1 week traditional diet, followed by phase 2, 5 weeks on test diet. Study site: Chihuahua, Mexico	Tarahumara Indians (Mexico) 12 adults (18 to 35 years), 1 boy (12 years). Five women (3 lactating) and 8 men. Baseline TC 121 mg/dL. Free-living	Tarahumara diet and test or westernized diet provided. Diet Composition Tarahumara "Western" Energy (kcal) 2,700 4,100 % of calories FAT 20 43 MUFA 10 19 PUFA 4 4 SFA 7 21 Dietary fiber 102 33 Chol (mg) <50 1,020	TC, LDL-C HDL-C and TG levels increased significantly in all subjects. Blood lipid results (mg/dL) Tarahumara "Western" TC 121 162 LDL-C 72 100 HDL-C 32 42 Increase in TC occurred very rapidly in response to the western diet. Women has a non-significantly higher increase in TC than men. Lactating women responded similar to non-lactating women. Adolescent boy had the highest initial and final TC level.	Test diet was 151 to 186% of estimated eucaloric needs. Response could be due to load response. Study complicated by large number of subgroups. Large percentage of SFA (21%) content in diet compared to US.
Rassias G. et al (Ref. 180)	Controlled, cross-over design dietary intervention clinical trial in free-living subjects. Purpose: compare the effects of diets supplemented with linoleic and SFA on serum lipids. Random order of diets; no wash-out between diets. 2 weeks on base line diet and 3 weeks on test diets Study site: Australia	Twelve mildly hypercholesterolemic individuals (five men seven women, ages 27 to 74 years. (5 subjects 20 to 30 and 7, 30 to 74 years). Baseline blood lipids mmol/L and (mg/dL) TC BMI Men 6.22 (240) 43 Women 6.17 (238) 56	Supplements provided in liquid form. 3-day food records maintained for each test period. Supplements-SFA and PUFA (linoleic) Diet composition (% of calories) BL SFA PUFA FAT 35.6 40.0 46.6 SFA 13.2 30.5 10.8 MUFA 11.6 9.2 10.8 PUFA 7.9 6.1 22.7	The linoleic-enriched diet significantly lowered TC 0.5 mmol/L compared to basal diet and 1.0 mmol/L compared to SFA-enriched diet. This decrease in TC occurred without a reduction in SFA content or replacement of SFA with PUFA. Comparing basal diet to PUFA enriched diet: the linoleic enriched diet did not decrease HDL-C levels. Data blood lipids mmol/L and (mg/dL) BL SFA PUFA TC 6.0(233) 6.5(251) 5.6(215) LDL 4.4(170) 4.6(177) 3.8(145) HDL 1.3(51) 1.6(63) 1.4(56)	Results suggest more alternatives in choosing nutrient substitutes for dietary saturated fat. Diets significantly lower in total or SFA but enriched in PUFA such as linoleic may also reduce TC levels.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Stacpoole P. W. et al (Ref. 184)	Dietary intervention clinical trial. Purpose: investigate the mechanism of cholesterol lowering action induced by high carbohydrate, very low fat feeding as reflected in changes in VLDL and LDL metabolism. Two phase dietary intervention: 1 phase basal diet for 1 month; wash-out 3 months, test diet 1 month. Study site: Shand Hospital, Florida	Four healthy controls (N=normal), four familial hypercholesterolemia (FH)-heterozygous, and one FH homozygous patients. Healthy volunteers 33 to 58 years, FH patients 20 to 65 years. Baseline blood lipids (mg/dL) N / FH TC 186 / 460 LDL-C 101 / 400 HDL-C 47 / 51	Whole body cholesterol balance and tracer kinetics methods used. Lipid profile, fecal sterol balance, apo B synthesis and metabolism. Compartmental analysis. Diet provided and supervised. Basal diet (BL) solid food; test diet, continuous nasal gastric infusion. Diet composition (% of calories) BL / Carb Carb 45% / 90.5% Fat 40% / 8.2% Prot 15% / 1.3% P/S 1.0 / Linoleic Chol (mg) 100 / none	Both normal controls and FH patients total cholesterol and LDL-C decreased significantly (mean difference 43 mg/dl and 123 mg/dl respectively) by consumption of high carbohydrate diet. HDL-C decreased non-significantly in all subjects, serum TG increased significantly. Blood lipid data BL: N / FH; Carb: N / FH TC 186 / 460 / 138 / 338 LDL-C 101 / 400 / 62 / 270 HDL-C 47 / 51 / 32 / 36 Other data: Decrease in fecal cholesterol and bile acid production and decrease in whole body cholesterol formation in all subjects. Cholesterol synthesis fell 24% (8.4 to 6.4 mg/kg per day) in controls and 58% (11.4 to 4.8 mg/kg/day) in FH subjects. Consumption of carbohydrate diet stimulated LDL-apo B clearance in all subjects.	As authors point out, there are still uncertainties whether frequent or continuous feeding of liquid formula containing mostly glucose is more effective in lowering total cholesterol than solid diets containing a variety of carbohydrates. Another possible issue is the safety of high carbohydrate extremely low fat diets as well as safety of liquid formula diets. For the above reasons application of study results, other than for suggestions of mechanism for control for cholesterol homeostasis, is not applicable to general public.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Dobs A. S. et al (Ref. 164)	Prospective, random, double blind, pravastatin and placebo- controlled clinical trial. Purpose: evaluation of drug and long-term dietary compliance, nutritional adequacy with a lipid-lowering diet. Subjects were randomly assigned to placebo or pravastatin (5, 10, 20 mg/day) for 12 weeks. After 12 weeks all subjects were placed on open-label pravastatin for the remaining 36 weeks. Multicenter trial Study sites: seven lipid treatment center in the United States	Two hundred and seventy-two adults: 206 men and 66 women; mean age 50 years (21 to 70 years); hypercholesterolemic (85th percentile) patients (76% men) aged.	Each subject had 6 weeks of dietary counseling. Basal diet (lipid lowering) for > 6 weeks. Seven, 1-day diet records kept for 1 year.	272 patients selected had elevated serum LDL after greater than 6 weeks of dietary counseling and as such were considered unresponsive to a diet lower in fat, SFA and cholesterol. Blood lipid data (mmol/L and mg/dL): Total cholesterol <1 week 8 weeks 48 weeks Men 4.6(176) 5.0(190) 92.9(186) Women 4.0(149) 3.1(116) 3.6(137) data from all subjects pooled: LDL-C decreased from 193 down to 150 mg/dL). Report given on 23 participants from John Hopkins in which pravastatin reduced TC 23% [about 265 down to 200 mg/dL] and LDL-C 30% [about 210 down to 150 mg/dL] over the year. TG and HDL did not change. Dietary compliance and evaluation given. 55% of men in study completed 7 diet records for 1 year. For both men and women the percentage of calories from total fat was (30%), SFA (8%), PUFA (9%) and MUFA (10%). Approximately two-thirds of participants ingested less that 67% of RDA of some essential mineral and vitamin nutrients.	Intervention with lipid lowering drug did not alter dietary compliance. Patients adhering to lipid lowering diets in which the fat content was similar to that recommended for general population (30% of calories), appeared to contain inadequate amounts of several essential nutrients (folic acid, vitamin B-6, calcium and zinc). Greater than 40% of women ingested less that 67% of the RDA for folic acid, vitamin B-6, vitamin D, calcium and Zn. Compared to general population the nutrient amounts were greater for zinc and calcium but less for vitamin B-6 and folic acid than that found in general population. In men the diet was inadequate in folic acid and zinc. Lipid lowering diet may be inadequate in several micronutrient. Other studies have however found these diets provide adequate amounts of these nutrients.
Todesco T. et al (Ref. 185)	Cross-over, random dietary intervention clinical trial in free-living subjects. Purpose: to test the effects of supplementation of short chain fatty acid (SCFA) on blood glucose and cholesterol levels 2 phases: control and test diet. Random order of diets Study site: medical school and hospital, Italy.	Six healthy volunteers, mean age 32 years; 3 males and 3 females; normal blood glucose and cholesterol levels. Baseline lipid data mmol/L mg/dL TC 5.0 193 LDL 3.2 123 HDL 1.25 48	Each diet period was 1 week including test diet. Diets similar except for supplementation of bread with propionate (9.9 g/150 g of carbohydrate). Maintained diet records day 0 and day 3 of each study. Diet composition (% of calories) Control Propionate Carb 52 53 Prot 17 18 Fat 29 29.5 Fiber 19.2 19.6	A significant decrease in blood glucose response was observed with use of propionate-supplemented bread compared to control bread. No significant changes were observed in total cholesterol, LDL-C, HDL-C or triglycerides. 5 subjects however showed a reduced level of HDL-C and increased triglycerides with propionate-supplemented bread use. Data: mmol/L (mg/dL) Control Propionate TC 5.0 (193) 4.8 (185) LDL-C 3.2 (123) 2.8 (77) HDL-C 1.3 (50) 1.1 (42) TG 1.3 1.8	Short dietary test period, non-steady state conditions, no wash-out between diets. No indication of other confounders for glucose or lipid response (concentration of PUFA, MUFA SFA or cholesterol). Does not confirm previous reports which suggest SCFA decrease total cholesterol by inhibiting HMGCoA reductase (or the synthesis of cholesterol).

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Ullman D. et al (Ref. 186)	Metabolic ward, dietary intervention clinical trial in free-living subjects. Purpose: First: to determine if carbohydrate-induced hypertriglyceridemia is avoided with 10-day phase in of 65% carbohydrate and 20% fat diet. Second: to determine if hypertriglyceridemia can be induced by an acute challenge of same diet. Study site: Oregon	Eight healthy nondiabetic adults (two women, six men) mean age 51. Mean Baseline blood lipid (mg/dL) TC 228 LDL-C 147 HDL-C 44 TG 254	Meals provided and compliance observed. Each diet period lasted 10 days. Study 1. Baseline (American) diet. Test diets increased in carbohydrate (65%) while decreasing in fat (20%). Study 2. (American) diet followed by acute 4 diet. Diet composition (% of calories) Amer 1 2 3 4 Carb 45 50 55 60 65 Prot 15 15 15 15 15 Fat 40 35 30 25 20 SFA 15 11 8 6 5 PUFA 6 8 8 8 8 MUFA 19 16 14 11 7 Chol 179 143 107 71 36	Study 1. Triglyceride or VLDL-TG did not significantly increase when carbohydrate concentration of diet was gradually phased in. TC was reduced significantly by phase 3 and phase 4. LDL-C was significantly reduced at all phases. HDL-C was significantly reduced at phase 4 of the diet. Study 1 data (mg/dL) Amer 1 2 3 4 TC 232 223 216 209 198 LDL-C 161 144 141 134 126 HDL-C 43 41 44 42 36 TG 213 232 237 230 230 Study 2. An acute switch to high carbohydrate diet significantly increased both TG and VLDL-TG in 6 of 8 patients. Study 2 data (mg/dL) Amer 65% Carb TC 243 233 LDL-C 174 143 HDL-C 43 41 TG 204 296	At least in some people, a gradual approach of phased increase in carbohydrate as replacement of calories from SFA, total fat and cholesterol may allow for better control of hypertriglyceridemia than previously reported.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Bae, C-Y et al (Ref. 154)	Clinical dietary intervention in free-living subjects. Purpose: to determine the effectiveness of American Heart Association Step 1 Diet (% of calories-fat 30% or less, SFA 10% or less and cholesterol less than 300 mg/day in lowering blood cholesterol. Study site: Minnesota Hospital and Medical Center	Eighty-seven (49 men and 38 women) completed the study. Mean age 50.1 years. Baseline lipid data: TC 243 mg/dl; LDL-C 169 mg/dl.	Dietitian instructed and followups. Food records maintained. Analysis of 4-day food records every 6 weeks. Blood lipid analysis at 6, 12 and 18 weeks. Diet Composition at Baseline (% of calories) Fat 31.6 SFA 10.4 PUFA 6.8 MUFA 11.5 Carbo 50 Prot 16.8 Chol (mg/d) 232 Fiber-soluble 5.9 Calories 1,975	Modest but significant decreases in TC (-3.6%) and LDL-C (-3.5%) were observed at 6 weeks. No further reduction in TC or LDL-C were found at 12 or 18 weeks. By 18 weeks, TC and LDL-C levels showed a tendency to return to and even exceed baseline levels. Small increase in HDL-C (2.1%) and TG (3.8%) at 18 weeks. Blood lipid data in mg/dL at (6 weeks) and (18 weeks) BL / AHA(6) / AHA(18) TC 242 / 235 / 245 LDL-C 169 / 163 / 170 HDL-C 49 / 49 / 50 Diet results: 1. total dietary fat decreased at 6, 12 and 18 weeks (minus 2.7, 2, and 2.6% respectively).2. SFA and cholesterol consumption decreased also at 6, 12 and 18 weeks for SFA (minus -1.6, -1.5, and -2.4) and -46% and -50% for cholesterol at 12 and 18 weeks.	The AHA Step 1 diet was not effective in improving plasma lipids of these subjects. This may be due to fact that most participants had already achieved a low level of SFA and cholesterol intake at baseline. All participants knew they were hypercholesterolemic prior to the study and were already following a self developed diet. Those subjects who responded the best were older, had higher LDL-C levels and had higher intake of total and PUFA at baseline.
Groth K et al (Ref. 169)	Clinical intervention by dietary instruction. Purpose: to evaluate the effectiveness of dietician instruction on reduction of blood cholesterol levels. Study site: Spokane Washington	Thirty women and 19 men, mean age 55 years. Mean baseline blood lipids: TC 6.95 mmol/L (268 mg/dL) LDL-C 4.68 mmol/L (176 mg/dL).	Four consecutive classes, 2 1/2 hr per/week. Class topics: (1) CHD the disease; (2) meal preparation; (3) fat definition and properties of specific foods; and (4) healthy food choices. Blood cholesterol levels determined prior to and after dietary instruction. Dietary instructional recommendations: total fat 20% of energy, cholesterol 100 mg/day, soluble fiber 50 g/day. Food recommendations few or lean cuts of meat, few or no dairy products, vegetables, whole grain products. Diet composition:	A significant reduction in TC and LDL-cholesterol before and last class (week 4). Reduction in TC and LDL-C was maintained 1 year after instruction. Blood lipid data: mmol/L (mg/dL) Pre / 4 week / 1 year TC 6.8(266) / 6.3(243) / 6.2(249) LDL 4.7(177) / 4.2(162) / 4.4(170) HDL 1.3 (50) / 1.2(46) / 1.3(50)	The measure of understanding of the study is evident by helping individuals realize an immediate (4 weeks) and sustained reduction in blood cholesterol levels (1 year). Study suggests that once dietary recommendations are understood, changes will be maintained. Nutritional instruction, therefore, could be instrumental in reducing blood cholesterol levels in the general population.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Maron D. J. et al (Ref. 17d)	Cross-sectional study. Purpose: Evaluate the effect of diet (SFA) on insulin levels in nondiabetic (obese) men with heart disease. Study site: Stanford University	Two hundred and fifteen nondiabetic free-living men, 32 to 74 years with angiographically proven coronary artery disease (CAD). Baseline lipids mmol/L (mg/dL) TC 4.4 (170) LDL 2.8 (108) HLD 1.3 (50) other: BMI 26.7	4-day food records and physical activity records maintained (4 years). Index of obesity: BMI; change in BMI, and waist to hip ratio (WHR). Fasted and response glucose and insulin levels measured. Diet Composition (% of calories) Total Fat 32 SFA 10 MUFA 12 PUFA 7.5 Chol 279 (mg/day)	SFA and cholesterol correlated positively with all three indexes of obesity and with fasted and insulin response. Data for correlation of diet and response in various indexes: SFA Chol BMI 0.18 0.16 change in BMI 0.23 0.18 Waist/hip 0.21 0.22 Fast insulin 0.26 0.23 Insulin response 0.17 0.21 Carbohydrate consumption correlated negatively with all measures of obesity and with both measures of insulin. Multivariant analysis showed that SFA, MUFA and cholesterol, positively and significantly correlated with fasting insulin	Limitation of study: dietary data self reported. Study demonstrated that SFA consumption is positively related to insulin concentration independently of obesity in nondiabetic men with heart disease.
Vorster H. H. et al (Ref. 19o)	Dietary intervention study. Random and controlled. Purpose: measure effect of 3, 7, or 14 eggs per week on serum lipid levels in subjects who followed a Western diet. Study site: South Africa	Seventy 18 to 19 year-old healthy male university students. Free-living subjects Baseline lipids mmol/L (mg/dL) TC 4.4 (170) LDL-C 2.8 (108) HDL-C 1.3 (50) other: BMI 22.3, nonsmokers	All subjects consumed baseline diet containing three eggs/week for 3 months. One group continued this diet for additional 5 months and remainder either consumed 7 eggs or 14 eggs/week for 5 months. Diet composition Run-in Experimental Cal 3190-3429 3238-3548 Fat% 38-40 39-41 P/S .7-.8 .7-.8 Chol 380 403, 556, or 800 (mg) Fatty acids C16:0 22.5 mg same C18:0 12.4 C18:1 14.5 C18:2 32 C20.4 .26 Group 1 = 3 egg/week Group 2 = 7 eggs/week Group 3 = 14 eggs/week	All subjects at steady state due to consumption of baseline diet for 3 months as determined by multiple blood lipid analysis over 3 month period. Only small differences within groups and no significant differences in total cholesterol, LDL-cholesterol or triglycerides between groups. Group 3 (14 egg/day) had high creatine value (119 versus 86 umol/L). Group 3 had significantly higher total protein, total phospholipid and arachidonic acid. Blood lipid data at 7 months mmol/L (mg/dL) Group 1 2 3 TC 4.3(162) 4.7(175) 4.3(160) LDL 2.6(98) 2.8(104) 2.6(97) HDL 1.2(45) 1.3(48) 1.2(45) There was a significant increase in with in all subjects (4.6 kg from baseline).	Egg intake in the range consumed did not increase blood cholesterol levels in self selected diet. Authors suggested several reasons for the above results such as a high fat diet with a, relatively low P/S ratio may cancel effects of additional cholesterol, second that there was a metabolic adaptation to compensate for increase in consumption of dietary Chol decrease in Chol synthesis or increase in Chol elimination and third that the phospholipid content may be hypocholesterolemic and thus counter act hypercholesterolemic effect of added cholesterol.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Grover S. A. et al (Ref. 170)	CHD primary prevention computer model to estimate lifetime benefit of risk factor modification. Purpose: To evaluate lifetime benefits of reducing total cholesterol to prevent CHD through dietary modification or medical intervention. Study site: Canada	Men and women, age 35 to 65 years of age, free of CHD. Blood cholesterol levels at baseline range 5.2 to 7.8 mmol/L or (200-low risk to 300 mg/dL-high risk) with and without additional CHD risk factor.	Computer model based on Framingham Heart Study, Canadian Life Tables, Canada Health Survey Data. Program estimate average expectancy associated with modifying one or more CHD risk factors. Into model following factors are incorporated: age, sex, diastolic blood pressure, total cholesterol, left ventricular hypertrophy, glucose intolerance and cigarette smoking. Adjustments also made for HDL using gender specific HDL modification for men and women.	Ability to forecast lifetime benefits depends on baseline levels, age, sex, and presence and absence of other risk factors. Reducing serum cholesterol levels 5 to 33% increases the average life expectancy 0.03 year or 11 days to 3.16 years. The average onset of symptomatic CHD would be delayed by 0.06 or 22 days to 4.98 years. Among 35 year old men and women, without other risk factors, reducing cholesterol from 300 to 200 mg/dL with diet or medication would increase life expectancy 1.64 year (men) and 0.98 year (women).	Computer model used is based on relatively short term clinical data - 5 to 10 year to predict lifetime benefits. Wide variation in results from reduction of blood cholesterol in men and women of various ages. Results similar to other models used to estimate benefit from lowering blood cholesterol. For example Taylor mode: a 6.7% decline in total cholesterol increased life expectancy 3 days to 3 months for low-risk men and women age 20 to 60 years.
Ekstedt B. et al (Ref. 165)	Diet and exercise intervention study. Controlled study in free- living subjects. Purpose: to determine the effect of low calorie, fat, and cholesterol diet on blood cholesterol and triglyceride levels. Study site: Sweden	Seven healthy males, age 21 to 37 years. Nonsmokers. Study included statement that subjects had normal cholesterol and triglyceride levels but blood lipid data not provided.	Stabilization diet (fat 26 to 30% of calories) and exercise (run 5 to 10 km, 2 to 4 times per week) for 1 month prior to study. Four different diets compared; 8 days each diet (solid food), one test per year, while cross country skiing 160 Km. Low calorie (LCa); High fat and high chol (HF/HC); high chol (HC) Std / LCa / HF/HC / HC Cal 3800 / 2300 / 3800 / 3800 Fat (%) 26 / 21 / 52 / 29 Chol (mg) 260 / 110 / 480 / 410 Carb (%) 57 / 60 / 34 / 56	A significant decrease in both total cholesterol and LDL-C by consumption of each of the test diets compared to levels at baseline. No significant change in HDL-C with standard or low energy diet. Significant increase in HDL-C with high fat/high cholesterol diet (19%) and high cholesterol diet (30%). Serum triglyceride decreased by more than 20% but no difference due to diet. Blood lipid data (actual values not provided); data presented as percent increase or decrease: Std / LCa / HF/HC / HC TC +26 / +35 / +20 / +31 LDL +38 / +50 / +41 / +50 HDL 6 / 8 / 19 / 30 Body weight decreased significantly on low calories diet (3 Kg).	Other results not shown in table were: heavy exercise, irrespective of fat, calorie, or cholesterol content of diet, decreased LDL-C levels in healthy men. Loss in short term body weight did not increase cholesterol lowering effect of low calorie, low fat and cholesterol diet. Short term heavy physical activity had stronger influence on blood cholesterol levels, than did fat or cholesterol content of diet. Large variance in triglyceride levels among individuals. Can only apply results to short term heavy exercise - diet and not moderate exercise and diet effects as may be common in general public.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Kok F. J. et al (Ref. 171)	Case-control study conducted 1986 to 1987. Purpose: to determine the levels of a trace element, antioxidant and PUFA levels in patients with atherosclerosis. Study site: Netherlands	Ninety-one CHD (cases) and 72 control male subjects, average age 53 years. Other confounders-proportion: alcohol (65%), smoke (28%), hypertension (35%), MI (35% in cases and 15% in controls). All subjects has coronary angiography. Stenosis in at least one coronary vessel: case subjects >85% and < 50% of controls.	Plasma selenium measured by neutron activation; tocopherol by high pressure liquid chronography; gas chromatography of methyl ester derivative of lipid extract of plasma PUFA.	Cases, compared to controls had significantly high levels of total cholesterol and LDL-cholesterol and lower levels of diastolic blood pressure and HDL-cholesterol. Plasma selenium was significantly lower in cases compared to controls. No significant differences in tocopherol or PUFA's. In subgroup of case where tocopherol is low (less than 1452 ug/dL), there is a corresponding significant lower ratio of selenium/PUFA.	Dietary history, which could impact on these results, was not provided in study. Study lacks a control group which had no previous history of or who had no MI or atherosclerosis. Also subjects had many other risk factors which may relate to the results i.e., smoking and not directly to atherosclerosis. The reason for evaluating the study was because of safety concerns with proposed changes dietary composition due to a decrease in SFA consumption and replacement with other nutrients such as PUFA and micronutrient status (such as antioxidants) have been expressed. Some previous reports suggested that selenium was significantly lower in acute MI or those who died from CVD.
Shea S. et al (Ref. 183)	Longitudinal, survey. Purpose: survey of Hispanic preschool children in New York, measurements include serum lipids, dietary index and body mass index (BMI).	One hundred and eight healthy (57 boys and 51 girls) Hispanic children, average age 4.5 years. Mean serum total cholesterol (TC) for 108 children was 158 mg/dL and LDL-cholesterol was 97 mg/dL.	Four 24-hour dietary record, 3 months apart. Two Willett semiquantitative food frequency questionnaires approximately 6 months apart.	Boys had slightly higher serum TC and LDL-cholesterol than the total group or the girls. Children in the highest tertile of total fat consumption (36.2% of total calories) compared to the lowest tertile (30.2% of calories) had significantly higher TC and LDL-cholesterol Furthermore, children in the highest tertile of SFA consumption (14.6 % of calories) compared to lowest tertile (11.2% of calories) had significantly higher TC and LDL-cholesterol levels. Blood lipid data (mg/dL): Nutr. SFA Tertiles 1st 2nd 3rd TC 152 152 172 LDL-C 92 91 108 Nutr. TF (total fat) TC 154 151 171 LDL-C 93 90 108	Findings suggest that dietary fat, particularly SFA, is increases blood cholesterol, especially LDL-Chol in preschool children. Correlation R^2 TC LDL-C SFA 0.12 0.16 TF 0.08 0.10 Data adjusted in multiple linear regression models for caloric intake, age, sex, and body mass index.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Prewitt T. E., et al (Ref. 178)	Controlled clinical trial, diet intervention in free-living subjects. Purpose: to compare effects of high (37% of calories) and low fat (20% of calories) diet on a. insulin like growth factor and b. blood cholesterol levels Study site: Chicago, IL.	Eighteen healthy premenopausal women, mean age 32 years. Subjects had higher than average levels of blood cholesterol (50th) percentile. Baseline blood lipid data other than range notated above was not provided in the paper. Other: mean BMI 30; n=12 BMI 23; n=6 BMI 38.4.	All subjects consumed the 37% fat diet for 4 weeks, followed by 20 weeks of a the 20% fat diet. Diet composition (% of calories) High fat / Low fat Fat 37% / 20% P/S 0.5 / 1.0 Chol (mg/d) 266 / 94 Meals provided and monitored on site. Absolute amount of SFA and PUFA dietary data not provided in study; no data on MUFA content provided.	When all subjects were considered, total cholesterol (TC) and LDL-cholesterol tended to decrease by consumption of low fat, low cholesterol diet Consumption of low fat diet by the obese group, decreased TC and LDL-cholesterol. Blood lipid data: Entire group versus Obese (mg/dL) 37% 20% 37% 20% TC 200 185 205 193 LDL 127 120 143 127 HDL 46 50 40 41 No relationship was observed between BMI and TC or LDL-cholesterol when all subjects were considered together or divided into normal weight or obese groups.	There was no run-in or diet stabilization period. The study did not use a wash-out period between diets or alternatively use cross over design. In premenopausal, obese women consumption of a diet in which fat was 20% of calories and 94 mg/day reduced TC and LDL-cholesterol. Variance in absolute amounts of PUFA, SFA, MUFA complicates interpretation and applicability of results to general public or a subpopulation.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Berlin E. et al (Ref. 157)	Clinical trial, dietary intervention, free-living, controlled, randomized study. Purpose: To compare the effects of high fat diet (40% of calories) and low fat diet (20% of calories), on blood cholesterol levels and lipoprotein fluidity in premenopausal women. Diets also varied in amount of PUFA and SFA. Study site: BHNRC, Beltsville Maryland.	Thirty-seven healthy women between 20 and 40 years of age selected, 31 finished the study.	Free choice dietary period for one menstrual cycle. All women were then placed on high fat diet for 4 months (4 menstrual cycles) and then switched to low fat diet for 4 months. Food was provided, eaten on site or prepared for home consumption. Approximately 2,200 kcal per day. Diet composition data (% of energy): Nutrient and diet intervention groups 1 2 3 4 Carb 45 45 64 64 Fat 39 39 19 19 Chol 374 289 230 199 (mg) SFA 44 27 21 12 (g) C18:1 30 33 15 17 (g) C18:2 15 26 7 13 (g) Fluidity measured by fluorescence anisotropies using the probe 1,6 diphenyl 1,3,5 hexatriene (DPH).	Plasma cholesterol levels were lower during luteal phase of menstrual cycle regardless of diet. Blood total cholesterol data (mg/dL): Diet groups 1 2 3 4 Follicle 160 152 157 154 Leuteal 148 140 152 149 In general low-fat, and higher portion of PUFA in the diet increased lipoprotein fluidity. Fluidity of VLDL was related to oleate and linoleate. Fluidity of LDL and HDL, however, showed an inverse relationship to oleate and linoleate content.	It is difficult to evaluate study based on P/S ratio, without grams or percent of SFA, PUFA, and MUFA in the diet. It is possible that the SFA content of the diet was the same throughout the study. This was not the case in this study as shown by composition in g of SFA content. No consistent relationship emerged from the study to indicate that lipoprotein fatty acid content determined either LDL-C or HDL-C fluidity. The dietary cholesterol content was more significant than fatty acid content in determining LDL fluidity. This result would suggest another important role of dietary cholesterol separate from its effect on blood cholesterol levels. Changes in fluidity of lipoprotein particles may in tern alter their interaction with receptors and therefore alter the fate of blood cholesterol levels

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Bazzarre T. L. et al (Ref. 155)	Cross-sectional Purpose: to examine the relationship of several cardiovascular disease risk factors (CDRF) such as blood pressure (BP), total cholesterol (TC), HDL-C, BMI and percent of fat with daily energy intakes (EI) and daily energy expenditure (EE). Study site: North Carolina	Farmers and farm wives. 84 men (mean age 53) 74 women (mean age 51). BMI for men was 62 and 43 for women.	Dietary data and activity records collected for 4 days. Subjects were instructed to maintain their normal diet and activities. No dietary composition provided in the study.	For both males and females, at every age group, energy expenditure (EE) was greater than energy intake (EI). Mean EI and EE were statistically less from females than for males. Mean systolic BP, diastolic BP, TC, HDL-C were within normal limits. Mean TC, HDL-C and diastolic BP was slightly higher in females than in males. Blood lipid data mmol/L (mg/dL) Males / Females TC 5.4(206) / 5.45(210) LDL 3.98(154) / 3.87(149) HDL 1.36(52) / 1.58(61) When EI compared to EE, farm men consumed and expended more energy than farm women. Energy data: Males / Females EI 2413 / 1761 EE 4300 / 2919 Balance(EI-EE) -1886 / -1158	EE obtained from a reliable activity record may be a more practical tool for assessing the possible relationship of energy metabolism to CHD risk factors such as total and LDL cholesterol. Males who expend energy (exercise) may reduce risk of CHD.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Demacker P. N. M. et al (Ref. 163)	Dietary intervention study. Cross-over design, in free-living subjects. Purpose: To compare the effect to two diets: one enriched in SFA and the other enriched in PUFA on postprandial lipoprotein metabolism Study site: Netherlands	Twelve normalipidaemic subjects (six males and six females), ages 21 to 26 years. Subjects had fixed pattern of daily activities, none smoked. Other: mean BMI was 22.	Subjects consumed each test diet 9 days with a 4-week wash-out with habitual diet. Lunch was prepared in hospital kitchen. Meals consumed at fixed time intervals. Dietary instruction was given and dietary records maintained for breakfast and dinner meals. Rate of absorption of retinyl palmitate was used as a marker to measure rate of fat absorption was added to lunch meal on day 9 of the study. Diets: contained 2,400 kcal; fat 36.5% and Carbo 47.5% of calories; and Chol 294 mg/day. [% of calories - diets:] SFA 21 PUFA 10 MUFA 12 9 PUFA 3 18	Consumption of the PUFA enriched diet resulted in a significant decrease in TC and LDL-C compared to SFA enriched diet. HDL-C was not significantly altered by diet. Blood lipid data (mg/dL) SFA PUFA TC 118 108 LDL-C 71 59 HDL-C 38 36 Other results: There was a 43% decrease in chylomicron and their ruminants as well as a 20% decrease in VLDL due to consumption of the PUFA enriched diet. Chylomicron remnants were 43% more rapidly removed on diet rich in PUFA compared to diet rich in SFA. Since the rate of absorption is the same, an increase in the rate of clearance of triglyceride and cholesterol rich particles may explain the significant decrease in blood levels of these lipoprotein particles by PUFA-enriched diet.	Because of the short duration of the study (9 days), applicable results refer to short half-lived lipoprotein particles [chylomicron, VLDL and their remnants]. Under these circumstances cannot conclude whether or not the PUFA enriched diet altered the level of HDL. Second, the PUFA enriched diet was also reduced in SFA (about 10% of calories). This decrease in SFA content may account for decrease in TC and LDL-C observed. Thus added PUFA when substituted of SFA did not negate the cholesterol lowering effect of decreasing the SFA content of the diet. If future studies support these results such that a PUFA enriched diet increases the rate of clearance for chylomicron remnants, this could suggest a decrease in a lipoprotein particle of atherogenic potential.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Seidell, J. C. et al (Ref. 182)	Cross-sectional survey Purpose: To determine is there is a relationship between linoleic and linolenic content in gluteal fat tissue and serum lipids. Study site: five populations in Europe (Sweden, Netherlands, Belgium, Italy and Poland)	Three hundred and twenty-seven men aged 38 from five European towns. Specific details of general health, except for smoking habits were not presented in the paper. No dietary data was available for evaluation.	Fat biopsies taken from the upper outer quadrant of the left buttock. Serum lipids [total cholesterol, HDL-cholesterol and triglycerides] were determined enzymatically after an overnight fast. LDL-cholesterol determined by the Fridewald equation.	Adipose linoleic content, which varied widely was lowest in men from Poland (8.6%) and highest in men from Belgium (16.7%). Linolenic acid content was lowest in men from Italy (0.5%) and highest in men from Sweden and the Netherlands (0.9%). Linoleic acid was negatively correlated with LDL-C (-0.15, $p<0.01$) and total cholesterol ($r=-0.17$, $p<0.01$). Linolenic acid was negatively correlated with serum triglycerides ($r=-.14$, $p<0.05$). There was a significant difference in HDL-C levels , with the highest level in men from Italy, Belgium, and Sweden and the lower concentration in men from Poland. Total cholesterol and LDL-C was highest in Italian males [TC= 6.2 mmol/L and LDL-C= 4.2 mmol/L] but lowest in Swedish men [TC= 5.7 mmol/L and LDL-C= 3.9 mmol/L].	The authors concluded that there were major differences in these adipose unsaturated fatty acids from different European communities which correlated with some, but not all serum lipids. Adipose linoleic and linolenic content did not adequately explain the significant differences observed in serum HDL-C and triglycerides.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Brown, S. A., et. al. (Ref. 160)	Dietary intervention; dietician-instructed and multiple interviews; free-living; meals provided; food consumption supervised; dietary records maintained and checked. Purpose: measure effect of dietary cholesterol on blood lipids. Study site: Austria.	Study 1: 81 normolipidemic [less than 240 mg/dL fasting TC, 175 mg/dL LDL-C]; healthy outpatient males (aged 20 to 50 years, mean age 29.6 year). Study 2: 14 of the 81 males participated.	Study 1. Two diets (3 weeks each) of 6-week study. First 3 weeks: low chol diet (fat 40%; Carb 45%; protein 15% of total calories; Chol less than 300 mg/day). Second 3 weeks: similar to first 3 weeks plus 6 eggs per day (1,300 mg Chol/day). Diet fat composition estimated based on percent of C-16 and C-18 for SFA, C-18:1 for MUFA and C:18:2 for PUFA. Study 1 fat content (% of calories) total fat 38% SFA 11% MUFA 13% PUFA 6% Study 2. Four diets compared, 3 weeks/diet, for a total 12 weeks. Percent of Carb and protein same as above. Estimate of fat distribution for study 2. Test diets 1 2 3 4 TF 45 44 45 44 SFA 11 11 8 8 MUFA 20 20 10 10 PUFA 7 7 20 21 chol (mg/d) 300 1,300 300 1,300	Study 1. In the 81 normotensive males, dietary cholesterol consumption increased total (12%), LDL-C (17%) and HDL-C (5%) significantly. Blood lipid data (mg/dL) 300 mg 1,300 mg TC 171 192 LDL-C 102 120 HDL-C 52 55 Study 2. LDL-C levels increased significantly (27%) on the high SFA-high cholesterol diet (diet 2) compared to SFA enriched diet with low cholesterol (diet 1). When subjects switched from SFA enriched, cholesterol rich diet to PUFA enriched low cholesterol diet; TC and LDL-C decreased significantly (31%) and HDL-C was unchanged (to diet 3). LDL-C was lowest on the PUFA enriched-low cholesterol diet. Adding cholesterol to PUFA increased LDL-C (25%) (diet 4). Study 2. Blood lipid (mg/dL) 1 2 3 4 TC 152 178 137 160 LDL-C 88 112 77 96 HDL-C 51 54 48 53	Results demonstrated that both dietary SFA and cholesterol increase total and LDL-C levels in normolipidemic males. The study included the use higher levels of total fat, dietary cholesterol and PUFA than is recommended for the general public.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Valsta, L. M. et al (Ref. 188)	Dietary intervention in free-living subjects. Cross-over design. Conventual mixed solid foods, meals provided and consumption monitored. Food records maintained. Duplicate portions of each diet collected daily and analyzed. Purpose: to compare effect of diets enriched in either MUFA or PUFA on serum lipoprotein Study site: Finland.	Fifty-nine healthy volunteers (30 men, 29 women), aged 18-65 years (median 25 years). At baseline subjects TC was 4.82 mmol/L or 186 mg/dL (men) and 5.23 mmol/L or 201 mg/dL (women). Subjects maintained normal lifestyle (same smoking habits, alcohol consumption, and exercise).	Study lasted 63 days. Baseline diet 2 weeks (SFA enriched), followed by two test diets (PUFA or MUFA enriched) for 25 days each. MUFA enriched diet used rapeseed oil and contained 5% SFA, 58% MUFA, 24% PUFA [n-6] and 13% PUFA [n-3]. PUFA enriched diet used sunflower oil and contained: 12% SFA, 23% MUFA, 65% PUFA [n-6]. Diets as % of total calories: BASE PUFA MUFA Fat 36 38 38 SFA 19 13 12 MUFA 11 10 16 PUFA 4 13 8 Chol (mg/d) 354 315 360	Dietary compliance assessed by plasma phospholipid fatty acids composition. Both PUFA and MUFA enriched diets significantly reduced TC and LDL-C from baseline. The MUFA enriched diet reduced TC and LDL-C more than PUFA enriched diet. Blood lipid data: mmol/L (mg/dL) BASE PUFA MUFA TC 5.3(205) 4.6(178) 4.5(174) LDL 3.2(123) 2.6(100) 2.4 (93) HDL 1.3 (51) 1.3 (50) 1.3 (51) The differences between test diets in TC and triglyceride (TG) were more pronounced in women but statically insignificant from men. Conversely, the test diets effected LDL-C and HDL-2 of men more than women.	MUFA enriched diets were shown to be equally effective as PUFA enriched diet in reducing TC and LDL-C levels in men and women. HDL-C was not significantly reduced by consumption of PUFA or MUFA enriched diet. If PUFA is at or below 10 to 13% calories, HDL-C levels do not appeared to be lowered. Study results suggest cannot rely on Key equation to predict the effect of MUFA and PUFA on serum cholesterol levels.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Zock P. L. and Katan M. B. (Ref. 193)	Dietary intervention. Random, multiple cross-over design in healthy free- living subjects; uses three consecutive periods; three test diets lasting 3 weeks each. Meals provided. Duplicate portions of each diet were analyzed each day. Food dairies maintained. Purpose: To compare the effects of C-18 fatty acids on serum cholesterol levels: SFA (stearic acid); trans MUFA (elaidic acid); PUFA, (linoleate acid) Study site: Netherlands	Twenty-six men, 30 women normolipidemic, completed study. Equal number of men and women in each test group. Mean total cholesterol men and women was 157 mg/dL; HDL-C was 53 mg/dL. Age ranged 19 to 48 years for men, mean 25 years; Age ranged 18 to 49 years, mean 24 years for women.	Diets did not differ from one another other than test fatty acid which was 8% of total energy. Trans fatty acid (TFA) prepared from high oleic acid sunflower oil; hydrogenated with sulfurized nickel catalyst, and mixed 75 parts of TFA to 25 parts oleic acid rich oil. Stearate (S.A.) inter-esterified from a mixture of 41 parts of hydrogenated high linoleic acid sunflower oil to 50 parts high oleic sunflower oil and 9 parts of unmodified high linoleic sunflower oil. Diets as % of total calories: L.O.= linoleate; Trans= trans elaidic; S.A.= stearate L.O. S.A. TRANS Fat 41 43 40 SFA 11 20 10 MUFA 16 17 23* PUFA 12 4 4 Chol (mg/MJ) 33 33 33 *7.7% as trans MUFA	Compared to levels of serum cholesterol on linoleate diet both stearate and trans fatty acid enriched diet significantly increased TC and LDL-C levels. In addition, both stearate and trans fatty acid enriched diet significantly reduced HDL-C compared to linoleate enriched diet. Blood lipid data (mg/dL) L.O S.A. TRANS TC 183 189 189 LDL 109 116 119 HDL 57 54 53	Consumption of trans fatty acid enriched diet which is closer to some subpopulation groups in U.S. increased blood risk factors for CHD. Broader spectrum of subjects than in earlier Mensink and Katan study. Trans fatty acid consumption of total calories and g/day: Current U.S. 3 to 4% or 7 to 10 g/day; Zock and Katan study 7.7% or 24 g/day; Mensink and Katan study 11% or 33 g/day. The authors suggest that every one percent of energy from trans fatty acids increases LDL-C 1.2 mg/dL and lowers HDL-C 0.6 mg/dL relative to oleic and linoleic acid. Therefore at current U.S. consumption of 3 to 4 % of calories, contributions from trans fatty acid could increase LDL-C by 4 mg/dL and decrease HDL-C by 2 mg/dL.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Mata P. et al (Ref. 175)	Dietary intervention in free-living healthy men and women. Controlled, cross-over design. Dietary diaries maintained. Compliance assessed by questionnaire and observation. Consumed solid foods. Purpose: determine long- term effects of MUFA versus PUFA enriched diets on risk factors for CHD. Study site: Spain	Seventy-eight subjects from 2 urban closed communities (46 men mean age 33 years and 32 women mean age 42 years). Plasma cholesterol levels above 90th percentile and below 10th percentile were excluded from study (specific baseline data not provided in the study). Subjects maintained habitual lifestyle throughout study.	Maintained usual diets [men: fat 37% and Carb 43% of calories (2,540) and women: fat was 36% and carb 48% of 2,000 calories] with exception of type of dietary oil. Phase 1: subjects consumed PUFA enriched diet (sunflower oil- enriched in linoleic acid) for 12 weeks. Phase 2: subjects consumed MUFA enriched diet (olive oil- enriched in oleic acid) for 28 weeks. Vegetable oils comprised 44% of dietary fat (16% of total calories) for men and 50% of dietary fat (18% of calories for women). Diet composition as % of total calories PUFA / MUFA FAT 37 / 36 SFA 12 / 12.5 MUFA 11 / 20 PUFA 12.8 / 3.4 CHOL (mg/day) 460 / 337	Blood lipids were analyzed in week 10 and 12 of the PUFA enriched diet and weeks 4, 8, 12, 16, 28 weeks of the MUFA enriched diet. In this study the PUFA is the baseline of comparative diet. Phase I. Blood lipid data at 12 weeks (expressed in mmol/L and mg/dL) Men / Women TC 4.93(190) / 5.2(201) LDL 3.3(126) / 2.48(96) HDL 1.0(39) / 1.3 (51) In Phase 2 (at week 16 for men and 28 for women respectively, on the MUFA enriched diet): nonsignificant reduction in TC and LDL-C, but HDL-C increased significantly for men. In women: TC increased significantly (to 5.7 mmol/L (220 mg/dL or by 9%), LDL-C was unchanged (2.4 mmol/L or 94 mg/dL) and HDL-C increased significantly (to 1.7 mmol/L or 66 mg/dL or by 30%). No blood lipid data was provided for men at week 28 of study. The authors used an atherogenic index defined as (TC:HDL-C) to compare the effects of PUFA to MUFA diets: in men the atherogenic index fell 12% and 17% in women.	Larger and longer dietary intervention study than many of previous studies. The paper did not report baseline cholesterol values. Study which lasted up to 28 weeks allows for some estimation of possible long-term effects of MUFA compared to PUFA on blood lipids. Compared to the PUFA diet, the MUFA enriched diet significantly increased HDL-C levels without increasing TC or LDL-C for both men and women. The increase in HDL-C due to consumption of the MUFA enriched diet was larger in females than males. Public health significance: diets were similar in the total fat content to the American diet, but had a higher percentage of MUFA suggest that longer term consumption may reduce total and LDL-C without reducing and perhaps increasing HDL-C levels.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Garry P. J. et al (Ref. 167)	Longitudinal, nonrandom, free-living study design. Purpose: to estimate the effect of dietary intake from protein, fat carbohydrate, and total energy on plasma lipid levels in healthy, elderly men and women. Length of study 9 years. Study site: New Mexico and the United States	One hundred and fifty-seven healthy elderly men (n=65) and women (n=92) outpatients from Albuquerque, NM. All subjects > 60 years (medium age 70 years). Subjects were caucasians, who for the most part were health conscious and educated.	Dietician instructed, maintained food records. Nutrient content of diets analyzed. Analysis of blood was at the same time annually. Nutritional and clinical data collected from 1989 to 1989. Analyzed nutritional status also grouped by age (cross-sectional or cohort differences).	No significant cross-sectional differences in energy, protein total fat and carbohydrates intake with age was noted. There was a significant longitudinal decrease in total fat, saturated and PUFA and cholesterol intakes in men and women. Significant decreases in total, HDL-C and LDL-C plasma cholesterol concentrations were reported in both women and men. Blood lipid data mmol/L (mg/dL) Women / Men TC 6.3(243) / 5.6(217) LDL 4.1(158) / 3.8(139) HDL 1.5(59) / 1.3(52) Longitudinal predicted changes (mg/dL) Women / Men TC -1.5 / -2.2 LDL -0.9 / -1.1 HDL -0.9 / -1.1 The decrease in total fat and cholesterol intakes were significantly correlated with the decrease in total plasma cholesterol.	Study found significant associations between changes in dietary intake and changes in plasma lipids over time. When both SFA and PUFA intakes decreased over time, HDL-C was also reduced (therefore HDL-C reduced even when PUFA does not substitute for SFA).

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Nguyen, L. B. et al (Ref. 194)	Dietary and drug intervention study. Controlled study in free- living subjects. Purpose: to determine the effects of cholesterol lowering drug and restriction of dietary cholesterol on synthesis and serum lipoprotein levels in two families with a lipid storage disease. Study site: New York and New Jersey	Two homozygous (male 28 years and female 9 years) and 2 obligate heterozygous subjects (female 25 years and male 47 years) with sitosterolemia, and 17 healthy control subjects [10 males and 7 females ranging between 19 and 60 years of age.	The metabolic ward diet consisted of: carbohydrate 53%, protein 17% and fat 30% of total calories, and cholesterol 223 mg/2,000 calories. Drug regiments consisted of: lovastatin (15 mg twice daily) and cholestyramine (15 g/day). The effect of diet alone on paired test subjects in a metabolic ward (one homozygous and one heterozygous), diet in combination with drug regiments was conducted for 3 weeks each followed by a 2-week wash-out on the basal diet. A second pair of test subjects were on free-living diets (contained the similar caloric profiles but differed in sterol content [high= 400/500 g/day cholesterol and 100 to 150 mg/day plant sterols: low =100 g/cholesterol and 50 mg plant sterol/day), one free-living heterozygous subject received no drug treatment.	Both homozygous subjects had elevated cholesterol levels compared to controls [>300 vs 185 mg/dl respectively]. Dietary sterol restriction was ineffective in lowering serum cholesterol levels in homozygous subjects. Neither lovastatin or low sterol diet produces a significant effect on reduced mononuclear leukocyte HMG-CoA reductase activity in homozygous or heterozygous subjects while lovastatin increased HMG CoA reductase 38% in controls.	Small study due to nature and rarity of the disease. Not all test subjects complied with both diet and drug treatments. Many confounders in study design and therefore difficult to make conclusions. There are marked abnormalities in cholesterol homeostasis in patients with homozygous sisterolemia. The results suggested a depressed cellular cholesterol synthesis due to a deficiency in HMG-CoA reductase that cannot be up regulated by a low sterol diet. Can not make public health conclusions from this study.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Meinertz H. et al (Ref. 195)	A controlled dietary intervention study in free-living subjects. Purpose: to compare the effects of two sources of dietary protein (plant and animal) with dietary cholesterol on serum lipoproteins in healthy subjects. Study site: Denmark	Twenty-one healthy active individuals (11 women and 10 men). Subjects had normal body weight, and normal cholesterol levels. Age range of subjects was 28 to 55 years.	All subjects received both the soy protein and the casein diets, with or without cholesterol enrichment in a cross-over design. Each dietary period lasted 31 days. The study included a 30-day wash-out period on a self selected diet. Diet composition (% total calories) Protein: Cas(g) Soy(g) (20%) 139 140 Fat (27%) Carbohydrate (53%) Cholesterol (mg) Low animal 72 12 plant 214 251 Cholesterol (mg) High animal 549 486 plant 579 637 casein = CAS soy protein = SOY Caloric intake from protein and fatty acid composition of both diets were very similar. SFA and stearic acids together was 11% of calories.	Body weight decreased on both diets casein and soy diets and on both low and high cholesterol diets. TC, triglycerides and VLDL-C levels were similar on casein and soy, regardless of the cholesterol content of the diets. On a low-cholesterol diets, the mean plasma levels of LDL-C and HDL-C were identical and not dependent on source of dietary protein. On a cholesterol enriched diet, however, LDL-C levels were significantly lower on the soy protein diet and HDL-C was significantly higher. Blood lipid data (mg/dL) Low Chol: CAS, SOY Enriched Chol: CAS, SOY TC: 124, 127, 138, 133 LDL: 68, 66, 81, 68 HDL: 42, 43, 47, 53	Results suggest an interaction between source of dietary protein (plant and/or animal) and dietary cholesterol on levels of blood LDL-C and HDL-C concentrations. On cholesterol enriched diet, the source of dietary protein appears to be more important in determining serum cholesterol levels than on a low cholesterol diet. This study is of public health significance, since the results suggest that on a cholesterol enriched diet, such as found in the U.S., casein (animal protein) increased LDL-cholesterol while simultaneously reducing the HDL- cholesterol.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Barr S. L. et al (Ref. 220)	Dietary intervention study. Randomized, double blind and controlled study in free-living subjects. Purpose: to compare the effects of a low fat diet and a low fat diet that is reduced in saturated fat on blood cholesterol levels in healthy males. Study site: New York	Forty-eight healthy males ages 21 to 32 years. Subjects with extreme dietary habits or ethanol intake were excluded. Other: men BMI 24 Baseline lipids (mg/dL): ADD Step 1 Sat TC 185 185 179 HDL 46 49 49 LDL 139 136 130 n=17 n=15 n=16	All subjects consumed baseline diet (3 weeks) equivalent to average American diet (AAD). Meals provided throughout 10-week study. Randomly assigned to three isocaloric diet groups (7 weeks). Group 1 (ADD); group 2 (AHA Step 1); group 3 (AHA + SFA). Diet composition: % of total calories AAD Step 1 SAT Fat 36 29 29 SFA 14 8.6 12 MUFA 14 12.8 10.6 PUFA 7 7.6 6.3 Chol (mg/d) 491 303 347	Refer to baseline data: Overall the switch to Step 1 diet significantly decreased total cholesterol by 0.36 mmol/L or 14 mg/dL (7.5%). Men on SFA/Step 1 diet had non-significant decrease in total cholesterol of 0.08 mmol/L or 3.1 mg/dL (1.6%) compared to AAD diet. Switch to Step 1 diet significantly decreased LDL-cholesterol 0.25 mmol/L or 9.6 mg/dL (8.1%). Consumption of SFA diet was associated with a decrease of 0.03 mmol/L or 1.1 mg/dL (1.1%). Switch to Step 1 diet significantly decreased HDL-cholesterol 0.11 mmol/L or 4.2 mg/dL (8.6%). Switch to SFA diet decreased HDL-cholesterol by 0.06 mmol/L or 2.3 mg/dL (4.6%.)	No significant decreases in total or LDL-cholesterol were observed in healthy males when total calories from fat was reduced from 37% to 30%. Significant reductions in total and LDL-cholesterol were observed in healthy males when both total fat and saturated fat content of the diet was reduced.
Lehtimaki, T. et al (Ref. 221)	Dietary intervention study. Controlled, switch-back in free-living subjects. Purpose: to compare the effect of dietary cholesterol on blood lipids and apolipoprotein E phenotypes in healthy males and females. Study site: Finland	Thirty-six normolipidemic students (16 female and 20 males, average age 23.9 years). Apo phenotypes were: E3/2 (n=9); E3/3 (n=11); E4/4 (n=3). Baseline lipids for all subjects estimated from figure of data at zero time: TC range (4.5 to 5.2 mmol/L (174 to 201 mg/dL)); LDL-C (2.4 to 2.9 mmol/L (93 to 112 mg/dL)) and HDL-C (1.4 to 1.7 mmol/L (54 to 66 mg/dL)]) Other: All participants were nonsmokers, used minimal alcohol, mean 21.9 BMI.	Baseline diet (3 weeks), followed by 3 week diet intervention which was followed by 3 week return to baseline diet. No eggs consumed on baseline diets. Dietary intervention included addition of three eggs (yolks)/day or addition of 750 mg extra dietary cholesterol. Energy intake was not measured during intervention. Body weights unchanged during the study.	There were no significant differences between males and females either during intervention or switchback. Three week of cholesterol enriched diet induced significant increase in total and LDL-cholesterol, and apo B concentration in all 4 phenotypes. In all phenotype groups, HDL-cholesterol increased with dietary cholesterol consumption. All lipid classes returned to original concentrations after switchback. The response in blood LDL-cholesterol and apo B to the cholesterol rich diet was greater in apo E4/4 subjects. The above statements on response to dietary cholesterol are the authors and supported by figures of the data in the paper.	Insufficient dietary data provided to evaluate study accurately. Did not record saturated fat and cholesterol contents in the baseline and intervention diets. Stronger responses by apo E4/4 phenotypes, suggests these individuals are more sensitive to dietary cholesterol (increased two-fold over other phenotypes). In Finland about 6% of the population is of the apo E4/4 phenotype.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Tremblay, A. et al (Ref. 217)	Diet and exercise intervention study in free-living subject. Individual recorded dietary records for 1 day /week throughout study. Meet once per week with dietitian and exercise specialist. Purpose: to determine the effect of a low fat diet and exercise on metabolic profiles (including blood lipids) in obese women. Study site: Canada	Four obese women, average age 42 years. On an average body weight was 92 kg, and % body fat 49. Baseline blood lipids (mg/dL): TC 214 LDL 157 HDL 38 TG 126	29-month study which included two experimental periods [period one (15 months) involved supervised aerobic exercise and the second period involved exercise plus low fat diet]. The dietary intervention by instruction was to maintain protein (0.9 g/kg body weigh) and carbohydrate intake but to reduce lipid consumption to 26 to 28% of total calories (no indication of what baseline macronutrient intake was).	Lipid intake in period 1 and 2 was 29 and 30% of total calories. A significant decrease in body weight, fat mass and percent body fat occurred in period 1. Substantial reductions in plasma cholesterol [from 214 down to 174 mg/dL] and LDL-cholesterol [157 down to 116 mg/dL] were observed in period 1 and 2. Plasma HDL-cholesterol was not changed [38 compared to 40 mg/dL] but apo A-1 (HDL) was significantly increased by exercise [105 compared to 122 mg/dL].	At end of 29 months subjects lost 11 kg (but were still obese). Plasma glucose and insulin response to oral glucose similar to nonobese subjects. Interventions appeared to normalize level of risk for diabetes which is also a risk factor for CHD. Results (n=4) suggested that long-term exercise program can reduce plasma total and LDL-cholesterol levels in obese subjects.
Bonanome, A. et al (Ref. 219)	A randomized, cross-over design, dietary intervention study in free-living subjects. Purpose: To compare the effects of MUFA and PUFA on blood lipids and the susceptibility of LDL-cholesterol to oxidation. Study site: Pauda Italy.	Eleven healthy males, mean age 22 years, body weight 76 kg and body mass index of 25. Blood lipid profile of subjects: blood cholesterol (4.68 mmol/L or 181 mg/dL); LDL-cholesterol of 3.2 mmol/L or 125 mg/dL and HDL-cholesterol of 1.1 mmol/L or 44 mg/dL.	Two solid food diets with each diet lasting 3 weeks separated by washout period of 7 days. Phase 1 was enriched in MUFA and phase 2 was enriched in PUFA. Dietary composition (% of total calories) MUFA PUFA Fat(45%) SFA 10 10 MUFA 30 5 PUFA 5 30 chol <200 <200 (mg/day) Grapeseed oil supplied most of PUFA in diet. Olive oil supplied most of MUFA in diet. Other: susceptibility to oxidative modification was measure in 2, 2'azobis (2-aminopropane) dihydro-chloride (AAPH). AAPH is a water-soluble diazo compound that generates free radicals by spontaneous thermal decomposition.	Both diets significantly lowered total and LDL-cholesterol. Blood lipid data mmol/L (mg/dL) Baseline MUFA PUFA TC 4.7(181) 3.8(148) 3.5(134) LDL 3.2(125) 2.6(100) 2.3 (90) HDL 1.1(44) 1.0 (40) 0.98(38) TG 1.1 0.8 0.7 Other: The peroxidation rate was significantly higher when patients were on PUFA diet compared to MUFA diet. No significant differences were observed for inhibition of peroxidation by either diet.	Replacement of calories from SFA by either MUFA or PUFA induced a significant hypocholesterolemic effect. In addition, the results of the study support the hypothesis that diets rich in MUFA increase resistance of LDL-cholesterol to oxidative modification, independent of their content of antioxidants. Changes in peroxidation rate suggest that once LDL-cholesterol is depleted of antioxidant content, a diet enriched in MUFA may allow LDL-cholesterol to resist oxidative stress. Ratio of oleic to linoleic in LDL was inversely correlated with the peroxidation rate.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Zimetbaum, P. et al (Ref. 218)	Epidemiological, prospective study. Purpose: to access the correlation of lipid and lipoproteins levels on CVD risk, stroke, dementia, and death in the elderly. Study site: New York, (10-year follow-up of the Bronx Aging Study (BAS))	Mean age of entry into BAS study was 79 years, who did not have any diagnosed terminal illness or dementia. From BAS enrollment of 488, 350 had two lipid determinations at 10 years. Subjects had about a 7 to 9 th grade education, 60% were men and 25% of women were smokers, 48% of subjects took diuretics.	Extensive medical and psychosocial histories taken, laboratory screening, neurological and neuropsychiatric testing. CVD included MI, stroke and other heart related deaths. All events verified by reviewing medical records and/or death certificates.	Mean blood lipid values: (mg/dL) Total Men Women chol 207 234 LDL-C 140 158 HDL-C 38 46 Proportional hazards analysis showed that men with consistently low HDL-cholesterol levels (<30 mg/dL) were independently associated with the development of MI, CVD and /or death. For women, elevated LDL-cholesterol (>171 mg/dL) was associated with MI.	Using both univariant and multivariant analysis, only a consistently low HDL-cholesterol was significantly and independently associated with MI or all cause mortality in elderly men even after controlling for smoking and hypertension. For elderly women only a consistently elevated LDL-cholesterol was associated with MI. No significant associations between lipids and dementia were observed for either men or women. These results are in contrast to Framingham report which reported that baseline low HDL-cholesterol levels was associated with increased risk of MI and or death in both elderly and middle aged men and women. Elevated total cholesterol was not found to be an independent risk factor for MI or death.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 91N-0097]

RIN 0905-AD08

Food Labeling: Health Claims and Label Statements: Dietary Fat and Cancer

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is authorizing the use on the labels and labeling of certain foods of health claims relating to an association between dietary fat and cancer. This final rule is issued under provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) and was developed in accordance with the final rule on general requirements for health claims, which is published elsewhere in this issue of the **Federal Register**. The agency has concluded that, based on the totality of the scientific evidence, there is significant scientific agreement among qualified experts that diets low in fat may reduce the risk of some cancers. Therefore, FDA has concluded that claims on certain foods relating fat reduction to reduced risk of cancer are justified.

EFFECTIVE DATE: May 8, 1993.

FOR FURTHER INFORMATION CONTACT: Helen HeChong Lee, Center for Food Safety and Applied Nutrition (HFS-226), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5558.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 27, 1991 (56 FR 60764), FDA proposed to authorize the use on food labeling of health claims relating diets low in fat to reduced risk of some types of cancer, particularly breast, colon, and prostate, in the general population (hereafter referred to as the lipids/cancer proposal). The lipids/cancer proposal was issued under provisions of the 1990 amendments (Pub. L. 101-535) that bear on health claims and in accordance with the proposed general requirements for health claims for foods (November 27, 1991, 56 FR 60537). As amended in 1990, the Federal Food, Drug, and Cosmetic Act (the act) provides that a food is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition unless the claim is made in accordance with section 403(r)(3) or (r)(5)(D) of the act (21 U.S.C. 343(r)(3) or 343(r)(5)(D)).

Section 3(b)(1)(A) of the 1990 amendments specifically requires that the agency determine whether claims respecting 10 nutrient/disease relationships meet the requirements of section 403(r)(3) or 403(r)(5)(D) of the act. The relationship between lipids and cancer is one of the claims required to be evaluated. In the **Federal Register** of March 28, 1991 (56 FR 12932), FDA published a notice requesting scientific data and information on the 10 specific topic areas identified. Relevant scientific studies and data received in response to this request were considered as part of the agency's review of the scientific literature on lipids and cancer and were included in the lipids/cancer proposal. Comments received in response to the notice and not specifically addressed in the lipids/cancer proposal are summarized and addressed below.

In addition to evaluating the scientific evidence, the lipids/cancer proposal identified qualifying and disqualifying nutrient levels for foods bearing health claims on fat and cancer. The lipids/cancer proposal also specified mandatory and optional information for health claim statements and provided sample messages. FDA requested written comments in response to its proposed rule. In addition, FDA held public hearings on January 30 and January 31, 1992, on all aspects of the proposed rules published in response to the 1990 amendments, including health claims for lipids and cancer.

II. Summary of Comments and the Agency's Responses

In response to its proposed health claim regulation on lipids and cancer, the agency received approximately 80 letters, each containing one or more comments, from consumers, consumer groups, health care professionals, professional organizations, State and local governments, a foreign government, trade associations, and industry. A number of comments received on this proposed rule were more appropriately addressed in other documents, and these comments were forwarded to the appropriate docket for response.

A. Validity Issues

1. Many comments addressed the basic issue of whether FDA should permit any health claims about total fat and/or any particular type of fat and cancer on food labeling. Several comments objected to the lipids/cancer claim and suggested that results from epidemiologic studies are often inconclusive and do not provide the information necessary to identify the type of fat that is responsible for cancer. Some comments felt that claims about saturated fat and cancer, but not about total fat and cancer, may be justified, but did not provide any data to document this conclusion. Other comments noted that results from animal studies suggest that dietary lipids do not affect noncarcinogen-induced tumorigenesis. Some comments suggested that animal studies reported conflicting results on the relationship between dietary lipids and cancer. Other comments expressed concern that rodent studies were extrapolated to humans without considering species differences.

Conversely, there was widespread support from organizations of nutritionists, organizations of health professionals, scientific societies, consumers, and food manufacturers for the agency's proposed rule. Most of these comments took the position that there was adequate scientific evidence to support claims about total fat and cancer, and concurred that these claims should be permitted. Some of these comments stressed that the recommendations from Federal government agencies and other authoritative scientific organizations, which concluded that diets high in fat increase the risk of cancer, are widely accepted in the scientific community.

FDA agrees that the totality of scientific evidence provides considerable support for a claim about the relationship between high intakes of dietary fat and increased risk of some cancers and that the conclusions and recommendations reached in a number of Federal government and other authoritative documents about this relationship demonstrate the existence of significant scientific agreement among experts qualified by experience and training to evaluate such evidence. In developing its proposed regulation, FDA has reviewed Federal government reports and other review documents as well as recent research articles relevant to dietary lipids and cancer risk. Authoritative documents consistently and independently conclude that dietary fat contributes to the risk of some cancers. Among human studies, results of international correlational studies consistently and strongly show that dietary fat may play a role in cancer. Also, the independent review by the Life Sciences Research Office (LSRO) concurred with FDA's conclusion that high fat intake increases

the risk of developing cancers. Furthermore, as discussed in section III of this preamble, new studies that became available for review after the publication of the lipids/cancer proposal are consistent with the agency's conclusion that high fat intake is associated with increased risk of some cancers.

FDA considers it appropriate to permit health claims about fat and cancer without identification of the type of fat that is responsible for the cancer. As the agency explained in the preamble of the proposal (56 FR 60764 at 60773), the available scientific evidence is inconclusive in linking a specific type of fat to cancer risk. As presented in the proposal, some evidence has been found in both human studies and animal studies that all three types of fat (saturated, monounsaturated, and polyunsaturated) may be associated with the risk of some types of cancer. Because it was not possible to clearly identify a particular type of fat or fatty acid, and because several types of fatty acids have been implicated in cancer risk, the agency based its claim on the total fat content of the diet, rather than on any specific type of fat or fatty acid. Further, as explained in section III of this preamble, the evidence from new animal studies generally supports the conclusion drawn in the proposal that total dietary fat is associated with the risk of cancer. Of course, if more conclusive evidence becomes available about specific roles of different types of fat, any interested person may submit a petition under the provisions of new § 101.71 to revise the regulation on identification of the specific types of fat that affect cancer risk, or FDA may itself initiate action to revise the regulation.

The agency does not consider the absence of evidence from noncarcinogen-induced tumorigeneses in animal studies to be a major flaw in determining the adequacy of the scientific evidence to support a relationship between dietary fat and cancer. The data, which indicate that fats cannot initiate tumorigenesis (tumor growth), do not call into question the validity of FDA's evaluation of animal studies. The current understanding of the process of tumorigenesis involves a two stage model: initiation of the carcinogenic process, followed by promotion of tumor growth. During initiation, a normal cell is altered to become a latent cancer cell. This is presumably accomplished when a carcinogen interacts with and subsequently alters the genetic apparatus of the cell. During tumor promotion, the altered genes are expressed to make new cells, a process leading ultimately to autonomous cell growth that is no longer responsive to normal physiologic growth regulatory signals. As FDA explained in the preamble of the lipids/cancer proposal, current knowledge about tumor growth shows that dietary fat affects the promotional stage, not the initiation stage, of carcinogenesis (56 FR 60764 at 60768). Substances affecting the promotional stage of carcinogenesis are appropriate subjects of health claims because, in the promotion stage, the ultimate development of cancer that cannot be controlled by the body is still in question. Thus, risk of cancer may still be reduced in the promotion stage.

As described in the lipids/cancer proposal, FDA agrees that extrapolation of the data from animal studies to humans is limited by differences in metabolism and physiology between species. However, experiments in different animal species permit more intensive observation under controlled experimental conditions. The agency believes that a careful evaluation of animal studies provides useful information and can provide valuable insight into mechanisms involved and specificity of fat versus other nutrients. Thus, the agency critically evaluated animal studies using the evaluation criteria found in the lipids/cancer proposal (56 FR 60764 at 60767). Furthermore, the rodents, which are used in most of the studies reviewed, have digestive and/or metabolic systems that are similar to humans and have been widely used in cancer studies. The agency did not include studies that utilized cell culture techniques because cells can be genetically transformed during the in vitro culture phase, thus generating data that are substantially different from findings in human physiology.

B. Cancer Sites

2. Although most comments took the position that claims about total fat and cancer should be permitted, a number of comments expressed differing opinions about whether claims should specifically address the types of cancer affected by a diet that is low in total fat. Several comments supported the agency's proposed § 101.73(b)(1)(iii) (56 FR 60764 at 60779) to restrict claims to cancer of the breast, colon, and prostate. One explained that, without some identification of affected cancers, the claims may be misinterpreted as meaning that all types of cancer are affected. The comment suggested that FDA require the phrase, "particularly colon, breast, and prostate cancer" in the health claim.

On the other hand, several comments suggested that FDA exclude the designation of specific cancer for the sake of simplicity or because of the inconclusiveness of the relevant scientific evidence. Some comments stated that the magnitude of the association between dietary fat and the risk of various cancers such as breast cancer, colon cancer, and prostate cancer varies so widely that it is misleading to presume that strong evidence supports each site. The comments asserted that claims should therefore not be site-specific.

FDA has reconsidered the issue of requiring claims to identify the specific sites of cancer that may be affected by total fat content in the daily diet. The agency no longer believes that the current state of the scientific evidence on this issue justifies such specific identification. As is fully discussed in the preamble of the lipids/cancer proposal (56 FR 60764 at 60772 and 60773), when FDA proposed such identification, the agency did so because an international correlation study found an association between fat intake and cancer of the breast, colon, and prostate, but not of cervical or lung (Ref. 38). The agency, therefore, concluded that the effect of fat on cancer may be site-specific. In view of the lack of evidence for other types of cancer, the agency believed health claims would not be justified unless the claims pertained only to cancer of the breast, colon, and prostate.

However, additional studies that were not available for review at the time of the lipids/cancer proposal contain further evidence that cancers of additional sites may also be affected by dietary fat intake. Further, the evidence for an association of an increased risk of breast cancer with dietary lipids appears not to be as strong as previously thought from the findings in many case-control and cohort studies (See section III of this document). Thus, FDA now concludes that the identification of specific sites of affected cancers is no longer as appropriate as FDA believed when it issued the proposal. In view of the weaker data on breast cancer and the possibility of a wider variety of affected sites, and taking into account comments received, FDA believes that health claims should not be permitted to refer to specific cancer sites. At the same time, the agency feels that it would be misleading to imply that risk of all cancers may benefit from low fat diets. Accordingly, FDA has included a provision in § 101.73(c)(2)(B) of the rule set forth below requiring that health claims use the terms "some types of cancer" or "some cancers" in specifying

the disease. All provisions in the rule addressing specific sites of cancer have also been revised accordingly.

FDA points out that the lack of consistency of more recent studies with earlier studies concerning the relationship between breast cancer and fat intakes does not bring into question the more general validity of conclusions pertaining to dietary fat intake and cancer that were discussed in the agency's response to the previous comment. The absence of clear evidence of a strong association between fat and breast cancer in many case-control studies may be due to the dietary homogeneity of the population studied. International correlation studies, which have the greatest variability in dietary fat intakes among the populations examined, have consistently found an association. But correlational studies cannot control for important confounding factors, such as family history of cancer and reproductive history, which may also explain the correlations found between fat intake and cancer mortality in these studies.

C. Advisability of Permitting Claims

3. Some comments asserted that, regardless of whether claims about total fat and cancer may be valid, such claims should not be permitted because of safety considerations. A number of comments maintained that health claims about total fat may increase the risk of heart disease from reduced intakes of certain nutrients (i.e., essential fatty acids and fat soluble vitamins). One of the comments stated that the polyunsaturated and monounsaturated fats in vegetable oils have well-documented advantages, particularly in beneficially affecting the ratio of blood total cholesterol to HDL-cholesterol (i.e., raising the level of HDL-cholesterol relative to total cholesterol levels). The comment also pointed out that vegetable fats are the primary source of vitamin E in U.S. diets, and asserted that half of the U.S. population is below the recommended level of consumption of this vitamin. The comment stated that there is emerging evidence for a protective role of vitamin E in cardiovascular and other important diseases.

The agency does not foresee that a health claim relating diets low in fat to reduced risk of cancer will increase the risk of coronary heart disease because of reductions in HDL cholesterol. Under the provision of 1990 amendments, FDA evaluated scientific evidence on the relationships between dietary fat intakes and the development of two chronic diseases, cancer, and cardiovascular disease, separately. FDA's evaluation of the lipids/cardiovascular disease relationship is found in a companion document elsewhere in this issue of **Federal Register**. In that document, FDA is requiring that foods bearing a saturated fat and cholesterol/heart disease claim be "low in fat" in addition to being low in saturated fat and cholesterol. All current dietary guidelines from the Federal government and other authoritative reports include recommendations for diets low in fat when dealing with diet and heart disease relationships. Diets containing 30 percent or less of calories from total fat are deemed helpful in reducing the risk of heart disease because they facilitate meeting dietary goals for saturated fat and cholesterol. Furthermore, these diets are useful in maintaining moderate calorie intakes and desirable body weights. None of the authoritative reports or guidelines have noted concerns or evidence for inadvertent safety problems if Americans were to follow general dietary guidelines for reducing fat intakes to 30 percent of calories or less. Admittedly, diets very low in fat may pose a risk. However, given current fat intakes in the U.S. population of approximately, on average 37 percent of calories from fat, and given the difficulty in lowering this level significantly within the context of dietary patterns in the United States, FDA has concluded that it is highly unlikely that the U.S. population will be able or motivated to lower total fat intakes to levels low enough to have adverse health effects. Indeed, reductions in total fat intakes, consistent with dietary guidelines, are likely to have a beneficial effect on blood HDL-to total-cholesterol ratios.

With respect to assertions that the lipids/cancer health claims will adversely affect the nutritional status of vitamin E or essential fatty acids or will have a negative impact on coronary heart disease because of decreased vitamin E consumption, FDA does not foresee that the lipids/cancer health claim will adversely affect the status of essential fatty acids and vitamin E. Deficiencies of essential fatty acids and vitamin E are very rare in the United States at this time. Furthermore, there is extensive epidemiologic evidence that low fat diets providing fat at 30 percent of calories or less are consumed by many population groups without apparent adverse effects (Ref. 141). Current dietary guidelines, which target no more than 30 percent of calories from fat to reduce coronary heart disease and cancer risks, are generally regarded as practical in controlling fat, saturated fat, cholesterol, and calorie intakes, and yet as more than adequate for providing adequate intakes of essential fatty acids, for facilitating absorption of fat-soluble vitamins, and for maintaining growth and development in children and adolescents 2 years of age and older (Ref. 141). Furthermore, the recommended approach to reducing intake of total fat is to increase consumption of vegetables, fruits, and whole grain products, choose lean meats, fish, and poultry, and low fat dairy products, and use fats and oils sparingly. These diets generally are not only low in fat, saturated fat, cholesterol, and calories, but also tend to be high in vitamins (including vitamin E and provitamin A). Additionally, essential fatty acid requirements can be adequately met with only about 1 percent to 5 percent of calories from fat, an intake level well below the recommended levels, and not practical to achieve in the United States. Thus, FDA sees little, if any possibility, that consumption of diets consistent with current dietary guidelines for fat intake will result in significant reductions in intakes of essential fatty acids or fat-soluble vitamins. Consequently, an adverse effect on risk of coronary heart disease is unlikely. Furthermore, scientific evidence is not clear, as yet, regarding the postulated, protective role of vitamin E in preventing the autoxidation of polyunsaturated fatty acids, a possible risk factor for heart disease.

4. A comment stated that the lipids/cancer claim ignores the positive role of fats in a healthy diet.

FDA agrees with the comment that dietary fats have important functions in foods and as a source of essential fatty acids and other nutrients. In the proposed rule, FDA acknowledged the physiologic functions of dietary fats. As described above, the agency foresees beneficial effects of reducing fat intakes relative to cancer risk, but does not foresee that nutritional deficiencies or harmful effects to health will occur. The agency does not consider it necessary to include statements in the health message as to the beneficial role of fats. The purpose of health claims is to provide useful information to consumers on nutrient/disease relationships. However, as noted in the final rule on general principles for health claims published elsewhere in this **Federal Register**, certain statements, including general statements about the role of nutrients in maintenance of good health, are considered to be dietary guidance outside the scope of the 1990 amendments. These types of dietary

guidance would be permitted as long as the information contained in them is truthful and not misleading.

D. Other Issues

5. A few comments stated that the proposed rule focuses only on fat and does not require that claims discuss other dietary components (e.g., complex carbohydrates or dietary fiber). These comments asserted that such a narrow focus is misleading and would not serve to educate the public about the broad issue of diet and cancer. The comments emphasized that health claims should be presented in the context of a total diet.

FDA agrees that health claims should be presented in a manner that enables the public to comprehend the relative significance of the claim in the context of the total daily diet. In fact, section 403(r)(3)(B)(iii) of the act specifically requires that a regulation that authorizes a claim require that the claim be stated in such a manner.

However, a review of the relationships of other dietary factors and cancer risk (apart from antioxidant vitamins and dietary fiber, which are discussed in final rules published elsewhere in this issue of **Federal Register**), is beyond the scope of the Congressional mandate. Thus, FDA does not agree that the lipids/cancer claim must specifically address the significance of other nutrients such as complex carbohydrates, dietary fiber, saturated fat, or cholesterol in relation to cancer risk. However, any interested party may petition the agency, in accordance with criteria described in the final rule on general requirements for health claims published elsewhere in this **Federal Register**, for additional nutrient/cancer claims to be authorized. As proposed, the fat/cancer health claim must include a statement that the development of cancer depends on many factors. This information is essential for understanding the context of the nutrient/disease relationship.

6. A few comments urged FDA to require health claims to advise that reductions in fat intake to less than 30 percent of total calories may be needed to reduce the risk of cancer. The comment argued that such information is needed because consumers may otherwise believe they are making meaningful reductions in fat intake when that is not the case. This comment pointed to FDA's observation in the proposal (56 FR 60764 at 60773) that studies with small differences in fat intakes among test groups (from 32 to 37 percent of total calories) failed to find a significant reduction in cancer risk.

FDA does not agree that it would be appropriate to require this information in the lipids/cancer health claim. This information would unduly add to the length and complexity of the health claim. However, FDA concurs that this information could be very useful to consumers. Thus FDA has provided for optional use of this type of information as part of a health claim, because it is contained in the significance statement of the final rule (new § 101.73(b)), and information from this section of the rule is permitted to be used on the label (new § 101.73(d)(1)).

7. In its proposed rule, the agency requested comments on whether a food that qualifies for a "reduced fat" or other comparative claim should be permitted to bear a health claim relating dietary lipids and cancer. Several comments supported FDA's proposal that foods must be "low fat" or "fat free" in order to carry this health claim. However, some comments objected to FDA's definition of "low fat." In addition to comments specifically addressing the proposed "low fat" or "fat free" requirement, FDA received a large number of similar comments on the "low fat" requirement that appeared in the general requirements for health claims, proposal (56 FR 60537).

FDA advises that the final rule is retaining the "low fat" qualifying criterion for health claims concerning fat and cancer. ("Fat free" foods necessarily meet the definition of "low fat;" therefore, to avoid redundancy, the agency is requiring only that a food meet the "low fat" definition.) Because the issue of "low" qualifying requirements is of a general nature (e.g., this criterion also pertains to the fat and heart disease health claim), most of the comments on this issue were filed in the docket of the proposal on general requirements for health claims. FDA has responded to all comments about this issue in the preamble of the final rule on general requirements for health claims, which appears elsewhere in this issue of the **Federal Register**. Discussions of FDA's definition of "low fat" are published elsewhere in this issue of the **Federal Register** in the final rule on requirements for nutrient content claims.

8. A few comments requested that FDA develop identical criteria for health claims on lipids and cancer and on lipids and cardiovascular disease, because the proposed criteria for these two topics are similar but not totally consistent, and any differences may be confusing to consumers. The comments further suggested that total fat be used as the "common denominator" because "consumers who reduce total fat intake are likely to be concurrently reducing saturated fat intake as well as cholesterol, even if not making a conscious attempt at either."

The agency will allow manufacturers to formulate their own claim combining the fat and cancer and the saturated fat/cholesterol and heart disease claim if the food meets the criteria for both claims. However, at this time, it is not appropriate to set identical requirements for health claims for dietary fat and cancer and for dietary saturated fat and cholesterol and risk of heart disease, because the two diseases differ in the nature of their relationship to dietary fat components. Current evidence demonstrates that it is total fat, rather than individual fat components, that is associated with an increased risk of cancer. However, there is a substantial body of evidence that demonstrates that high levels of saturated fat and cholesterol, rather than total fat, are associated with an increased risk of cardiovascular disease. For this reason, FDA has decided to maintain separate criteria for the fat/cancer and the saturated fat and cholesterol/heart disease health claims.

9. Several comments stated that the lipids/cancer health claim should identify energy intake as an independent factor for cancer rather than reduced fat intake, because energy excess, not fat, is the factor that increases risk of carcinogenesis. Another comment stated that, if fat has an independent effect on carcinogenesis, the need to reduce fat intake becomes more important, because by reduction of fat intake, reductions in intakes of energy and fat could be efficiently achieved.

FDA agrees that the scientific evidence on the association between dietary lipids and cancer includes studies that demonstrate that total energy intake may be an independent risk factor for cancer (Refs. 11, 17, and 23). However, the 1990 amendments instructed the agency to determine whether claims respecting dietary lipids and cancer, not energy intake and calories, meet the requirements of section 403(r)(3) of the act. The agency found that, currently, there is adequate evidence from animal studies and from human studies that total fat is a risk factor for some cancers, independent of the effect of total calories. Furthermore, decreasing the fat content of the diet appears to be a practical approach to reducing energy intakes and maintaining desirable body weights. However, if a health claim regarding energy intake and cancer is desired, such a claim can be handled by the petition process set forth in the general

requirements for health claims final rule published elsewhere in this issue of the **Federal Register**.

10. One comment suggested that FDA exclude omega-3 fatty acids from the calculation of total fat for deciding whether a food is "low fat" relative to cancer risk, because the effect of omega-3 fatty acids may be neutral or, even, tumor-suppressing.

The agency does not agree that the scientific evidence is adequate to establish that omega-3 fatty acids are neutral with respect to cancer risk. Most animal studies, although concluding that a diet high in fish oil suppresses tumorigenesis, have methodologic problems which make it difficult to extrapolate results to humans. Specifically, the diets used in most of these studies provided insufficient amounts of the essential fatty acid, linoleic acid, to support optimal tumor growth. Therefore, it is not possible to determine whether the observed tumor-suppression by the fish oil diets was caused by an insufficiency of essential fatty acids (linoleic acid) to support tumor growth, or by a direct inhibitory effect of the omega-3 fatty acids contained in the fish oils. FDA is, therefore, not persuaded to exclude omega-3 fatty acids from the calculation of total fat for deciding whether a food is "low fat" with regard to cancer risk.

However, interested persons who believe there is adequate scientific evidence to support a beneficial relationship between omega-3 fatty acids and cancer risk, may use the petition process described in the final rule on general requirements for health claims, published elsewhere in this **Federal Register**.

11. A number of comments on the general requirements proposal for health claims (56 FR 60537) suggested that FDA revise provisions of all health claims rules to be more understandable.

The agency agrees that all health claims rules should be made more understandable wherever practicable. FDA has, therefore, made a variety of nonsubstantive revisions of provisions of the regulations set forth below for clarity. For example, provisions have been grouped into general and specific requirements. The general requirements reference other regulations containing nutrition labeling requirements. The specific requirements are separated into requirements pertaining to the food and those pertaining to the claim. The model health claims have been simplified. The regulation has also been modified to permit fish and game meats that meet the requirements for "extra lean" in § 101.62 to bear the health claim. This change is in response to comments on the proposed fat and cardiovascular disease health claim, and will make both final rules consistent with each other. "Extra lean" fish and meats can play an important role in a low fat diet. Consistent with other health claims regulations, this regulation also permits the claim to indicate the prevalence of cancer in the United States.

12. A comment suggested that the final rule include a requirement that, in order to qualify for the lipids/cancer health claim, a food must contain a minimum amount of dietary fiber, because fiber intake is another dietary risk factor for cancer.

The agency disagrees that dietary fiber should be required to be included in a fat/cancer health claim, but does agree that diets rich in foods containing dietary fiber and many other nutrients are associated with reduced cancer risk. Dietary components that have been implicated in cancer development include fat, antioxidant vitamins, and fibers. Among these dietary components, fat intake has been reported as the most strongly associated component. Under the 1990 amendments, FDA evaluated scientific evidence on three separate health claim topics relevant to cancer: Fat and cancer, antioxidant vitamins and cancer, and fiber and cancer. Of these three topics, FDA has concluded that there is significant agreement about the relationship between fat and cancer. FDA's evaluation and decision about the other two health claims (published elsewhere in this issue of **Federal Register**) is that diets rich in fruits, vegetables and grain products, which are generally low in fat and high in dietary fiber and vitamins A and C, are associated with reduced cancer risk. However, the agency did not find the evidence sufficient to attribute this relationship to a specific nutrient contained in plant foods. Furthermore, the agency's review of scientific evidence found that almost all animal studies of fat and cancer employed defined experimental diets containing the same amounts of vitamins and fibers. Animal studies on the association of dietary fat with cancer development provide substantial support for the conclusion that the effect of fat intake on cancer development is independent of the effects of fiber and antioxidant vitamins. Therefore, the agency is not persuaded to add fiber content as a required qualifying criterion for the fat and cancer claim.

III. Review of New Scientific Evidence

In addition to its evaluation of the comments, FDA has evaluated the scientific literature that has become publicly available since the issuance of the proposal. The following represents a summary of the agency's evaluation of this literature.

A. Human Studies

1. Studies Submitted as/with Comments

No new human studies that meet the criteria for selecting articles to review, which are described in the lipids/cancer proposal, were submitted with comments.

2. Update of the Scientific Literature

Studies that became available after publication of the lipids/cancer proposal are discussed below and described in Table 1.

A new correlational study on cancers of the colon, rectum, prostate, and breast was reviewed (Ref. 92). Incidence rates for these cancers and food consumption data were compared among Chinese in Shanghai, Chinese Americans in San Francisco, and Americans in Connecticut. The study demonstrated that the incidence rates for the four types of cancer were much higher among Americans and Chinese Americans than for Shanghai Chinese and that the Americans and Chinese Americans consumed much more meat and milk products than the Shanghai Chinese. The authors interpreted the results of the study to demonstrate that low fat diets were associated with the lower incidence rates of the four types of cancer found among the Shanghai Chinese. However, because the design of this study allowed correlations to be made only between a population's cancer incidence rates and its per capita food consumption, rather than studying individuals who actually have cancer, inferences cannot be made about the causal nature of diet on risk of cancer. The study was unable to control for important risk factors for these cancers, such as lifestyle factors, family history, reproductive and endocrine factors, total energy intake, and differences in body weight.

A new correlational study that compared dairy fat and lard intake data from 36 countries with cause-specific cancer mortality rates was also reviewed (Ref. 93). World Health Organization (WHO) mortality statistics for 1985–1987 were correlated with intake data obtained from 1979–1981 Food and Agricultural Organization (FAO) food balance sheets. FAO's food balance sheets are approximations of actual consumption and are not separated by age and sex. The authors were able to adjust for total caloric intake but were not able to adjust for potential confounding factors, such as smoking

and family history. The study demonstrated highly significant correlations between intakes of dairy fat or lard fat and mortality from all causes, total cancer, and colon and rectal cancer among both men and women and from lung cancer and prostate cancer for men and breast cancer for women.

a. *Pancreatic cancer.* The agency reviewed two new case-control studies on diet and pancreatic cancer, which were published in 1991 (see Table 1). One study conducted in Poland (Ref. 94) demonstrated no association between risk of pancreatic cancer and total dietary fat or saturated fat. The highest intake of dietary cholesterol measured in the study was associated with a statistically significant relative risk (the incidence of cancer of the exposed group/the incidence of cancer of the unexposed group) of 4.3 for pancreatic cancer. However, the highest intakes of monounsaturated fatty acids and of polyunsaturated fatty acids were associated with statistically significant decreased risks (see Table 1). The second case-control study, which was conducted in the Netherlands, did not analyze for total dietary fat or for saturated fat (Ref. 95). Consumption of eggs was associated with a statistically significant increased risk and daily consumption of vegetables showed a protective effect in this study.

b. *Bladder cancer.* One case-control study on bladder cancer conducted in Spain was reviewed (Ref. 96 and Table 1). An increased risk of bladder cancer was found with dietary saturated fat but not with total fat. The results of this study may be biased by the inclusion of 208 prevalent cases of bladder cancer, approximately half of the cancer cases. Case-control studies usually select incident cases of cancer for participation, which are new cases, i.e., those not previously diagnosed. Prevalent cases are patients who have survived the disease for at least some amount of time and are generally not included in case-control studies of cancer because the traits contributing to their survival may modify potential risk factors of the disease.

c. *Lung cancer.* A prospective cohort study on lung cancer published in 1991 was reviewed (Ref. 97 and Table 1). The cohort consisted of 1,878 men employed by the Western Electric Company in Chicago. The men were 40 to 55 years old in 1958 when enrolled in the study and were followed for 24 years. Dietary information was collected in 1958 and in 1959 when all the men were clinically free of cancer. After adjusting the results for smoking and percent of calories from fat, an increment of dietary cholesterol of 500 mg per day was associated with a relative risk of lung cancer of 1.9.

d. *Breast cancer.* Five new case-control studies on diet and breast cancer were reviewed (see Table 1). One study that examined only postmenopausal breast cancer found no association with dietary fat (Ref. 99). However, the study suffered from low participation rates among both the cases and controls, which prohibits generalization of the study results to the total population.

A case-control study of both premenopausal and postmenopausal breast cancer among Singapore Chinese showed no effect of diet on postmenopausal women (Ref. 100). No effect on breast cancer risk for premenopausal women was found for total fat, for saturated fat, for monounsaturated fatty acids or for cholesterol; polyunsaturated fatty acids demonstrated a protective effect. The median level of dietary total fat consumed on a daily basis was 33 grams (g) for cases and 34 g for controls; total fat intake ranged from 26 g to 41 g in this study. The authors did not adjust the results for total calories.

A French case-control study found limited evidence that fat is associated with breast cancer risk when the results were analyzed by menopausal status (Ref. 101). However, for all women analyzed together regardless of menopausal status, total fat was associated with a relative risk of 1.6, saturated fat was associated with a relative risk of 1.9 and monounsaturated fatty acids were associated with a relative risk of 1.7. Polyunsaturated fatty acids were not associated with risk of breast cancer. The results were not adjusted for total calories; thus, the increased risk associated with the fats may actually be due to a higher caloric intake by the cancer cases. Several food items were associated with an increased risk of breast cancer among all women, including high fat cheese, fruits rich in beta-carotene, and desserts and chocolate.

A case-control study conducted in Moscow found that dietary fat was not associated with risk of breast cancer in either premenopausal or postmenopausal women (Ref. 102). Gram levels of daily total fat intake were not provided. Several nutrients were associated with a protective effect, including polyunsaturated fatty acids, beta-carotene, vitamin C, calcium, and cellulose. Risks associated with food items were not examined in this study.

A large case-control study conducted in Italy examined the risk of breast cancer associated with fat intake from seasonings (Ref. 103). A moderate association was found for total fat seasonings and for butter and oil, but no association was found for margarine. The results were not adjusted for total calories and very limited dietary information was collected.

e. *Colorectal cancer.* Three new studies on colorectal cancer were reviewed (see Table 1). The most informative study of the three was conducted in Majorca (Ref. 104). An increased risk of colorectal cancer was found to be associated with total calories, and, after adjustment for total calories, an increased risk was also associated with cholesterol, protein, and carbohydrates (Ref. 104). A protective effect was demonstrated with fiber from legumes. Colorectal cancer risk was not found to be associated with high consumption of total dietary fats or saturated fats. However, this lack of association between colorectal cancer and dietary fat may be a result of the population's consumption of primarily monounsaturated fatty acids rather than animal fats.

f. *Prostate cancer.* Two additional case-control studies on the association between dietary factors and risk of prostate cancer were reviewed (Refs. 105 and 106 and Table 1). One study conducted in Spain from 1983 to 1987 found that risk of prostate cancer was increased by a diet rich in animal fats but not by a diet rich in vegetable fats (Ref. 105). Also, meat consumption was associated with increased risk, but different types of meat were not significantly linked to prostate cancer. The study did not adjust for total calories; however, the relative risks associated with animal fats and with meat consumption were large enough (see Table 1) that after adjustment for calories the relative risk estimate would most likely remain elevated.

A case-control study of prostate cancer conducted in Utah demonstrated that dietary factors were not associated with risk of prostate cancer among young men (aged 45 to 67 years) (Ref. 106). However, among men aged 68 to 74 years, risk was increased for total calories, and after adjustment for total calories, an increased risk was associated with total fat, protein, and also for monounsaturated fatty acids and polyunsaturated fatty acids. For both age groups, the baseline level of total fat intake was about or less than 66 g per day.

In addition to the studies in Table 1, several review articles on the relationship between dietary fat and cancer were published recently (Refs. 107, 108, 109, and 110). Two of these review articles stated that the evidence for a putative effect of dietary fat on breast cancer risk is based primarily on

international correlational studies, whereas case-control studies and cohort studies have found only weak associations or no association between dietary fat and breast cancer risk (Refs. 107 and 108). Kinlen (Ref. 107) suggests that the international correlations with fat may be a reflection of the effects of calorie restriction in poor countries or over-nutrition in affluent countries during the years of growth which directly influences known risk factors for breast cancer, such as age at menarche and body size.

A recent review on prostate cancer (Ref. 109) stated that, overall, the epidemiology studies on diet and prostate cancer implicate fat as the main dietary component associated with increased risk. Specifically, recent case-control studies are supportive of an association of fat to prostate cancer, whereas cohort studies have shown either an equivocal and no effect.

B. Animal studies

1. Studies Submitted as/with Comments

No new animal studies that meet the criteria for selecting articles to review, which is described in the lipids/cancer proposal, were submitted with comments.

2. Update of the Scientific Literature

FDA reviewed 22 new animal studies dealing with the relationship between dietary fat and cancer that were not available for review in the proposed rule (see Table 2). Dietary fat and mammary tumorigenesis was the subject of nine studies. The role of fat in colon tumorigenesis was evaluated in five studies, while the role of fat in tumorigenesis at pancreas, skin, or lymph were evaluated in two studies for each tumor site. Fat and leukemia or fat and liver tumor was the subject of one report for each tumor site.

a. *Role of total dietary fat.* Six mammary tumor studies examined the effects of total fat on tumorigenesis. Among these, three studies (Refs. 112, 113, and 114) reported a significant association of high dietary fat with the development of mammary tumors. For example, Kumaki and Noguchi (Ref. 112) measured the influence of high dietary fat on the malignant intensity and hormone receptors of 7,12-dimethylbenzanthracene (DMBA)-induced mammary tumor in female rats fed either a low fat (0.5 percent corn oil) or a high fat (20 percent corn oil) diet after DMBA administration. Tumor incidences in the high fat fed group were significantly higher than in the low fat fed group (86 percent versus 46 percent, respectively) and tumors were significantly larger in the high fat fed group than in the low fat fed group (13.9 millimeters (mm) versus 7.9 mm, respectively). In this study, the 0.5 percent corn oil diet provided inadequate linoleic acid (about 0.3 percent by weight) for growth of the mammary tumors. The deficiency of linoleic acid, rather than decreased total fat, could have reduced tumorigenesis.

Cohen et al. (Ref. 113) examined the effects of dietary fat and fiber in the N-nitrosomethylurea (NMU)-induced rat mammary tumor model. The number of tumor-bearing rats and the mean number of tumors per rat were significantly higher in rats fed a high fat diet (23.5 percent corn oil) than in those fed a low fat diet (5 percent corn oil). The latent period was also significantly prolonged in the low fat fed group. The diets used by Cohen et al. were not isocaloric and body weights were significantly lower in the 5 percent corn oil group from weeks 11 to 15 of the study. Therefore, the results could have been caused by differences in energy intake rather than fat per se.

Gonzalez et al. (Ref. 114) studied the effects of different amounts and types of fat on the growth of human breast carcinoma in athymic nude mice. They reported that a diet with 20 percent corn oil by weight significantly elevated the volume of transplanted mammary tumors (estrogen-dependent MDA–MB231 and nonestrogen-dependent MCF–7) in mice, compared to effects of a diet containing 5 percent corn oil. Diets used in this study were not isocaloric and the differential intakes among groups confound an attribution of the dietary fat to the results per se. The MDA–MB23 cell line was estrogen-dependent and estrogen provided in the drinking water and implanted pellets may have affected tumor growth in these groups.

Studies by Zhu et al. (Ref. 115), Aksoy et al. (Ref. 116), and Khoo et al. (Ref. 117) reported no association between dietary total fat and tumorigenesis in rodents. Zhu et al. (Ref. 115) measured the effect of total dietary fat and dietary energy restriction on growth of methylnitrosourea (MNU)-induced mammary tumorigenesis in female rats. When the diets were isocaloric (50 kilocalories (kcal) per day or 35 kcal per day), tumor yield (number or weight) was not different between the two diet groups (45 percent fat diet by energy and 25 percent fat diet by energy). In this study, diets differed in the provision of linoleic acid: The 25 percent fat diet provided about 1.7 percent linoleic acid by weight. This amount was most likely inadequate for tumor growth.

Aksoy et al. (Ref. 116) attempted to identify effects of different levels of dietary fat on MNU-induced rat mammary tumorigenesis. These authors reported no difference in the incidence, yield, or mortality among groups fed diets containing 12 percent, 25 percent, and 45 percent fat by energy. The 12 percent or the 25 percent fat diets (which provided about 0.7 percent or 1.9 percent linoleic acid by weight) may not have provided adequate linoleic acid for tumor growth. In this study, rats consumed the same amount of calories, and body weights were not different among groups even though the experimental diets were not isocaloric.

Khoo et al. (Ref. 117) tested the anticancer effect of dietary stearic acid. In this study, mammary tumors were induced by NMU and cultured in vitro. The cultured, tumor cells were implanted in the flank of rats. Rats were fed either a powdered control diet or a diet containing 20 percent stearic acid by weight. Feeding was continued for 6 weeks before and 25 days after tumor implantation. The stearic acid-supplemented diet did not affect the growth (size or weight) of the transplanted tumors. The adequacy of dietary linoleic acid for tumor growth in this study cannot be determined because the fatty acid composition in the diet was not reported.

Six new studies examined the effects of dietary fat on development of chemically-induced colon tumors in rodents. Two studies measured the effect of total fat (Refs. 118 and 119). Nicholson et al. (Ref. 118) measured the influence of dietary fat (beef suet, rich in saturated fats and corn oil, rich in linoleic acid) on colorectal tumorigenesis. Wistar rats were fed diets containing 5 percent or 20 percent fat (beef suet or corn oil) by weight. The 5 percent beef suet diet significantly reduced azoxymethane-induced colon adenocarcinoma compared to the 20 percent beef suet diet (12 carcinomas versus 28 carcinomas, respectively, in the 5 percent and 20 percent beef suet groups). The difference in tumor yield between the 5 percent corn oil and 20 percent corn oil diets was not statistically significant (1 carcinoma versus 2 carcinomas, respectively, between the 5 percent and 20 percent corn oil groups). The beef suet diets provided limited linoleic acid (0.6 percent to 1 percent).

Behling et al. (Ref. 119) measured the effects of varying levels of dietary calcium and butter fat on lipid utilization and development of colon tumors in dimethylhydrazine dihydrochloride (DMH)-initiated rats. These authors found no difference in

intestinal tumors in rats fed either a diet with 5 percent butter fat plus 1 percent corn oil or a diet with 20 percent butter fat plus 1 percent corn oil. The experimental diets provided limited linoleic acid (about 0.6 percent by weight), and this may have decreased the possibility of identifying effects of total dietary fat.

Hietanen et al. (Ref. 120) measured modulation by quantity and degree of saturation of dietary fat of oxidative stress and chemically-induced liver tumors in rats. These authors found a significantly increased incidence of liver tumors in rats fed a diet containing high levels of polyunsaturated fatty acids (PUFA; 25 percent sunflower seed oil by weight) compared to rats fed a diet containing low concentrations of polyunsaturated fatty acids (2 percent sunflower seed oil by weight). Tumor incidences were 80 percent versus 42 percent for groups fed 25 percent or 2 percent sunflower seed oil, respectively. The 2 percent PUFA diet in this study provided about 1.6 percent linoleic acid, which may not have been adequate for tumor growth. Body weight changes were not significantly different among groups, although diets were not isocaloric.

Smith et al. (Ref. 121) measured the effects of a high fat diet and a CCK-receptor antagonist on growth of a human pancreatic tumor cell line in nude mice. In this study, a high fat diet (20.3 percent fat by weight: 4.3 percent chow fat plus 16 percent corn oil) significantly increased tumor volume and protein content compared to values for tumors from mice fed a chow diet. Fatty acid composition of the chow diet was not reported. However, the chow diet may not have provided adequate linoleic acid for tumor growth, and a limitation of linoleic acid, rather than low total fat, could have reduced tumor growth.

Longnecker et al. (Ref. 122) studied the development of pancreatic neoplasms in elastase-1-simian virus transgenic mice. The authors reported no difference in incidence of tumor between groups of mice fed a 5 percent corn oil diet or a 20 percent corn oil diet. The applicability of the results of this study in genetically transformed mice to human cancer studies is not clear.

Thus, among the 11 studies that examined the effect of dietary fat on tumorigenesis, 6 studies (3 mammary tumor studies, 1 colon tumor study, 1 pancreatic tumor study, and 1 liver tumor study) reported significant reductions in the risk of tumorigenesis, measured by incidence, multiplicity, or latency, by reducing fat intakes from about 20 percent to about 5 percent. However, the evaluation of the studies was difficult because many studies suffered a critical and a common limitation in the methodology: diets were limited in linoleic acid, which is necessary for optimal tumor growth.

b. *Effects of types of fat.* Four studies examined the effects of different types of fat on mammary tumorigenesis (Refs. 117, 123, 124, and 125). All four studies reported inconsistent or insignificant effects of different types of fat.

Buckman et al. (Ref. 123) studied whether oleate influences the linoleate-enhanced metastasis of murine mammary tumors. Diets contained 13.5 percent to 61 percent linoleic acid and 12 percent to 47 percent oleic acid. Total fat was 20 percent by weight. Diets did not significantly affect latent period, incidence, or yield of tumors. These diets provided adequate linoleic acid for optimal tumor growth at the mammary gland. The authors reported that a low linoleic acid to low oleic acid diet reduced lung metastasis compared to the other three diets (low linoleic acid to high oleic acid, high linoleic acid to moderate oleic acid, and high linoleic acid to low oleic acid). Values were 10 nodules, 62 nodules, 78 nodules, and 90 nodules, respectively, for mice fed these four diets. The low linoleic acid to low oleic acid suppressed tumorigenesis, in terms of metastasis, in lung but not in liver.

Lasekan et al. (Ref. 124) fed rats diets with 20 percent fat by weight and examined DMBA-induced mammary tumorigenesis. The concentrations of linoleic acid and oleic acid, respectively, in the dietary fat were 72.9 percent and 12.4 percent linoleic acid-rich safflower oil diet (SL diet), 17.2 percent and 71.1 percent safflower oil diet (SO diet), 5.6 percent and 6.7 percent olive oil diet (OO diet), and 16.9 percent and 67.9 percent linoleic acid-rich olive oil diet (OL diet). The concentrations of linoleic acid in the diets were 14.6 percent (SL diet), 3.4 percent (SO diet), 1.1 percent (OO diet), and 3.4 percent (OL diet) by weight. Dietary concentrations of linoleic acid, oleic acid, or linoleic acid to oleic acid ratio did not consistently affect latent period, incidence, or yield of mammary tumors. The OO diet showed a significant tumor-lowering effect, which disappeared when linoleic acid was added. Tumors per rat were 3.0, 5.1, 3.5, and 5.0 in rats fed the OO, OL, SL, and SO diet, respectively. Because the OO diet was limited in linoleic acid, the findings support the "about 4 percent linoleic acid requirement" for mammary tumorigenesis in rodents (Refs. 20 and 71).

Khoo et al. (Ref. 117) also showed that 20 percent supplementation of stearic acid to a control diet did not affect mammary tumor growth in rats. Fatty acid composition of the control diet was not reported for this study, and the adequacy of linoleic acid content cannot be determined. Hirose et al. (Ref. 125) also reported no difference in mammary tumor yields between the 10 percent soybean oil group and the 10 percent safflower oil group. Both of these diets contained sufficient linoleic acid for optimal tumor growth.

Three studies (Refs. 118, 125, and 126) examined the effects of different types of fat on colon tumorigenesis. One study (Ref. 118) reported that a diet containing 20 percent beef suet produced significantly more tumor than a diet containing 20 percent corn oil (28 carcinoma versus 2 carcinoma, respectively). The 5 percent beef suet diet also elevated tumor yield compared to the 5 percent corn oil diet (12 carcinoma versus 1 carcinoma, respectively). The beef suet diets, although providing limited linoleic acid, nevertheless increased colon tumor development. The findings suggest that the effects of saturated fatty acids (SFA) may be promoting and those of polyunsaturated fatty acids (PUFA) may be protective for colorectal tumorigenesis.

Conversely, Nutter et al. (Ref. 126) measured the effects of dietary fat and protein on DMH-induced tumor development and immune responses in male mice. These authors reported that 4.7 percent beef tallow (BT) diets were protective for colon tumorigenesis in mice compared to 4.7 percent corn oil (CO) diets (3.2 tumor per tumor-bearing mouse versus 12.3 tumor per tumor-bearing mouse, BT versus CO, respectively). This study suffers limitations in methodology: the total fat level, 4.7 percent, was too low, and the beef tallow diet was limited in content of linoleic acid (about 0.3 percent by weight).

The other study by Hirose et al. (Ref. 125) reported that incidence or yield of experimental tumorigenesis at the colon was not different between the 10 percent soybean oil group and the 10 percent safflower oil group in rats. The diets provided adequate linoleic acid for optimal tumor growth.

Two studies on skin tumors (Refs. 127 and 128) were also reported. Locniskar et al. (Ref. 127) compared the effects of fish, coconut, and corn oils on skin tumors induced by DMBA and benzoylperoxide in mice. Leyton et al. (Ref. 128) measured the effects of different types of dietary fat on DMBA- and phorbolester (12-O-

tetradecanoylphorbol-13-acetate, TPA)-elicited tumorigenesis at mouse skin. Both studies found a significant protective effect of PUFA (corn oil) and a significant promoting effect of SFA (coconut oil) on skin tumorigenesis. In both of these studies, diet groups with the highest dietary corn oil (15 percent by weight in one study and 10 percent by weight in the other study as the sole fat source) showed the lowest yield of papilloma (3.4 tumors versus 11.7 tumors, 1 percent CO versus 15 percent CO in SENCAR mice) or carcinoma. The results differ from the "about 4 percent linoleic acid requirement" for optimal tumorigenesis for mammary tumorigenesis in rodents (Refs. 129 and 130) and suggest that the linoleic acid requirement may be different for tumors at different sites.

The results of the recently reported studies show that, when the requirement of linoleic acid for optimal tumor growth is met, types of dietary fat do not have specific effects on tumorigenesis of the mammary gland. The study results on colon tumor are equivocal: dietary PUFA was promoting in one study and was protective in the other. The two studies in skin tumor consistently reported a protective role of dietary PUFA, which suggests a different level of linoleic acid requirement for tumorigenesis at different sites.

c. *Fat intake versus energy intake.* Because energy intake and fat intake are highly correlated, it is possible that the association between dietary fat and cancer is confounded by energy intake. It also has been demonstrated in animal and human studies that energy intake in excess of an essential requirement is of primary importance in determining the incidence of induced and spontaneous tumors. During the preparation of the proposal on the lipids and cancer health claim, FDA carefully reviewed studies with isocaloric diets or similar energy provisions. The agency reached the tentative conclusion that the totality of the evidence from both animal and human studies showed that the effect of dietary fat on tumorigenesis is independent of the effect of energy (Refs. 11, 17, and 23).

Two new animal studies examined the relationship between fat and cancer with isocaloric diets or similar energy provisions (Refs. 115 and 116). One study (Ref. 115) reported that calorie restriction, rather than fat content, significantly reduced tumor growth in this study. Another study by Aksoy et al. (Ref. 116) reported no difference in the growth of mammary tumors among 12 percent, 25 percent, and 45 percent fat-fed groups. However, both of these negative studies suffered from the same methodological problem: diets were limited in linoleic acid (about 1.7 percent linoleic acid in one study and about 0.7 percent to 1.9 percent linoleic acid in the other). Because of this common limitation that linoleic acid in the diet was not sufficient for optimal tumor growth, the studies cannot be adequately evaluated for the effect of fat on cancer. In conclusion, although the newly reported studies were not adequate to evaluate the energy-independent effect of fat on cancer development, from several studies previously reviewed, the agency found adequate evidence to conclude that the effect of fat is independent of the effect of energy.

d. *Omega-3 fatty acids and fish oil.* In one study (Ref. 125), mammary tumor was induced by dimethylbenzanthracene and dimethylhydrazine, and the effects of perilla oil (an omega-3 fatty acid rich plant seed oil), soybean oil, and safflower oil were tested at 10 percent by weight. Incidence rates were not different among groups but the tumor yield was significantly lowered by perilla oil feeding, compared to soybean oil or safflower oil feeding (4.4 tumors, 6.5 tumors, and 5.7 tumors per rat: perilla oil, soybean oil, and safflower oil, respectively). Perilla oil is rich in linoleic acid (13.7 percent) compared to soybean and safflower oils, which contain 1.7 percent and 0.1 percent linoleic acid, respectively. Perilla oil is also relatively low in linoleic acid (15.9 percent) compared to soybean and safflower oils, which contain 52.6 percent and 74 percent linoleic acid, respectively. This study suffers the common methodological limitation in that perilla oil diet containing about 1.6 percent linoleic acid may have provided inadequate linoleic acid for tumor growth.

One recent study on colon tumorigenesis (Ref. 129) also reported a protective effect of omega-3 fatty acid. In this study, mice were fed a 19.2 percent fat diet with various sources: beef tallow, soybean oil, and a commercial fish oil product (MaxEPA). The MaxEPA diet significantly lowered and the beef tallow diet significantly elevated the yield of adenocarcinoma of the colon, compared to other groups (mean tumor per animal was 1.23 mean tumor, 0.47 mean tumor, and 0.23 mean tumor for the beef tallow, soybean oil, and fish oil group, respectively). Diets provided adequate linoleic acid for optimal tumor growth. This result suggests that the high fish oil diet (MaxEPA) may have a protective role in dimethylhydrazine-induced colon tumorigenesis in Swiss-Webster mice.

Another study (Ref. 125) found an inconsistent effect of different types of fat on tumorigenesis at the colon. A 10 percent perilla oil diet significantly lowered incidence of colon tumors compared to a 10 percent soybean oil diet or a 10 percent safflower oil diet in rats. Tumor incidences were 4 percent, 9 percent, or 9 percent for the perilla oil, soybean oil, or safflower oil diets, respectively. Tumor yield was not different among groups. In this study, the perilla oil diet provided about 1.6 percent linoleic acid by weight, which might have been limiting for optimal tumor growth.

There were two lymphoma studies (Refs. 130 and 131), which showed an adverse effect of omega-3 rich fatty acid on tumorigenesis. Both studies used AKR mice and examined the growth of xenograft lymphoma. The composition of dietary fat tested were fish oil versus beef tallow in one study and fish oil versus hydrogenated beef tallow in the other. Diets in both of these studies were severely limited in linoleic acid (0.01 percent to 0.48 percent by weight in one study and 0.004 percent to 0.18 percent by weight in the other study). Due to this methodological problem, the results are not useful for evaluating the effect of fat.

Hence, results of the recently reported studies are contradictory for the effect of omega-3 fatty acid on tumor development. One (Ref. 129) of the four studies studied the development of colon tumor with an adequate linoleic acid provision in the diet. In this study, the fish oil (MaxEPA) at 19.2 percent by weight significantly reduced tumor yield. The study, however, suffers from the limitation that the amount of dietary fish oil used was impractically high. Overall, the recent studies failed to adequately refute or support the effects of fish oil on tumorigenesis. Further studies are required to elucidate the effects and mechanism of omega-3 fatty acids on tumorigenesis.

e. *Mechanisms of carcinogenesis.* Although several mechanisms have been proposed, the biochemical mechanism by which fat affects tumorigenesis has not been definitely established. As discussed in the lipids/cancer proposal, hypotheses include fat-induced alteration in membrane peroxidation, immune function, gene expression, metabolism of chemical carcinogens, metabolism of hormones, metabolism of eicosanoids, and turnover rate of intestinal mucosal cells (56 FR 60764). Recent studies have not further elucidated the mechanisms for the effect of fat on tumorigenesis.

After reviewing the animal studies, Schatzkin et al (Ref. 132) concluded that increasing the amount of dietary fat increases mammary tumorigenesis, whether measured in terms of incidence, multiplicity, or latency; the production of tumors is enhanced when a high level of fat is fed after, not before, initiation, suggesting a promotional effect of dietary fat; the tumor-enhancing effects of high levels of saturated or polyunsaturated fat are similar when the diets contain a minimal amount of polyunsaturated fat to provide essential fatty acids; and that dietary fat and total calorie intake seem to have separate tumor enhancing effects.

On the other hand, Kritchevsky (Ref. 133) noted that all of the studies relating to fat and experimental carcinogenesis show that increasing levels of dietary fat increases tumor incidence; the effect seems to be exerted principally in the promotion phase and plateaus at between 5 and 10 percent of fat in the diet; and energy from the fat-rich diets, rather than fat per se, may be the factor enhancing tumorigenesis. He concluded that:

> The possibility that the problem may be energy rather than fat permits us to make broader dietary choices without excluding specific nutrients. * * * The call for reductions in fat intake to 15 percent or 20 percent of energy may be considered drastic, but a modest reduction (perhaps to 30 percent of energy) might not be out of order.

Another comprehensive review of studies (Ref. 134) reached conclusions similar to those of Kritchevsky. The authors concluded that:

> High dietary fat (20 percent by weight or 40 percent by energy) significantly elevates incidence and multiplicity of mammary gland tumors induced chemically in rodents. High dietary total fat also clearly promotes tumorigenesis at the colon and pancreas. On the other hand, moderate to severe dietary restriction in animals yields fewer neoplasms, particularly in the mammary gland. Intake of a high-fat diet even at moderate restriction would not lead to promotion because the dietary restriction would have the opposite effect. This finding could obviously be transformed to humans. However, most human populations do not voluntarily undergo lifelong dietary restriction but rather eat ad libitum.

Therefore,

> A diet which is high in complex carbohydrate (65 percent to 70 percent by energy) and moderate in fat (20 percent to 25 percent) and protein (10 percent to 15 percent) would be recommended.

C. Conclusions About New Evidence

The agency has reviewed several new research articles, and several review papers, which were published since the proposal. Among the human studies, one correlational study was supportive of the hypothesis that high fat diets increase the risk of cancers of the colon, rectum, prostate and breast (Ref. 92), and another correlational study supported the relationship between increased cancer risk and dairy fat and lard fat (Ref. 93). A new case-control study on pancreatic cancer was consistent with the earlier reports that this cancer is not associated with dietary fat (Refs. 94). A study on bladder cancer suggested that an increased risk was associated with saturated fat but not with total fat (Ref. 96).

The results of several new human case-control studies on breast cancer demonstrated no effect of total dietary fat on postmenopausal breast cancer risk (Refs. 99, 100, and 102). Moreover, the evidence for an effect of dietary fat on premenopausal risk was extremely limited in the new studies reviewed, and the study that found an increased risk associated with fat for all women (not separated by menopausal status) did not adjust for total calories (Ref. 101). The case-control studies on breast cancer which examined associations with food found increased risks from total food (Ref. 101) and from fats used as seasonings (Ref. 103), but not from meat (Ref. 101).

However, for a number of reasons, case-control studies are at a disadvantage compared to correlational studies in their ability to detect an association between dietary fat and cancer risk. The range of dietary fat intake is usually narrow in case-control studies because the populations studied are homogenous in terms of dietary parameters. It is extremely difficult for an epidemiology study to detect an increase in cancer risk associated with dietary fat when the difference in fat intake between cases and controls is minimal. Also, the average fat content of the diet in Western countries is seldom less than 30 percent to 35 percent of total calories. Although it is not known for certain how low the fat content of a diet needs to be before a reduction in cancer risk is achieved, it is at least less than 30 percent of total calories. Thus, it is not surprising that the results of case-control studies investigating the relation between dietary fat and cancer are often equivocal.

A new study on colorectal cancer did not demonstrate an increased risk associated with total dietary fat or saturated fat but did show an increased risk with total calories and with cholesterol (Ref. 104). Two new case-control studies on prostate cancer both found an increased risk associated with dietary fat (Refs. 105 and 106).

The evidence from the new animal studies generally supports the conclusion drawn in the lipids/cancer proposal that dietary total fat is associated with the risk of cancer. Among eleven animal studies, six studies (three in mammary tumor, one in colon tumor, one in pancreatic tumor, and one in liver tumor) reported significant reductions in the risk of tumorigenesis, measured by incidence, multiplicity, or latency, by reducing fat intakes from about 20 percent to about 5 percent.

Regarding types of fat, the new studies provide the same conclusion as the one that the agency drew in the proposal: currently, there is not enough evidence to delineate specific roles of different types of fat on tumorigenesis. The new studies show that when the requirement of linoleic acid for optimal tumor growth is met, various types of dietary fat do not affect tumorigenesis at the mammary gland differently. The study results on colon tumor are equivocal; dietary PUFA was promoting in one study and was protective in the other. The two studies on skin tumor consistently reported a protective role of dietary PUFA, which suggests a different level of linoleic acid requirement for tumorigenesis at different sites.

It is difficult to disassociate the effect of fat from the effect of total energy. The two new animal studies did not provide further evidence that dietary fat has an energy-independent effect on carcinogenesis. There are two new studies that utilized isocalorie or similar calorie provisions (Refs. 115 and 116). One of these studies reported that energy intake rather than fat intake affects cancer development. However, both studies suffered the common methodologic limitation that linoleic acid in the diet was insufficient and were not adequate to evaluate the effect of fat. However, several studies previously reviewed by the agency (Refs. 11, 17, and 23) provided adequate evidence to conclude that the effect of fat is independent of the effect of energy.

As was the case with studies reviewed in the proposal, new studies on omega-3 fatty acid and tumor development do not provide conclusive evidence. Among the four new studies of omega-3 fatty acid and cancer, only one study (Ref. 129) in colon tumor provided adequate linoleic acid in the diet. The fish oil (MaxEPA) at 19.2 percent by weight significantly reduced tumor yield, suggesting that the fish oil may reduce DMH-induced colon tumor risk. The study, however, suffered from the limitation that the amount of dietary

fish oil used was unpractically high. Additional studies are required to elucidate the effects and mechanisms of omega-3 fatty acids on tumorigenesis.

The new studies reviewed did not further elucidate the mechanisms for the effect of fat on tumorigenesis. The existing hypotheses include alterations in membrane peroxidation, membrane fluidity and microenvironment, immune function, gene expression, metabolism of chemical carcinogens, metabolism of hormones, metabolism of eicosanoids, and turnover rate of intestinal mucosal cells (as discussed in the lipids/cancer proposal).

Thus, new animal studies provide some, although inconclusive, evidence that dietary total fat is associated with risk of some cancers. Mammary tumor, colon tumor, pancreatic tumor, and liver tumor may be affected. Evidence is inconclusive regarding specific roles of different types of fat including fish oils. The evaluation of the new studies was greatly hampered by the common limitation in the experimental design of limited linoleic acid in the diet.

As discussed previously in this preamble, several comments suggested that FDA drop the specification of types of cancer affected from the health claim. In view of the new evidence, FDA believes that the scientific evidence on lipids and risk of specific cancers is not as yet definitive. Further evidence has to be accumulated to draw clear conclusions regarding effects of different types of fat, effects at different tumor sites, effects of omega-3 fatty acids, the quantitative relationship between fat and energy, and mechanisms by which fat affects cancer development. Methodological limitations in the human and animal studies on dietary lipids and cancer are discussed in the lipids/cancer proposal and elsewhere in this document.

In conclusion, the evidence found in the new studies in humans and animals supports the agency's tentative conclusion in the proposal that the totality of publicly available scientific evidence supports an association between dietary fat and cancer risk. Evidence is also accumulating that total energy intake is an additional risk factor for cancer. However, the evidence for which types of cancer are affected is equivocal. Therefore, the agency is not authorizing the phrase "particularly cancers of the colon, breast, and prostate" or any other site to be included in the health claim.

IV. Environmental Impact

FDA has determined that under 21 CFR 25.24(a)(11), this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the Federal Register of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the Federal Register. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the Federal Register announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

VI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. New § 101.73 is added to subpart E to read as follows:

§ 101.73 Health claims: dietary fat and cancer.

(a) *Relationship between fat and cancer.* (1) Cancer is a constellation of more than 100 different diseases, each characterized by the uncontrolled growth and spread of abnormal cells. Cancer has many causes and stages in its development. Both genetic and environmental risk factors may affect the risk of cancer. Risk factors include a family history of a specific type of cancer, cigarette smoking, alcohol consumption, overweight and obesity, ultraviolet or ionizing radiation, exposure to cancer-causing chemicals, and dietary factors.

(2) Among dietary factors, the strongest positive association has been found between total fat intake and risk of some types of cancer. Based on the totality of the publicly available scientific evidence, there is significant scientific agreement among experts, qualified by training and experience to evaluate such evidence, that diets high in total fat are associated with an increased cancer risk. Research to date, although not conclusive, demonstrates that the total amount of fats, rather than any specific type of fat, is positively associated with cancer risk. The mechanism by which total fat affects cancer has not yet been established.

(3) A question that has been the subject of considerable research is whether the effect of fat on cancer is site-specific. Neither human nor animal studies are consistent in the association of fat intake with specific cancer sites.

(4) Another question that has been raised is whether the association of total fat intake to cancer risk is independently associated with energy intakes, or whether the association of fat with cancer risk is the result of the higher energy (caloric) intake normally associated with high fat intake. FDA has concluded that evidence from both animal and human studies indicates that total fat intake alone, independent of energy intake, is associated with cancer risk.

(b) *Significance of the relationship between fat intake and risk of cancer.* (1) Cancer is ranked as a leading cause of death in the United States. The overall economic costs of cancer, including direct health care costs and losses due to morbidity and mortality, are very high.

(2) U.S. diets tend to be high in fat and high in calories. The average U.S. diet is estimated to contain 36 to 37 percent of calories from total fat. Current dietary guidelines from the Federal Government and other national health professional organizations recommend that dietary fat intake be reduced to a level of 30 percent or less of energy (calories) from total fat. In order to reduce intake of total fat, individuals should choose diets which are high in vegetables, fruits, and grain products (particularly whole grain products), choose lean cuts of meats, fish, and poultry, substitute low-fat dairy products for higher fat products, and use fats and oils sparingly.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met.

(2) Specific requirements. (i) *Nature of the claim.* A health claim associating diets low in fat with reduced risk of cancer may be made on the label or labeling of a food described in paragraph (c)(2)(ii) of this section, provided that:

(A) The claim states that diets low in fat "may" or "might" reduce the risk of some cancers;

(B) In specifying the disease, the claim uses the following terms: "some types of cancer" or "some cancers";

(C) In specifying the nutrient, the claim uses the term "total fat" or "fat";

(D) The claim does not specify types of fat or fatty acid that may be related to the risk of cancer;

(E) The claim does not attribute any degree of cancer risk reduction to diets low in fat; and

(F) The claim indicates that the development of cancer depends on many factors.

(ii) *Nature of the food.* The food shall meet all of the nutrient content requirements of § 101.62 for a "low fat" food; except that fish and game meats (i.e., deer, bison, rabbit, quail, wild turkey, geese, ostrich) may meet the requirements for "extra lean" in § 101.62.

(d) *Optional information.* (1) The claim may identify one or more of the following risk factors for development of cancer: Family history of a specific type of cancer, cigarette smoking, alcohol consumption, overweight and obesity, ultraviolet or ionizing radiation, exposure to cancer-causing chemicals, and dietary factors.

(2) The claim may include information from paragraphs (a) and (b) of this section which summarize the relationship between dietary fat and cancer and the significance of the relationship.

(3) The claim may indicate that it is consistent with "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office.

(4) The claim may include information on the number of people in the United States who have cancer. The sources of this information must be identified, and it must be current information from the National Center for Health Statistics, the National Institutes of Health, or "Nutrition and Your Health: Dietary Guidelines for Americans," USDA and DHHS, Government Printing Office.

(e) *Model health claims.* The following model health claims may be used in food labeling to describe the relationship between dietary fat and cancer:

(1) Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers.

(2) Eating a healthful diet low in fat may help reduce the risk of some types of cancers. Development of cancer is associated with many factors, including a family history of the disease, cigarette smoking, and what you eat.

Dated: October 30, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

Note: The following tables will not appear in the annual Code of Federal Regulations.

BILLING CODE 4160-01-F

TABLE 1
Lipids and Cancer: Human Studies 1991 to Present

Study	Study Design	Subjects	Methods	Results	Comments
Zatonski et al., 1991 (Ref. 94)	Case-Control; Poland; Pancreatic (Exocrine) Cancer; study conducted 1985 to 1988	110 cases (surrogates interviewed for 71%); 195 controls (all directly interviewed)	Interview using dietary questionnaire containing 80 food items; diet assessed 1 to 2 years before interview; 43% of cases were histologically confirmed and remainder diagnosed radiologically	Adjusted for smoking and total calories: Total fat: RR=0.3 (0.1-1.0) SFA: RR=0 3 (0.1-1.0) MUFA: RR=0.1 (0.3-0.6) PUFA: RR=0.2 (0.1-0.6) Cholesterol: RR=4.3 (1.6-11.6)	Only cholesterol showed a positive relation with pancreatic cancer; substantial use of proxy interview of cases introduces bias; median daily total fat intake was 113 g for cases and 105 g for controls
de Mesquita, et al., 1991 (Ref. 95)	Case-Control; Netherlands; Pancreatic (Exocrine) Cancer; study conducted 1984 to 1988	164 cases (surrogates interviewed for 50% males and 46% females); 480 controls (surrogates interviewed for 34% males and 26% females)	Interview using dietary questionnaire containing 116 food items; diet assessed 1 year before interview; 68% of cases were histologically confirmed; others diagnosed clinically	Adjusted for smoking and total calories: Oil and Fats: RR=1.1 for highest quintile (NS) Total meat: RR=1.6 for highest quintile (NS) Cheese: RR=0.8 (NS) Milk: RR=0.8 (NS) Eggs: RR=2 3 and daily consumption of vegetables RR=0.3 for highest quintile (statistical significance and test for trend significance for both)	Total fat and saturated fat not analyzed in this study; consumption of eggs is associated with a statistically significant increased risk and daily consumption of vegetables show a protective effect; large percentage of proxy interview of cases may introduce bias
Riboli, et al., 1991 (Ref. 96)	Case-Control; Spain; Bladder Cancer; Study conducted 1985 to 1986	432 cases (all males); 792 controls; 2 sets of controls: population-based and hospital-based	Interview using dietary questionnaire containing 60 food groups; diet assessed 1 year before interview; all cases histologically confirmed	Adjusted for smoking and total calories: Total Fat: No association Saturated Fat: RR=2.2 (1.4-3.6) for highest quintile and trend highly significant (p=.0005) PUFA, MUFA: No associations Cholesterol: RR=1.4 (0.9-2.2) P/S Ratio: RR=0.7 (0.5-1.0)	Increased risk associated only with saturated fat; no association with total fat. Mean daily total fat intake was 99 g for cases and 95 g for controls Slightly low participation rates (cases: 72%; controls: 71% hospital and 66% population); results possibly biased by inclusion of 208 prevalent cases because they are survivors
Shekelle, et al., 1991 (Ref. 97)	Prospective Cohort; Western Electric Co. employees, Chicago; Lung Cancer	1,878 men aged 40 to 55 years in 1958 followed 24 years	Dietary information on foods and beverages consumed preceding 28 days collected at exam 1 and exam 2, 1 year later (all clinically free of cancer)	Adjusted for smoking and percent calories from fat: Dietary Cholesterol: 605-794 mg/day RR=1.3 795-1,909 mg/day RR=1.9 (results similar when adjusted for energy intake) Multivariable model implicated cholesterol from eggs but not from other sources	Increment of dietary cholesterol of 500 mg/day associated with RR=1.9 (1 1-3.4) Followup data not available so cannot assess changes in dietary cholesterol after baseline measurement

TABLE 1--continued

Study	Study Design	Subjects	Methods	Results	Comments
Graham, et al., 1991 (Ref. 99)	Case-Control; New York; Postmenopausal Breast Cancer; Study conducted 1986 to 1989	439 incident cases; 494 age-matched community controls	Interview using dietary questionnaire on 172 foods; diet assessed 2 years before interview; all cases were histologically confirmed; results adjusted for age, education, age at first pregnancy, number of pregnancies, age at menarche, relative with breast cancer, benign breast disease, and Quetelet index	Cases and controls consumed same calories. No association found between breast cancer risk and total fat or saturated fat; Fat RR= 0.9 (0.6-1.4); SFA RR=1.0 (0.7-1.5). Dietary carotene, vitamin C protective but no effect shown for supplement use; dietary fiber borderline protective RR=0.7 (0.5-1.1); adjustment for total calories did not change results	No association found between breast cancer risk and dietary fat. Mean daily total fat consumption was 82 g for cases and 83 g for controls. Low participation rates may introduce bias: 56% of eligible cases and 46% of eligible controls participated in study, thus results may not be generalizable to total population
Lee, et al., 1991 (Ref. 100)	Case-Control; Singapore Chinese; Pre- and Postmenopausal Breast Cancer; Study conducted 1986 to 1988	200 incident cases (109 premenopausal and 91 postmenopausal); 420 age-matched hospital controls (207 premenopausal and 213 postmenopausal)	Interview using dietary questionnaire on 90 foods; diet assessed 1 year before interview; all cases were histologically confirmed; results adjusted for age and age at birth of first child for premenopausal women and for age, height, education, nulliparity, family history of breast cancer for postmenopausal women	Postmenopausal women: no significant effects for any dietary variable Premenopausal women: Total fat, SFA, MUFA, and cholesterol showed no significant effect; P/S Ratio: RR=0.4 (0.2-0.8); Decreased risks found for PUFA: RR=0.5 (0.3-0.8); increased risk found for red meat after controlling for all other dietary variables: RR=4.0 (1.9-8.5)	Results not adjusted for total calories. No effect of diet on postmenopausal women. No effect found for total fat, SFA, MUFA, cholesterol and protective effect found for PUFA on premenopausal women. Median daily fat consumption was 33 g for cases and 34 g for controls. Hospital controls may have misrepresented their usual diet if preclinical symptoms (1 year before interview) affected diet
Richardson, et al., 1991 (Ref. 101)	Case-Control; France; Pre- and Postmenopausal Breast Cancer; Study conducted 1983 to 1987	409 incident cases; 515 hospital controls (348 premenopausal and 575 postmenopausal for total study population)	Interview using dietary questionnaire on 55 foods current diet assessed, but if changed over past 12 months, former diet was used; all cases were histologically confirmed; results adjusted for age, menopausal status, family history of breast cancer, history of benign breast disease, alcohol consumption, and age at menarche	Multivariate Model: All women: Fat 1.6 (1.1-2.2) SFA 1.9 (1.3-2.6) MUFA 1.7 (1.2-2.5); PUFA, cholesterol no significant effects Premenopausal women: MUFA 2.0 (1.1-3.7) SFA, MUFA, retinol, beta-carotene, fat, vitamin E no significant effects Postmenopausal women: SFA: 2.0 (1.2-3.1) Retinol: 2.8 (1.2-2.8) Total fat, MUFA, beta-carotene, vitamin E no significant effects Food Associations (all women): Total Food RR=1.7 (1.1-2.4); High fat cheese RR=1.4 (1.0-1.9); Desserts and chocolate RR=1.7 (1.2-2.5); Meat, Olive Oil, Nuts - nonsignificant	Results not adjusted for total calories or for body size. Limited evidence that fat is associated with breast cancer risk when analyzed by menopausal status. Total food was positively associated. Use of hospital controls could lead to selection of controls whose diseases are associated with high fat diets, although study excluded cardiovascular disease controls

TABLE 1--continued

Study	Study Design	Subjects	Methods	Results	Comments
Zarídze, et al., 1991 (Ref. 102)	Case-Control; Moscow; Pre and postmenopausal Breast Cancer; Study conducted 1987 to 1989	139 incident cases (58 premenopausal and 81 postmenopausal); 139 clinic controls (54 premenopausal and 85 postmenopausal) matched by age and neighborhood	Dietary questionnaire on 145 food items; diet assessed for average consumption during year prior to diagnosis for cases and for year prior to interview for controls. Data analyzed for pre- and postmenopausal women separately. Adjusted for total energy for all analyses; weight, height and Quetelet's index were assessed but none had a significant effect so results were not adjusted for these variables	Premenopausal women: Adjusted for total energy, age at menarche, age at first birth: Magnesium intake: RR=.02 (.0005-.08) only significant finding Postmenopausal women: adjusted for total energy, age at menarche, and education: Total fat, SFA, MUFA, cholesterol, protein: Nonsignificant PUFA: RR=0.1 (0.03-0.7) Mono- and disaccharides: RR=0.02 (0.002-0.3) Cellulose: RR=0.04 (0.01-0.3) Beta-carotene, vitamin C, potassium, calcium, magnesium, and retinol equivalents all showed significant protective effects	Dietary fat not associated with breast cancer risk in either pre- or postmenopausal women. Results showing protective effects of some nutrients are difficult to interpret due to multiple comparisons and multiple models used in analysis, especially in light of the small number of study participants
D'Avanzo, et al., 1991 (Ref. 103)	Case-Control; Italy; Pre- and postmenopausal Breast Cancer; Study conducted 1983 to 1989	2,663 incident cases (1,122 premenopausal and 1,541 postmenopausal); 2,344 controls (884 premenopausal and 1,460 postmenopausal)	Dietary questionnaire on few selected indicator foods to obtain data on fat intake in seasonings (butter, margarine and oil); current diet assessed; all cases histologically confirmed; results adjusted for age, area of residence, education, history of benign breast disease, family history of breast cancer, nulliparity, age at first birth, age at menarche, menopausal status, age at menopause, body mass index, oral contraceptive and other female hormone use	Total Fat (from seasonings) RR=1.5 (1.2-1.7) Butter RR=1.6 (1 2-2.1) Oil RR=1.2 (1.0-1.6) No effect shown with margarine consumption	Results not adjusted for total calories. Moderate association between intake of added fat in seasonings and breast cancer risk. Use of hospital controls could lead to selection of controls whose diseases are associated with high fat diets, although gastrointestinal diseases were excluded. Assessment of current diet rather than diet before onset of illness could bias results. Very limited dietary information available
Benito, E., et al., 1991 (Ref. 104)	Case-Control; Majorca; Colorectal Cancer; Study conducted 1984 to 1988	286 incident cases; 295 population controls and 203 hospital (ophthalmology and orthopedic); controls matched to cases by age and sex	Interview using dietary questionnaire on 99 food items; diet assessed in year preceding interview; all cases histologically confirmed; results adjusted for total calories and for age, sex, estimated weight 10 years prior to interview, number of meals per day, education, job category, and activity in the workplace	RR's for quartiles of consumption: Total Calories: RR=1.0, 1.6, 1 6, 2.6 After adjustment for total calories: Cholesterol: RR=1.0, 0.9, 1.7, 1 7 Fiber from legumes: RR=1.0, 0.8, 0.5, 0.4 Protein: RR=1.0, 1.1, 1.7, 2.5 Carbohydrate: RR=1.0, 1.5, 1 4, 2 2 No effects found for total fat or saturated fats	Increased risk of colorectal cancer found for total calories, cholesterol, protein, and carbohydrates and protective effect found for fiber from legumes. No effect on colorectal cancer risk was found for increased consumption of total fats or saturated fats. This lack of association may be due to the population's consumption mainly of MUFAs rather than animal fats. Mean percentage of calories from fat was 37% for colon cancer cases, for rectal cancer cases and for controls

TABLE 1--continued

Study	Study Design	Subjects	Methods	Results	Comments
Yeung, et al., 1991 (Ref. 138)	Correlational (Biochemical) Study; China and American; Colorectal Cancer	42 male and 50 female Chinese and 34 male and 33 female Chinese Americans; the two populations have fourfold difference in colorectal cancer risk	24-hour food, urine and stool samples analyzed; all subjects were randomly selected from volunteers	Chinese American diets were higher in fat and protein and lower in carbohydrates, stools contained more cholesterol and bile acids, and no difference in fatty acids, and urine contained more 3-methyl-histidine and malonaldehyde. Authors interpreted results to demonstrate that high fat, high protein, low carbohydrate diets are associated with increased colorectal cancer risk	Authors interpretation does not follow from study's findings due to methodological flaws: results are correlational only--no cases of colorectal cancer actually existed among participants; diet was assessed for 24 hours only; Chinese had higher participation rate than Americans; confounding by environmental and lifestyle factors were not controlled for in study
Geltner-Allinger, et al., 1991 (Ref. 139)	Case-Control; Sweden; Colon Cancer	35 cases (16 men, 19 women); 46 population controls (26 men, 20 women)	Limited dietary intake information, diet assessed for preceding year; stool samples analyzed for bile acids and lipid concentrations; rectal biopsies collected for colonic epithelial cell proliferation rate analysis	No differences found in the concentration of fecal bile acids or in colonic cell proliferation rates. No differences found in dietary intake of fat and fiber; female cases consumed slightly more calcium than controls (574 mg versus 370 mg)	Biological marker study; very small numbers of participants and very limited dietary assessment. No conclusions can be drawn from this study
Clausen, et al., 1991 (Ref. 140)	Clinical Study; Denmark; Colon Cancer	17 patients with colonic adenomas, 17 patients with colon cancer, and 16 healthy controls	Analyzed stool samples for short chain fatty acids; compared molar production velocities of short chain fatty acids from glucose, ispagula, wheat bran, and albumin in fecal incubations; no dietary assessment conducted	Fecal concentrations of total short chain fatty acids and concentrations and ratios of the individual fatty acids did not differ among the two sets of patients and controls. Molar production velocities did not differ except for the ratio of butyrate production to total short chain fatty acid production from fiber was reduced in colon cancer and adenoma patients compared to controls	Authors speculate that the low ratios of colonic butyrate formation combined with low fiber diets may increase the risk of colonic neoplasia. Study provides very limited evidence that high fiber diets may reduce the risk of colon cancer, and no information is provided by study as to type of fiber responsible

TABLE 1--continued

Study	Study Design	Subjects	Methods	Results	Comments
Yu, et al., 1991 (Ref. 92)	Correlational Study: China and U.S.: Colon, Rectal, Prostate and Breast Cancer	Chinese in Shanghai, Chinese Americans and Americans compared	Incidence rates of cancers of the colon, rectum, female breast, and prostate compared using Connecticut SEER data for White Americans, San Francisco SEER data for Chinese Americans, and data from the cancer registry at the Shanghai Tumor Institute for Shanghai Chinese. Incidence rates were standardized to the 1970 age distribution of the world population. Food consumption data compared using FAO data for U.S. and from two Chinese publication sources for China	Incidence rates for colon cancer among Americans were 4 times the Chinese rates, for rectal cancer among Americans were 2 times the Chinese rates, for prostate cancer among Americans were 26 times Chinese rates, and for postmenopausal breast cancer among Americans were 10 times the Chinese rates. Americans consumed 6 times more meat and eggs, 55 times more milk, slightly more fats and oils, and 3 times more fruit than Chinese	Study was correlational in design; there is no way to determine by this study if the persons who actually have these cancers also eat the putative diet. Study did not control for the very important known risk factors of these cancers such as lifestyle factors, family history, reproductive factors, and endocrine factors
Kesteloot, et al., 1991 (Ref. 93)	Correlational Study; 36 countries; Total Cancer and several types of cancer	Men and Women in 36 countries	Cause-specific cancer mortality rates using 1985 to 1987 WHO data were compared with dairy and lard fat intake obtained from food balance sheets from 1979 to 1981 FAO data	Highly significant correlations were found between dairy fat plus lard fat intake and mortality from all causes, total cancer, colon, and rectal cancer among both men and women and from lung cancer and prostate cancer for men only and breast cancer for women only. Correlations remained significant when adjusted for total caloric intake or for total caloric intake minus total fat intake	Study was correlational in design; thus, the diet of the persons with the diseases studied are not being analyzed directly. Study did not control for the very important known risk factors of these cancers such as lifestyle factors (e.g., smoking), family history, reproductive factors, and endocrine factors. Food balance sheet data from FAO are approximations of actual consumption and these data are not separated by age and sex
Bravo, et al., 1991 (Ref. 105)	Case-Control; Spain; Prostate Cancer; study conducted 1983 to 1987	90 cases; 180 controls from same hospital matched by age and date of hospital admission; controls were those with diseases other than urologic diseases or a primary tumor	Interview on types and amounts of foods usually consumed; obesity measured by body mass index; all cases were histologically confirmed; results were not adjusted for total calories	Risk of prostate cancer was increased by a diet rich in animal fats: RR=2.6 (1.3-5.0) Diets rich in vegetable fats, and vitamins A and C deficiencies were not associated with increased risk of prostatic cancer. Meat consumption was associated with increased risk: RR=2.3 (1.2-4.4) but different types of meat were not significantly associated with increased risk. No risk associated with obesity	Study demonstrates an increased risk of prostate cancer with diets rich in animal fats and with meat consumption. Results were not adjusted for total calories which severely limits the validity of the results. Hospital controls used, some with gastrointestinal diseases, and usual diet was assessed so that disease may have affected diet

ABLE 1--continued

Study	Study Design	Subjects	Methods	Results	Comments
West, et al., 1991 (Ref. 106)	Case-Control; Utah; Prostate Cancer; Study conducted 1984 to 1985	358 incident cases (179 aged 45 to 67 and 179 aged 68 to 74); 679 population-based controls (387 aged 45 to 67 and 292 aged 68 to 74), matched by county of residence	Interview using dietary questionnaire containing 183 foods; cases' diet assessed for 3-year period prior to diagnosis or prior to symptoms; controls' diet assessed 3 year prior to interview; all cases histologically confirmed; interviewers not blinded to case or control status of respondent. Results were adjusted for total calories. Interaction and confounding between dietary variables and demographic and lifestyle factors were assessed but none found; therefore, authors reported only crude relative risks	No associations between dietary variables and prostate cancer found for men 45 to 67 years of age, either for all tumors combined or when subdivided by tumor aggressiveness. Males aged 68 to 74: For all tumors: Total Fat RR=1.7 (1.0-3.1) Protein RR=1.7 (1.0-2.9) For aggressive tumors: Total Calories RR=2.5 (1.0-6.5) Total Fat RR=2.9 (1.0-8.4) MUFA RR=3.6 (1.3-9.7) PUFA RR=2.7 (1.1-6.8) No dose-response seen; cholesterol not associated with prostate cancer risk for either age group	Study demonstrates that dietary fat is associated with prostate cancer risk among older men. Bias may have been introduced due to low participation rates: 77% of eligible cases and 77% of eligible controls participated. Interviewers were not blinded as to case or control status of respondent; this may have introduced bias if the interviewers were aware of the association between dietary factors and prostate cancer

TABLE 2
Lipids and Cancer: Animal Studies

Study	Objectives/ Tumor Types	Experimental Animals	Methods	Results	Comments
Cohen et al., 1991 (Ref. 113)	Tested effects of fats and fiber in the N-nitromethylurea-induced rat mammary tumor model	Virgin female F-344 rats 5-day old 30/groups	Diet: varied in fat and fiber I 23.5% CO II 23.5% CO plus 10% fiber III 5% CO IV 5% CO plus 10% fiber The fiber was soft white wheat bran. Base diet was AIN-76A Rats received intravenous N-nitrosomethylurea (NMU) and fed diets for 15 weeks Tumor incidence and development measured. Blood levels of 17B-estradiol and progesterone also measured	5% CO diet sign reduced incidence (63 versus 90%) and multiplicity (1.1 versus 2.5 tumors per rat) and significance prolonged latency period compared to 23.5% CO diet Fiber significance reduced incidence and multiplicity of tumors in the 23.5% CO group but not in the 5% CO group No difference in hormone levels	Nonisocaloric diets used; food consumption not reported; significantly decreased body weight in the low fat, compared to other groups
Gonzalez et al., 1991 (Ref. 114)	To measure affects of different amounts and types of fat on growth of human breast carcinoma in athymic nude mice	Athymic nude mice Female 5 to 13 weeks old	Diet I 5% CO, 3.87 kcal/g II 20% CO, 4.55 kcal/g III 20% butter, 4.55 kcal/g IV 19% BT + 1% CO, 4.55 kcal/g V 19% FO (MO) + 1%, 4.55 kcal/g linoleic acid level (wt %) I 2.8 II 11.2 III 0.36 IV 0.9 V 0.75 After tumor transplantation, mice were fed the diets for 6 to 8 weeks. Tumor growth (number and volume of carcinoma) measured as well as lipid peroxidation in carcinoma Human breast cancer cell lines, MCF-7 and MDA-MB231, were used	Higher tumor volume in the high CO group (V) than low CO group (I); significant in the MDA-MB23 cell line transplanted mice. (0.4-4 cm3 versus o.2-3,4 cm3, II versus I) Among high fat groups (II-V), high CO significantly raised and FO significantly lowered tumor volume Tumor volume was intermediate in the BT and butter groups MCF-7 carcinoma MDA-MB231 carcinoma mean carcinoma volume (om3) (A) (B) I 3.4 0.5 0.2 II 4.0 1.5 0.4 III 2.4 1.2 0.1 IV 2.4 0.8 V 0.2 0.6 0.0 Significance: I II III IV versus II I versus II versus V I versus III II versus V II vs V V vs V	Diets III, IV, and V did not provide adequate linoleic acid for tumor growth The carcinoma cell line MDA-MB23, but not the MCF-7, was estrogen-dependent, and mice in this group was provided with exogenous estrogen in the drinking water; biologic plausibility to extrapolate the result to human is questioned

TABLE 2--continued

Study	Objectives/ Tumor Types	Experimental Animals	Methods	Results	Comments
Zhu et al., 1991 (Ref. 115)	To measure effects of dietary calorie restriction and fat reduction on growth of mammary carcinoma in rats	Female Sprague-Dawley rats 50-day old 19 to 23/groups	Diet: calorie restriction versus fat I 50kcal/day, 45 energy % fat II 35 kcal/day, 45 energy % fat III 50 kcal/day, 25 energy % fat IV 35 kcal/day, 25 energy % Diet: I & II (wt%): FO 16.28, lard 3.04, SSO 2.39; III & IV (wt%): FO 7.8, lard 1.46, SSO 1.14 Rats were injected with methylnitrosourea (MNU) and fed Diet I until tumor size was approximately 1 cm3 then fed with the experimental diets for 10 ± 2 weeks. Tumor development and liver glutathione measured	No difference in tumor number and weight between diets I and III, and II and IV 30% caloric reduction significantly reduced tumor yield (I versus II, and III versus IV)	Linoleic acid in diets III and IV may not have been adequate for tumor growth: therefore, comparisons between I and III or II and IV are not valid to test the effect of total fat
Buckman et al., 1990 (Ref. 123)	To measure whether oleate influences the linoleate-enhanced metastasis of murine mammary tumor	Weanling Female BALB/cAnN mice 12/groups	Diet: 20 wt% total fat I: SO 15.5, Triolein 0, CCO 4.5, 18:2n-6/oil 61, 18:2n-6/diet 12.2, 18:1n-9/oil 10.5 II: SO 15.5, Triolein 4.5, CCO 0, 18:2n-6/oil .5, 18:2n-6/diet 12.3, 18:1n-9/oil 24.5 III: SO 2.6, Triolein 11.5, CCO 5.9, 18:2n-6/oil 15.5, 18:2n-6/diet .1, 18:1n-9/oil 47 IV: SO 2.6, Triolein 0, CCO 17.4, 18:2n-6/oil 13.5%, 18:2n-6/diet 2.7%, 18:1n-9/oil 12 (wt %) Spontaneous tumor cell line (4526 murine mammary tumor cell line) was injected into mammary fat pad of mice and metastasis to lung, kidney, and liver measured	No difference in latency period, incidence, or yield of tumors among groups Most metastasis found in lung, some in liver, none in kidney Lung metastasis was significantly higher in the low linoleic acid to low oleic acid group (IV) compared to the other three groups (10, 62, 78, & 90 nodules: low linoleic to low oleic, low linoleic to high linoleic, high linoleic to moderate oleic, & high linoleic to low oleic, respectively No difference in liver metastasis among groups	Tumor cells grown in vitro were used: ability to extrapolate to humans is limited The effect of total fat not tested The effect of oleic acid not consistent Diets provided adequate linoleic acid and were isocaloric
Khoo et al., 1990 (Ref. 117)	To test the anticancer effect of stearic acid in transplanted mammary tumorigenesis in rats	Female F344 rats 4 to 6-week old 30/groups	Diet Control powdered diet (fat content not reported) and the control diet plus 20% stearic acid by weight Rats were fed the diets for 6 weeks before and 25 days after tumor implantation. Mammary tumor was induced in the rats by nitrosomethylurea and maintained in passage. The 8th passage cells were implanted in the flank of rats	Dietary stearic acid did not significantly affect the growth (size or weight) of transplanted tumor. Dietary stearic acid did not affect FA composition in tissues	Composition or level of dietary fat not provided: adequacy of linoleic acid cannot be judged. If the control diet was common chow or fat free diet both diets contained insufficient linoleic acid for tumor growth

TABLE 2--continued

Study	Objectives/ Tumor Types	Experimental Animals	Methods	Results	Comments
Aksoy et al., 1990 (Ref. 116)	To identify effects of different levels of dietary fat on MNU-induced rat mammary carcinogenesis	Female Sprague-Dawley rats 50 day-old 90/3 groups	Diet g/100g I II III PO 3 7.8 16.3 lard 0.56 1.46 3.04 SSO 0.44 1.14 2.39 Total fat 12 25 45 (energy %) Rats were fed experimental diets for 6 months and methylnitrosourea (MNU) -induced tumor development and plasma lipids measured	No difference in tumor incidence, or yield, or in mortality among groups	Diet I and II may not have provided adequate linoleic acid for mammary tumor growth Nonisocaloric diets used; however, rats consumed the same amount of calories and body weights were not different among groups
Lasekan et al., 1990 (Ref. 124)	To compare effects of safflower and olive oils on DMBA-induced mammary tumorigenesis	Female Weanling Sprague-Dawley rats 25/groups	Diet: 20 wt% fat High linoleic acid SO: SL diet High oleic acid SO: SO diet Olive oil: OO diet OO diet w/ linoleic acid supplementation : OL diet Linoleic content (wt%) SL 14.6 SO 3.4 OO 1.1 OL 3.4 Rats were fed the diets for 16 weeks, and 7, 12-DMBA-induced tumorigenesis measured	No difference in lag time or incidence OO diet significantly lowered tumor yield compared to SO or OL diets Linoleic supplementation of the OO diet (makes OL diet) significantly enhanced the yield; no difference in yield between OO and OL diets Tumors Diet /rat statistics SL 3.5 a,b SO 5.0 a OO 3.0 b OL 5.1 a (statistical: different letters in the statistics column show a significant difference)	Isocaloric diets; no difference in body weight or food intakes among groups OO diet which was limited in linoleic acid content resulted in a significantly lower tumor yield. This result was abolished by supplemental linoleic acid; the results support a linoleic acid requirement of about 4% by weight for induced mammary tumor genesis in rodents
Hirose et al., 1990 (Ref. 125)	The effects of diets supplemented with perilla oil (n-3 linoleic rich) and soybean and safflower oils (n-6, linoleic-rich) on DMBA-induced mammary and colon carcinogenesis	Female SD rats 5-week old 10/groups	Diet: 10% perilla oil 10% SBO 10% SO SO SBO perilla oil 18:2n-6 74 52.6 15.9% 20:4n-6 - 0.3 0.1% 18:3n-3 0.1 .7 13.7 Rats were fed the diets for 33 weeks after the injection of initiator (7, 12-DMBA) and promotor (1, 2-dimethylhydrazine, DMH). Incidence and development of tumor measured	Mammary Perilla oil significantly lowered tumor yield compared to SBO or SO (4.4, 6.5, 5.7, tumors per rat: perilla oil, SBO, or SO, respectively) No difference in yield between SBO and SO. No difference in incidence among groups Colon perilla oil significantly lowered tumor incidence compared to SOB or SO (4, 9, or 9% incidence: perilla oil, SBO, or SO). No difference in incidence between SO and SBO No difference in yield among groups	Perilla oil may not have provided adequate linoleic acid for tumor growth

TABLE 2--continued

Study	Objectives/ Tumor Types	Experimental Animals	Methods	Results	Comments
Kumaki and Noguchi, 1990 (Ref. 112)	To measure the influence of high dietary fat on malignant intensity and hormone receptors of DMBA-induced mammary carcinoma	Female 50-day old Virgin Sprague-Dawley rats 36 to 38/groups	Diet I 0.5% CO II 20% CO Rats were fed diets for 20 weeks, and 7, 12-DMBA-induced incidence and growth of tumor tested. DNA index, S-phase fraction and hormonal receptors for estrogen, progesterone were also tested.	High fat diet significantly elevated incidence (86 versus 46%), size (13.9 versus 7.9 mm diameter) and shortened latency period (10.0 versus 13.9 weeks) compared to low fat diet No difference in hormonal receptors	Low fat diet did not provide adequate linoleic acid for growth of tumor or the animal Nonisocaloric diets used; however, body weight was not different between groups
Wan et al., 1991 (Ref. 136)	To compare effects of fish oil or safflower oil on protein synthesis and catabolism of mammary tumor grown in the peritoneal cavity	Female Pathogen-free F344 rats 60 ± 5 g	Diet I 19.5% MO + 0.5% SO II 20% SO Rats were fed the diets for 5 weeks, inoculated with mammary ascites tumor cells (13762 MAT) and fed the diets for 2 weeks Tumor size, protein turnover, and plasma lipids were measured	No difference in tumor weight between groups Significant decrease in tumor volume by FO feeding Significantly increased w-6 FA and significantly reduced w-3 FA in plasma lipids No difference in protein turnover rate in tumor or in whole body between two diet groups Significantly prolonged liver protein turnover in FO group compared to SO group	Rats were pair-fed and diets were isocaloric FO diet did not provide adequate linoleic acid for tumor growth Additional antioxidants (vitamin E and tertiary butylhydroquinone) were used
Takata et al., 1990 (Ref. 137)	To measure the effects of two different types of unsaturated FA on NMU-induced mammary carcinogenesis	Female Sprague-Dawley rats 6-week old 10 (control) and 30 (test)/groups	Diet: 5 wt% I) 4.7 wt% EPA plus 0.3 wt % linoleate II) 5 wt% linoleate Rats fed the diets for 20 weeks, N-nitroso-N-methylurea (NMU) -induced tumor incidence and yield tested	Significantly lower tumor incidence and yield (weight or number) in the EPA group EPA diet reduced prostaglandins (PGE2, TXB2, and 6-keto PGF1) in tumor, compared to linoleic acid diet	EPA diet did not provide adequate linoleic acid for tumor growth or animal growth. Unrealistically low total fat

TABLE 2--continued

Study	Objectives/ Tumor Types	Experimental Animals	Methods	Results	Comments
Bunce and Abou-El-Ela, 1990 (Ref. 135)	To measure eicosanoid synthesis and ornithine decarboxylase activity in mammary tumors in rats fed varying levels of n-3 and n-6 fatty acids	Virgin female Sprague-Dawley rats 50-day old 25/groups	Diet CO PO BCO BO MO (wt% per diet) I 20 - - - - II - 20 - - - III - - 20 - - IV - - - 20 - V 15 - - - 5 VI 10 - - - 10 VII 5 - - - 15 VIII - - - 10 n-6FA U-3FA (% per diet) I 12.1 0 II 16.8 0 III 11.3 .3 IV 12.6 0 V 9.3 1.4 VI 6.5 2.9 VII 3.6 1.2 VIII 6.7 2.9 Rats were administered i.g. 7, 12-DMBA and fed diets for 112 days Incidence and multiplicity of the tumor examined. Prostaglandin (PGE, LTB4, and LTC4) synthesis and ornithine decarboxylase (ODC) activity also tested	Incidence of adenocarcinoma: significantly lower in groups III, VI, and VII than groups II, IV, and VIII; n-3 FA level or n-6 FA/n-3FA ratio did not consistently affect the incidence Tumor yield (number/rat) was significantly lower in group II than groups IV and III; n-3 or n-6 FA did not consistently affect the yield No difference in latency period among groups	Diets provided adequate linoleic acid for growth of the animal as well as the tumor
O'Neill et al., 1991 (Ref. 142)	To measure modulation of colonic nuclear aberrations and microcapsule-trapped gastro-intestinal metabolism in benzopyrene treated mice consuming human diets	Male C57/B6 mice 6-week old 36/6 groups	Diet: I & II III IV V fat 15 45 15 energy % Protein 2.7 .1 2.7 2.7 wt% Fiber 2.1 2.1 2.1 5.6 wt% Fiber: nonstarch polysaccharide. Protein: beef protein Mice were fed the diets for 3 weeks and received benz(a)pyrene by gavage. Colonic nuclear aberration was examined histologically and by using HPLC	Benz(a)pyrene increased the nuclear aberrations by 8-fold The extent of benz(a)pyrene-induced nuclear aberrations was decreased to 2-to 3-fold by increased fiber or fat in the diet	FA composition in the diet not reported and the adequacy of dietary EFA is not known Nuclear aberration, not cancer development, was measured

TABLE 2--continued

Study	Objectives/ Tumor Types	Experimental Animals	Methods	Results	Comments
Nutter et al., 1990 (Ref. 136)	To measure effects of dietary fat and protein on DMH-induced tumor development and immune responses	Weanling, BALB/c mice Male 280/10 groups	Diet: varied in fat and protein Total fat: 5 wt% Total protein: 11 wt% Diet CO BT Casein NFDM Lyophilized beef (wt%) I 4.7 31.5 II 2.9 - 11.4 III 4.7 31.5 IV 5 12.1 - V 5 20 - Diet V was AIN-76A diet Mice were fed until 51 weeks of age. Incidence and development of the dimethylhydrazine (DMH)-induced tumor as well as immune response was measured. DMH was injected subcutaneously for 10 weeks	CO plus NFDM diet significantly elevated tumor yield compared to other groups Number of tumors per tumor-bearing mouse I 12.3 II 2.6 III 3.2 IV 5.3 V 4.4	Total fat levels in the diets do not match between the levels described in the Methods and the levels found in authors' Table 1 BT diets may not have provided adequate linoleic acid for growth of tumor The effect of CO on tumor yield was not consistent
Nicholson et al., 1990 (Ref. 118)	To measure the influence of dietary fats (beef suet rich in saturated fat and corn oil rich in linoleic acid) on colorectal carcinogenesis	Wistar rats Male 5-week old 57/groups	Diet 5% beef suet (BS) 20% beef suet 5% corn oil 20% corn oil FA composition in diet linoleic arachidonic (%) 5%bs 12.7 2.3 20%bs 5.4 0.5 5%CO 42.4 0.9 20%CO 48.6 0.5 Animals were fed the diets for 16 weeks before and 6 weeks after azoxymethane, which was injected once a week for 6 weeks. Yield (#) of adenoma and carcinoma measured. Mucosal and tumor FA composition also measured	No difference in adenoma yields The BS diets produced significantly more carcinoma than CO diets (1 versus 12 carcinoma, 5% CO versus 5% BS; 2 versus 28 carcinoma, 20% CO versus 20% BS) 20% BS produced significantly more carcinoma than 5% BS (28 versus 12 carcinoma; 20% BS versus 5% BS); difference for CO was nonsignificant (2 versus carcinoma; 20% CO versus 5% CO) Arachidonic acid was higher in tumors than in colonic mucosa regardless of fat source N-6 FA may suppress the development of colorectal carcinoma. The data also suggest an association of prostaglandins with colorectal tumor development	Nonisocaloric diets used; however, no difference in food consumption or in body weight BS diets, which may have provided insufficient linoleic acid for tumor growth, had elevated tumorigenesis. The results suggest linoleic acid requirements may be different for different tumor sites

TABLE 2--continued

Study	Objectives/ Tumor Types	Experimental Animals	Methods	Results	Comments
Behling et al , 1990 (Ref. 119)	To measure the effect of varying levels of dietary calcium and butterfat on cecal enzyme activity and development of DMH-initiated colon tumors in rats	Weanling male Sprague-Dawley rats 112/4 groups	Diet: I 1% CO + 5% butter fat + 2.5 g Ca/kg II 1% CO + 5% butter fat + 10 g Ca/kg III 1% CO + 20% butter fat + 2.5 g Ca/kg IV % CO + 20% butter fat + 10 g Ca/kg Diets fed for 2 weeks before and 31 to 34 weeks after the injection of DMH Incidence and development of intestinal tumor examined. Enzymic activity in cecum and lipid extraction in feces also measured	No difference in tumor yield among groups High Ca increased fecal lipids	All diets may not have provided adequate linoleic acid for tumor growth The study focused on the effect of Ca, not lipids
Lindner, 1991 (Ref. 129)	The effect of n-3 PUFA on colon cancer in mice. Effects of high fat and high cholesterol diets and low fat cholesterol free diets in mice	Swiss-Webster mice 6 to 7-week old 174/4 groups	Diet (wt%) BT: Tot fat 19.2, n-6FA 3.5, n-3FA 0, MUFA 7.5 SO: Tot fat 19.2, n-6FA 14.3, MUFA 2.8 FO MaxEPA: Tot fat 19.2, n-6FA .8, n-3FA 4.4, MUFA 5.2 Low fat: Tot fat 3.5, n-6FA 2.0, n-3FA 0, MUFA 1.0 Mice were fed the diets for 4 weeks, received 1.2-DMH for 11 weeks Tumor development in the intestinal tract (from esophagus to rectum) was examined. Plasma lipids also examined	Significantly higher body weight in BT group than low fat or FO groups and in SO group than low fat group No difference in mortality Higher colon tumor incidence in the BT groups; significance between BT and FO group. Tumor incidence in other sites (kidney, liver, skin, and scrotum) was lower in the BT group (significance between BT and low fat group) Colon tumor No difference in adenoma yield. Significantly higher adenocarcinoma in BT group than SO or FO group. FO was protective; adenocarcinoma yield was the lowest in the FO group; significance between FO and BT group. (Mean tumors per animal 1,23, 0.47 and 0.23; BT, SO and FO) Oleic acid and MUFA content (%) in the plasma or in colon mucosa were linearly correlated with tumor yield; dietary MUFA was reflected in plasma but not in colon mucosa n6 PUFA or linoleic acid was not associated w/ tumor yield; dietary level of linoleic acid was reflected in plasma and colon mucosa n-3 PUFA and EPA level in plasma or colon mucosa was significantly, negatively correlated w/ tumor production	The FO (MaxEPA) may have a protective role in DMH-induced colon tumorigenesis in Swiss-Webster mice The effect of carcinogen, DMH, was different among sites of tumorigenesis and the findings cannot be generalized to cancer sites beyond colon

TABLE 2--continued

Study	Objectives/ Tumor Types	Experimental Animals	Methods	Results	Comments
Smith et al., 1990 (Ref. 121)	The effects of high fat diet and CCK-receptor antagonist on growth of human pancreatic tumor cells in nude mice	Male 5 to 6-week old Athymic nude mice 15/groups	Diet 4.3% fat chow diet 20.3% fat diet: 4.3% fat in the chow + 16% CO Mice were injected w/ SW-1990 human pancreatic adenocarcinoma cell line and fed the diets for 23 days. The effects of dietary fat and CCK-receptor antagonist L364718 on pancreatic tumor development examined	Among L364718 untreated animals, the high fat diet significantly increased tumor volume and protein content in tumor, compared to the chow diet L364718 significantly decreased tumor yield; endogenous CCK (cholecystokinin) may promote the growth of pancreatic tumor in mice	FA composition of chow diet not reported. The chow diet may have provided insufficient linoleic acid for tumor growth Tumor cells, assayed in vitro, were used
Longnecker et al., 1990 (Ref. 122)	To measure the development of pancreatic neoplasms in elastase-1-simian virus transgenic mice	Elastase 1 simian virus transgenic mice Strain Tg (Ela-1, SV4oE) Bril 18 Female and male 11 to 23/groups	Diet chow: 5-6% fat AIN-76A: 5% CO Hi-fat: 20% CO Diets were fed for 22 to 23 weeks. At autopsy, incidence and multiplicity of the tumor examined	Incidence of exocrine carcinoma: significantly reduced by chow diet No difference between AIN-76A and high fat diets Incidence of islet cell tumor: no difference among groups	Genetically transformed, transgenic mice were used: extrapolation of results to human is questionable Extremely low total fat Linoleic acid content of the chow diet is not known
Oth et al, 1990 (Ref. 131)	The modulation of CD4 expression in lymphoma transplanted to mice fed n-3 PUFA	Adult AKR mice	Diet No fat, basal diet I 1% FO II 1% BT III 4% FO IV 4% BT V 6% FO VI 6% BT VII 8% FO VIII 8% BT IX 16% FO X 16% BT FO: 23 7% SFA, 30.3% n-3 FA, 1.3% linoleic acid Experimental diets were fed for 6 weeks before and 2 weeks after tumor xenograft by intraperitoneal transplantation. RDM-4 tumors in ascites were harvested and examined. Cell surface markers tested as well	Considerably (statistics not tested) faster tumor growth in the FO-fed donor than in the BT- or no-fat-fed donors Significantly reduced CD4 cell surface marker in the FO groups than BT groups; other markers such as CD8, H2K, Thy-1, and LFA-1 markers were not affected No effect of total fat	Both BT and FO diets may not have provided adequate linoleic acid for tumor growth

TABLE 2--continued

Study	Objectives/ Tumor Types	Experimental Animals	Methods	Results	Comments
Ayachi et al., 1990 (Ref. 130)	To test the suspectibility of lymphoma cells to lymphokine-activated killer (LAK) cells in mice fed high fat, fish oil diets	AKR mice	Diet 4% FO 4% HBT 8% FO 8% HBT 16% FO 16% HBT n-6 FA content HBT: 0.1 wt% FO: 2.2 wt% Mice were fed the diets for 6 weeks before and 12 to 15 weeks after the intraperitoneal graft of RDM4 lymphoma cells	Tumor yield was significantly greater in the FO group than in the HBT group FO increased resistance of lymphoma cells to lysis by lymphokine activated killer cells in vitro No effect of total fat	Experimental diets may not have provided adequate linoleic for growth of tumor and the mice Total fat in 4 to 8% fat diets was unrealistically low Due to the limitation in dietary linoleic acid, results are not useful for evaluating the effect of fat
Locniskar et al., 1991 (Ref. 127)	To compare the effects of fish, coconut, and corn oils on skin tumor promotion by benzoyl peroxide in mice	Weanling Female SENCAR mice 30/groups	Diet: 10% total fat CCO / CO / MO (wt%) A: 8.5 / 1.5 / - B: 7.5 / 1.5 / 1.0 C: 4.5 / 1.5 / 4.0 D: - / 1.5 / 8.5 E: - / 10.0 / - Mice were fed 5% CO diet for 3 weeks, treated with an initiator, 7,12-DMBA, fed 10% CO diet for 2 weeks, fed the experimental diets (A-E) for 52 weeks, and treated with benzoylperoxide (promoter) biweekly. Latency, incidence, and yield of papilloma and carcinoma examined. Ornithine decarboxylase (ODC), vascular permeability, and hyperplasia of the dorsal skin were also examined	Papilloma Significantly higher cumulative tumor probability in Diet A than Diet B, D, and E, but not C. Papilloma yield was significantly greater in Diet A or Diet C than Diet B, D, and E (Tumor probability was mathematically calculated) Carcinoma Significantly higher tumor incidence and cumulative tumor probability in Diet A and Diet E: no difference in incidence among Diet B, C and D. Carcinoma yield not reported No difference in ODC activities or vascular permeability among groups. Significantly greater hyperplasia in Diets B and C than Diets A, D, and E	Low total fat in the diets Except Diet E, all the diets may have provided inadequate linoleic acid for tumor growth. Diet E with adequate linoleic acid resulted in the longest latency period, lowest tumor incidence, and least tumor yield The results suggest that growth of skin tumor may not require 4% dietary linoleic acid and that the effect of dietary fat on tumorigenesis is site-specific In the 10% fat diet, high PUFA in the diet showed a protective effect and high SFA in the diet showed a promoting effect while the effect of n3 FA-rich diet was intermediate

TABLE 2--continued

Study	Objectives/ Tumor Types	Experimental Animals	Methods	Results	Comments
Leyton et al., 1991 (Ref. 128)	To measure effects of type of dietary fat on phorbol-ester-elicited tumor promotion in mouse skin	Female SENCAR and DBA/2 mice 4-week old 30 mice/groups	Diet Initiation period: 5 wt% total fat Co CCO C18:2n-6 all 1.7% 3.3% 1.0% promotion period: 15 wt% total fat CO CCO C18:2n-6 I 1.0 14 0.8 II 3.6 11.4 2.2 III 6.0 9.0 3.5 IV 7.9 7.1 4.5 V 9.9 5.1 5.6 VI 12.5 2.5 7.0 VII 15. 0. 8.4 7,12-DMBA initiated and 12-0-tetradecancyl-phorbol-13-Acetate(TPA)-promoted papilloma development determined	Papilloma incidence: No difference among groups Significant inverse correlation between CO level and papilloma yield (r = 0.92), 5.4 tumors versus 11.7 tumors per mouse; 15% CO versus 10% CO in SENCAR mice). Similar results found in DBA/2 mice The results suggest that increasing dietary CO or decreasing SFA may suppress skin tumor in mice TPA elevated epidermal PGE2 in all diet groups: the extent was negatively correlated with dietary CO	The effect of total fat not tested Low PUFA/high SFA diet significantly enhanced DMBA- and TPA-induced skin tumor yield than high PUFA/low SFA diet; this result is inconsistent with the 4 to 5 wt% linoleic acid requirement found in mammary and pancreatic tumorigenesis in rats. The results suggest that the effect of dietary fat may be specific for tumor sites
Jenski et al., 1991 (Ref. 143)	To measure the release of cytosolic components from leukemic cells inoculated into mice fed menhaden oil or coconut oil	BALB/c mice Female and male 4/groups	Diet I 10% MO + basal chow diet II 10% CCO + basal chow diet III 20% MO + ICN fat free diet IV 20% HCO + ICN fat free diet Mice were fed the diets for 5 weeks, inoculated intraperitoneally with murine leukemia cell line T27A, and fed the diets for 1 week Membrane permeability of tumor cells was examined in vitro by examining 51CR release from the cells	Increased membrane permeability in the MO groups The enhanced membrane permeability was correlated with n-3 FA (DHA and EPA) incorporated into the tumor cells	Diets may not have provided adequate linoleic acid for optimal tumor growth Tumor development not measured. Eradication of tumor was measured indirectly by measuring cell permeability intravenously

TABLE 2--continued

Study	Objectives/ Tumor Types	Experimental Animals	Methods	Results	Comments
Hietanen et al., 1990 (Ref. 120)	To test the modulation of dietary fat, varied in the quality and the quantity, of the oxidative stress and chemical-induced liver tumors in rats	Male wistar rats 4-week old	Diet SSO land (wt%) I 2 0 II 1 III 12.5 0 IV 1 11.5 V 25 0 VI 1 24 Rats were fed for 10 weeks prior and 33 weeks after the N-nitrosodimethylamine (NDMA) administration by gavage Tumor prevalence as well as plasma lipids and lipid peroxidation were measured	High-PUFA diet (25% SSO) significantly elevated tumor incidence compared to low PUFA diet (2% SSO), (80% versus 42%; 25% SSO versus 2% SSO) Fat type did not significantly affect tumor incidence High-PUFA diets (25% or 12.5% SSO) reduced plasma cholesterol and TG concentration compared to high SFA diets (25% or 12.5% lard diets)	Except 12.5% SSO and 25% SSO diets, all diets may have provided inadequate linoleic acid for tumor growth Nonisocaloric diets used: body weight changes were not significantly different among groups Due to limitations in study design, the effect of dietary fat on cancer development cannot be evaluated

Abbreviations
BCO: black currant seed oil
CO: corn oil
EFA: essential fatty acid
i.p.: intraperitoneal
PUFA: polyunsaturated fatty acid
SBO: soybean oil
BO: borage oil
CCO: coconut oil
FO: fish oil
MO: menhaden oil
PrO: primrose oil
SO: safflower oil
BS: beef suet
DMBA: 7, 12-dimethylbenzanthracene
FA: fatty acid
MUFA: monounsaturated fatty acid
RR: relative risk
BT: beef tallow
DMH: 1, 2-dimethylhydrazine
HBT: hydrogenated beef tallow
NFDM: nonfat dried milk
SSO: sunflower seed oil
Ca: calcium
EPA: eicosapentaenoic acid
HCO: hydrogenated corn oil
PO: palm oil
SFA: saturated fatty acid

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 91N-0095]

RIN 0905-AB67

Food Labeling: Health Claims and Label Statements; Sodium and Hypertension

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing its decision to authorize the use on the label or labeling of certain foods of health claims relating to an association between dietary sodium and high blood pressure. The agency has concluded that, based on the totality of the scientific evidence, there is significant scientific agreement among qualified experts that diets low in sodium may help lower blood pressure in many people. Therefore, FDA has concluded that claims on certain foods relating sodium reduction to reduced risk of high blood pressure are justified. This action is in response to provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) that bear on health claims, and is developed in accordance with the final rule on general requirements for health claims, which is published elsewhere in this issue of the **Federal Register**.

EFFECTIVE DATE: May 8, 1993.

FOR FURTHER INFORMATION CONTACT: Ellen M. Anderson, Center for Food Safety and Applied Nutrition (HFF-266), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5375.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 27, 1991 (56 FR 60825), FDA proposed to authorize the use on food labeling of health claims relating diets low in sodium to lower blood pressure in some people. The proposed rule was issued under provisions of the 1990 amendments (Pub. L. 101-535) that bear on health claims and in accordance with the proposed general requirements for health claims for food (56 FR 60537, November 27, 1991). As amended in 1990, the Federal Food, Drug, and Cosmetic Act (the act) provides that a food is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition unless the claim is made in accordance with section 403(r)(3) or (r)(5)(D) of the act (21 U.S.C. 343(r)(3) or (r)(5)(D)).

Section 3(b)(1)(A) of the 1990 amendments specifically requires that the agency determine whether claims respecting 10 nutrient/disease relationships meet the requirements of section 403(r)(3) or (r)(5)(D) of the act. The relationship between sodium and hypertension is one of the claims required to be evaluated. In the **Federal Register** of March 28, 1991 (56 FR 12932), FDA published a notice requesting scientific data and information on the 10 specific topic areas identified in the 1990 amendments. Relevant scientific studies and data received in response to this request were considered as part of the agency's review of the scientific literature on sodium and hypertension and were included in the proposed rule. Comments received in response to the notice and not specifically addressed in the proposed rule are summarized and addressed below.

In addition to evaluating the scientific evidence, the proposed rule identified qualifying and disqualifying criteria for foods bearing health claims on sodium and hypertension. The proposed rule also specified mandatory and optional information for health claim statements and provided a sample claim. FDA requested written comments in response to its proposed rule and solicited comments on several issues in particular. The agency asked whether foods with minimal nutritional value should be allowed to bear health claims and whether a statement of the recommended range of sodium intake (500 to 2,400 milligrams (mg) per day) should be required or remain optional. The agency requested comments on requiring the use of the terms "sodium" rather than "sodium chloride" and "high blood pressure" rather than "hypertension," and on allowing the terms "salt" in addition to "sodium" and "hypertension" in addition to "high blood pressure." The agency also requested comments on whether a statement indicating that identified hypertensives should consult their physicians should be allowed or required, on the safety of the recommendations to reduce sodium and salt intake, and on the proposed "Consumer Summary on Sodium and High Blood Pressure."

On January 30 and 31, 1992, FDA held public hearings on all aspects of the proposed rules published in response to the 1990 amendments, including health claims for sodium and high blood pressure (57 FR 239).

In response to its proposed health claim regulation on sodium and hypertension, the agency received approximately 100 comments from consumers, consumer advocacy groups, State health departments, organizations of health professionals, the food industry, and Government agencies. A number of comments were received that were more appropriately addressed in other documents, and these comments were forwarded to the appropriate docket for response.

II. General Comments

1. One comment noted that it is difficult to find a variety of foods that meet recommended dietary sodium levels and expressed the hope that this regulation would encourage industry to provide more low sodium foods.

FDA strongly encourages innovation in providing consumers with a wider variety of choices. FDA's labeling and education initiatives in the early eighties resulted in a 60 percent increase in sodium content labeling from 1978 to 1988 (Ref. 46) and the introduction of additional low sodium products (Ref. 56). The current initiatives include not only sodium/hypertension health claims, but also mandatory sodium labeling, a daily value (DV) for sodium, sodium disqualifying levels for health claims, and sodium disclosure levels for nutrient content claims. FDA anticipates that these regulations will motivate manufacturers to develop and market a broader range of lower salt products for the American consumer.

2. Another comment argued that consumers will wrongly believe that consumption of foods with too much sodium to qualify for a sodium/hypertension health claim will necessarily lead to exceeding current dietary guidelines.

FDA disagrees. Rather, the agency believes that health claims will encourage the availability and consumption of foods that will help consumers meet dietary guidelines. Furthermore, auxiliary educational programs, consistent with the dietary guidelines philosophy, can help consumers understand that, by consuming a variety of foods, some higher in sodium and some lower in sodium, they can meet total dietary intake goals.

3. One comment opposed sodium restrictions on foods, arguing that restrictions would be likely to hinder the development of low fat foods and that reducing fat in the diet is more important than reducing sodium. The comment submitted supporting data from surveys in which nutritionists and

physicians rated their most important health concerns (Refs. 137 and 142). Although reduction in sodium intake was ranked as a "high priority" for good health (Ref. 142) and a "moderate priority" for improved heart health (Ref. 137), the comment noted that the survey results indicate that reducing fat was considered a higher priority than reducing sodium.

It was not clear whether the comment objected to sodium/hypertension health claims, to disqualifying levels for sodium on other health claims, or to both. In the 1990 amendments, Congress specifically identified sodium and hypertension as one of ten topics to be evaluated for health claims and did not limit claims to the highest priority health issues. FDA evaluated the totality of the scientific information and the extent of the scientific agreement among qualified experts and concluded that claims for sodium and hypertension should be allowed. In addition, the provisions of the 1990 amendments state that health claims may not be made on a food that contains a nutrient that increases the risk of a disease or health-related condition. Sodium was one of four nutrients identified by the agency as increasing the risk of a disease or health-related condition.

FDA disagrees that these survey results are relevant to its duty under the 1990 amendments with regard to health claims for sodium and hypertension. FDA need only establish that a relationship between sodium and hypertension is supported by the totality of the scientific evidence and by significant scientific agreement among experts qualified by experience and training to evaluate such evidence. A poll of scientists ranking sodium/hypertension concerns relative to fat/heart disease concerns does not contribute to this process.

FDA recognizes the importance of encouraging the development and use of more low fat foods. The agency has authorized two health claims that may appear only on foods low in fat (final rules on lipids and cardiovascular disease and on lipids and cancer health claims, published elsewhere in this issue of the **Federal Register**). Sodium is a disqualifying nutrient for these and other health claims, because diets high in sodium increase blood pressure in many people and, therefore, increase the risk of high blood pressure and associated risks of heart disease and stroke. (See the final rule on general requirements for health claims, published elsewhere in this **Federal Register**).

4. Several comments asserted that the agency adequately considered safety concerns regarding reductions in sodium intake in the proposed regulation. The Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology (FASEB) prepared a final independent evaluation of the scientific evidence on sodium and hypertension (Ref. 138) and submitted this as a comment. An earlier draft of the report (Ref. 108) was discussed in the proposed rule (56 FR 60825 at 60829). The FASEB report (Ref. 138) concluded that severe sodium chloride restriction (less than 20 milliquivalents (meq) or 460 mg sodium per day) may have adverse consequences, but that, in the absence of obvious salt-losing disorders, there is no evidence that avoiding high sodium chloride intakes would be deleterious to health. Other comments, including a review article (Ref. 144), disagreed with FDA's assessment, arguing that there is inadequate scientific evidence that curtailing sodium will safely reduce the risk of hypertension; that there is a growing body of scientific evidence that reducing sodium may put some healthy people at risk, that no populations with free access to salt choose such low levels and the risks of these levels have not been considered; that severe restriction in animals results in some risks; that in the older literature, extremely low sodium intake in humans resulted in some symptomatic distresses; and that FDA has no studies that demonstrate safety and efficacy of universal sodium restriction, especially in normotensives. The comments submitted no data demonstrating that daily dietary intakes of 2,400 mg sodium are unsafe.

The agency has considered and addressed the safety concerns and believes that the recommended goal of 2,400 mg per day is safe. The National Academy of Sciences, which recommended the 2,400 mg daily goal, is considering dropping the current target goal to 1,800 mg sodium per day (Ref. 62). Furthermore, the 1989 Recommended Dietary Allowances (Ref. 63) identify 500 mg sodium as a safe minimum daily intake for adults, and 2,400 mg is well above this safe minimum intake level. Other authoritative documents also agree that a moderate sodium intake is safe (Refs. 38, 43, and 62). Numerous experiments with low sodium diets have been conducted with no serious consequences. Finally, dietary guidelines since the early eighties (Refs. 9, 22, and 85) have recommended moderation in sodium intake with no ill effects. Given these conclusions, the lack of data demonstrating safety concerns with daily consumptions of 2,400 mg sodium, and the extreme difficulty in achieving an intake of sodium at or below the 500 mg per day minimum safe level in the U.S. diet, FDA concludes that there are no safety risks associated with use of the sodium/hypertension health claim.

5. A few comments from health professionals supported FDA's description of the special considerations and risks involving sodium losses during sustained exercise or training in hot temperatures. One comment specifically supported responding to these risks with education efforts as proposed by the agency.

FDA acknowledges these comments.

6. Some comments supported FDA's conclusion in the proposed rule that the study results (Refs. 33 and 72) that suggest some individuals may respond to sodium reduction with blood pressure increases rather than decreases may be due to random variations and require additional research to determine if the results of these few studies are significant and reproducible. Other comments disagreed. One comment stated that many people believe that the results of the INTERSALT study (Ref. 37) confirm this heterogeneous blood pressure response.

FDA acknowledges that there is wide variability in blood pressure response to changes in sodium intake, but disagrees that recommended sodium intake goals pose safety risks. The INTERSALT (Ref. 37) and other study results (Refs. 41, 44, 45, 76, 80, 94, 97, 100, 106, 107, 109, 121, 122, and 123), in spite of large background fluctuations and a dilution effect of including nonresponsive individuals, clearly show that reducing sodium intake has a measurable and beneficial effect on reducing average blood pressure. The agency encourages additional studies under controlled conditions; however, FDA disagrees that this normal variability, which commonly occurs with physiological measurements, calls into question the safety of current intake recommendations of 2,400 mg per day.

7. A few comments supported FDA's conclusion in the proposed rule that the possible adverse changes in plasma lipids in response to sodium restriction (Refs. 2, 40, 49, and 89) do not pose safety concerns for the general public consuming recommended intakes of sodium. One comment indicated that the sodium intakes in these studies were very low and that the observed effects could have been due to dehydration. Other comments disagreed. One comment, accompanied by three studies, accused FDA of failure to give

the plasma lipid studies proper consideration.

In preparing its proposal, FDA reviewed the plasma lipid studies submitted. Sodium intake levels in these studies were very low (460 and 780 mg daily) relative to current U.S. intakes (approximately 3,000 to 6,000 mg daily) and dietary guidelines (2,400 mg daily). Also, the intervention periods were very short (one week or less). The agency encourages additional research, but disagrees that a few studies involving sodium intakes of 460 to 780 mg daily are relevant or raise safety concerns for the general public consuming well in excess of this amount or for public health agency recommendations encouraging moderate sodium intakes of 2,400 mg per day.

8. One comment included recent study data (Ref. 91), which the comment believed linked reduced sodium intake to high plasma renin levels and risk of myocardial infarction.

FDA reviewed the study data submitted and located a review article associated with the original study (Ref. 96). The incidence of myocardial infarction was low (27 instances in 1,717 subjects over 8.3 years) in a narrow and limited population group (predominantly nonwhite, hypertensive males with 20 percent excluded for renin levels outside the limits established for the study). Furthermore, sodium intakes per se were not evaluated in relationship to potential risk. It is unclear whether there is a causal relationship or whether renin levels simply serve as a marker for high risk. It is clearly premature to extrapolate the results of one study with a variety of limitations to the effects that a modest reduction in dietary sodium may have on the general population.

9. One comment mentioned that sodium restriction might precipitate sodium depletion in people with "wasting" nephropathy or chronic renal failure, but that it might also ameliorate their hypertension. The comment noted further that, at this time, there is not enough information to know what might occur and that patients with these diseases need specific advice from their physicians.

FDA agrees that there is not enough information to know if sodium restriction to 2,400 mg would pose any concern or be of any benefit with regard to "wasting" nephropathy or chronic renal failure. These are serious diseases and persons with these conditions should be under a physician's supervision and monitoring. Should these persons need to be concerned about their sodium intake, mandatory nutrition labeling of sodium content on all foods can help them meet specific dietary goals set by their physicians and health care consultants.

10. A couple of comments expressed concern that, in consuming low sodium foods, individuals might be missing important nutrients.

FDA disagrees. Many nutrient-rich foods are relatively low in sodium and will qualify for sodium/hypertension health claims (e.g., fruits, vegetables, and some dairy products). Additionally, substitute foods formulated to be low in sodium must be nutritionally equivalent to the foods that they are intended to replace (21 CFR 101.3(e)). Failure to maintain nutritional equivalency results in identification of the substitute food as an "imitation" product. With the mandatory labeling of a core set of nutrients, including sodium, for foods generally (see the final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**), people consuming low sodium foods as part of a total diet can select a variety of foods and meet nutrient needs.

11. One comment stated that FDA has determined that current U.S. intakes of sodium are not safe. The comment argued, therefore, that current levels are not generally recognized as safe (GRAS), that the food industry should bear the burden of proof that current levels are safe, and that, in the absence of such proof, FDA is obligated to require that salt levels be reduced and the food industry is obligated to lower the levels of salt currently being added to foods.

FDA disagrees. Salt has traditionally and historically been regarded as a GRAS substance (21 CFR 182.1), and the GRAS safety review in 1982 (47 FR 26590, June 18, 1982) deferred regulatory action until the impact of the sodium labeling initiatives (47 FR 26580, June 18, 1982; 49 FR 15510, April 18, 1984) could be assessed. The agency is not aware of any new data that would raise significant additional safety concerns. There is thus no basis for reopening the question of salt's GRAS status at this time.

III. Statement of the Relationship of Sodium and Hypertension

In the proposed rule (56 FR 60825), FDA tentatively concluded that, based on the totality of the scientific evidence, there is significant scientific agreement among qualified experts that there is a relationship between sodium intake and high blood pressure. Some comments agreed with this conclusion, often providing no evidence. A few comments disagreed and provided specific reasons for their objections.

12. Several comments supported FDA's conclusion that there is sufficient evidence of and significant agreement about a relationship between sodium and hypertension. The FASEB report (Ref. 138) concluded that "both observational data and intervention trials document a small, but consistent effect of dietary sodium chloride on blood pressure." The report further noted that the association between sodium intake and blood pressure may be more meaningfully extrapolated to a population than applied to an individual, that additional studies are necessary to assess the dose-response relationship, and that human data provide no evidence that blood pressure at one age is related to salt intake at an earlier age. A submitted study by Espinel (Ref. 143) identified specific patients and levels of salt intake that triggered hypertension. The results were repeated between 2 months and 1 1/2 years later and remained stable and reproducible.

A few comments and a review article (Ref. 144) disagreed and noted that the scientific data on sodium and hypertension are variable, complex, inconsistent, and more complicated than previously accepted. These comments argued that the epidemiological (i.e., observational) evidence is weak and that information from a natural setting where individuals select their own diets provides no information on how alterations would affect blood pressure. They also argued that modification studies have been short-term, that there are few long-term maintenance studies and data, and that the data are insufficient to support significant long-term effects, including long-term blood pressure changes and reduced rates of stroke and cardiovascular disease. These comments noted that, in contrast, clinical trials of lifesaving drugs often last several years. They suggested that FDA erroneously cited the INTERSALT study to establish that a lifetime lowering of sodium chloride would lower risk of hypertension, and that FDA should avoid giving prescriptive recommendations on weak observational data.

These comments argued further that there is significant controversy regarding the relationship between sodium and hypertension and, therefore, insufficient scientific agreement to support a health claim. The comments noted that the FASEB Report (Ref. 108) concluded that the within-population study data were inconclusive or showed low correlation, and that there was only sparse or inconclusive long-term information

about the relationship. They observed that no consensus was reached at the Workshop on Salt and Hypertension (Ref. 103), and noted that the Dietary Guidelines Advisory Committee (Ref. 135) reported that such a lack of consensus, especially relative to guidance for nonhypertensives, was apparent. (Other comments indicated that, even though consensus was not an aim of the workshop, a large degree of consensus was exhibited.) The comments observed that FDA acknowledged in its proposal the highly polarized views at the Hypertension Workshop (Ref. 103) and the controversy over the interpretation of the INTERSALT results (Ref. 37). The comments argued that the intense and continuing nature of the debate over the relationship between sodium and hypertension evidences lack of significant scientific agreement. The comments accused FDA of not attempting to understand the controversy and change its public health policies, but rather simply dismissing new studies and asserting that there is significant agreement among scientists.

FDA agrees with the FASEB report that there is a small but significant effect of sodium on blood pressure and with the Espinel study results demonstrating that sodium intake can trigger hypertension. This position is consistent with the tentative conclusions reached in the proposal. FDA noted in the proposed rule that the science is complicated by the multifactorial nature of the blood pressure response and that blood pressure varies for each individual and among different individuals. Nonetheless, in spite of large average fluctuations in confounding variables and the resultant impact on blood pressure response, there continues to be a small, significant, and independent impact of sodium on blood pressure, which is supported by the FASEB report (Ref. 138), the National Academy of Sciences' Report (Ref. 62), the Surgeon General's Report (Ref. 43), the INTERSALT study (Ref. 37), and other recent studies (Refs. 41, 44, 45, 55, 71, 76, 80, 90, 94, 97, 100, 106, 107, 109, 121, 122, and 123).

FDA recognizes that data from carefully controlled clinical trials are stronger than data from human observational studies. The methodologic problems in observational studies are more difficult to address adequately, and there are more individually negative observational studies than trials. Furthermore, pooling of studies is more difficult for observational studies, because of the need to control for confounding variables. Finally, most observational studies are cross-sectional, so they do not establish time-orders (i.e., cause precedes effect). However, despite these limitations, FDA contends that, in general, the human observational data support a relationship between sodium and hypertension. The recent, multinational INTERSALT study (Ref. 37) used carefully standardized methodologies and comprehensive data analysis. The study reported a significant relationship between sodium intake and systolic blood pressure (SBP) for the pooled within-center data and for changes in blood pressure with age for the across-center data. This conclusion is likewise supported by other authoritative reports (Refs. 43 and 62) and is consistent with and strengthened by the experimental evidence provided by randomized clinical trials.

FDA acknowledges that long-term, prospective study data are limited and sometimes inconclusive. However, obtaining definitive, long-term human data on the development of hypertension may be difficult due to a wide variety of factors: (1) the long time necessary for the development of the disease, (2) the large sample and control populations needed for statistical significance, (3) the small absolute magnitude of the effect of sodium on blood pressure, (4) the wide variations in salt content in foods and food products, (5) the large day-to-day and year-to-year variability in dietary sodium intake, (6) the large fluctuations in blood pressure response in the individual, (7) the multifactorial response of blood pressure to a wide variety of nutritional and environmental factors, and (8) the ethical considerations of encouraging or maintaining long-term, high-sodium diets in a control population. The feasibility of obtaining definitive study data was discussed in greater detail in the proposed rule on general requirements for health claims (56 FR 60537 at 60548 through 60549). Nonetheless, although three long-term intervention studies were inconclusive (Refs. 42, 70, and 124), the abstract (Ref. 123) and the recently reported final study results (Ref. 145) of the 18-month Trials of Hypertension Prevention (TOHP) Collaborative Research Group, which were published subsequent to the proposed regulation, reported conclusively that a reduction in sodium intake reduced blood pressure in the sodium intervention group and also showed a trend towards a reduced incidence of hypertension. The 18-month followup of the Koopman study (Ref. 76) also documented reduced blood pressure in response to reduced sodium intake. The results of these clinical trials are thus consistent with and strengthen the INTERSALT results (Ref. 37), which are cross-sectional. Additionally, the INTERSALT study provides useful information for making limited inferences on long-term effects of sodium reductions on blood pressure. The INTERSALT study reported a statistically significant relationship between sodium intake and the slope of SBP and diastolic blood pressure (DBP) with age; i.e., the difference in blood pressure of older individuals in a population relative to younger individuals in the same population is greater in populations with high sodium intake than in populations with low sodium intake. The lack of definitive long-term studies is, therefore, not sufficiently problematic to disallow sodium/hypertension health claims, given the strength of the short-term clinical data relating sodium intake and blood pressure, the difficulties associated with obtaining long-term sodium/hypertension data, and the long history of support by authoritative bodies for public health policies encouraging all people to reduce their sodium intake.

Finally, FDA recognizes that, as is typical in science, there is a wide range of opinion regarding the relationship between sodium and hypertension, and consensus is rarely reached. A requirement for "significant scientific agreement" has not been interpreted by FDA to mean a requirement for consensus. (See final rule on general requirements for health claims, published elsewhere in this issue of the **Federal Register**.) FDA believes that there is sufficient scientific evidence to provide strong support for a relationship between dietary sodium intake and high blood pressure, and that there is significant scientific agreement that the evidence supports the relationship. In the proposed rule, FDA summarized Government and authoritative reports that concluded that the evidence was sufficiently strong to support a relationship between salt or sodium and high blood pressure, and many of these reports recommended that sodium intake be decreased (Refs. 38, 43, 62, 63, and 85). The interim and final FASEB reports (Refs. 108 and 138) concluded that the totality of the data supports a relationship between dietary sodium chloride and blood pressure. The INTERSALT study (Ref. 37) reported evidence of a relationship between sodium and high blood pressure. Most authors supported the INTERSALT findings and favored sodium restriction

(Refs. 50, 52, 60, 69, 75, 111, and 114), whereas only a few authors considered the effect to be too small and opposed sodium restriction (Refs. 90 and 120). The other scientific studies evaluated in the proposed sodium/hypertension health claim regulation generally supported a relationship between sodium and high blood pressure, although a few were inconclusive or not supportive. Finally, most of the reports at the Hypertension Workshop (Ref. 103) supported reductions in dietary sodium intake (Refs. 94, 95, 97, 98, 102, 104, 105, and 113), while only a few were in opposition (Refs. 110 and 112). Vigorous, spirited debate is necessary to the scientific process and should be encouraged. However, despite the existence of differences of opinion, FDA concludes that, based on the totality of the scientific evidence, there is significant scientific agreement among qualified experts that diets high in sodium are associated with high blood pressure.

13. One comment questioned FDA's evaluation of the INTERSALT data (Ref. 37), indicating it was possibly serious abuse of the scientific data, including a possibly intentionally misleading interpretation. The comment stated that the INTERSALT authors, in their abstract, concluded both that there was no relationship between sodium intake in a society and the prevalence of hypertension within that society, and that there was a positive association between the level of sodium in a society's diet and the rate of rise in blood pressure with age. The comment argued that, if both statements are correct, then the societies with higher sodium intakes must have had lower blood pressures earlier in life, could not have had more hypertension even after 40 years, and must have had lower blood pressures from 20 to 60 years of age.

The FASEB report (Ref. 138) summarized the results of the INTERSALT study, noting that, after adjustments for age and gender, sodium was significantly correlated with SBP in 39 of the 52 centers and with DBP in 33 of the 52 centers, and that there was a significant linear relationship between average sodium excretion and the slope of SBP with age for all 52 centers, which remained significant when four populations with low salt intakes were excluded.

FDA disagrees with the comment criticizing FDA's evaluation of the INTERSALT study. The conclusions of both the FASEB report (Ref. 138) and the authors of the INTERSALT study are consistent with FDA's interpretation and not with those of the objecting comment. In the discussion, the INTERSALT study authors noted that some of the results across the centers were no longer statistically significant when the results from four centers with low sodium excretion were excluded. They attributed this to diminished statistical power due to an upper limit of sodium intake that was lower than anticipated, which resulted in a range of intakes too narrow to provide adequate detection sensitivity. They also noted that multiple confounding factors, such as climate, physical activity, and acculturation, would affect results across several centers but would be less likely to confound results within centers. The authors concluded by emphasizing that the data across the centers showed a significant positive association between sodium intake and the slope of increasing blood pressure with age for all 52 centers, which remained significant when the 4 populations with low salt intakes were excluded. These results are consistent with the findings within the centers. FDA believes that it has presented an accurate summary of the INTERSALT results that neither intentionally nor unintentionally misrepresented the authors' findings. FDA also believes that the INTERSALT study provides a useful piece of evidence for supporting the sodium/hypertension relationship that is consistent with and strengthens conclusions in recent consensus and authoritative reports (Refs. 43, 85, 62, and 63).

14. A couple of comments contended that, because there is controversy surrounding the interpretation of the INTERSALT data, FDA is legally and scientifically obligated to independently review the primary data tapes and to make the original data publicly available.

FDA disagrees and notes that it is not reviewing primary data for any of the studies it is evaluating. Rather, the agency reviewed and summarized publicly available scientific reports and publications of results from the INTERSALT study, including both significant and inconclusive findings (56 FR 60825 at 60829 through 60830). FDA considered all these results in determining whether the totality of scientific evidence supported a relationship between sodium and hypertension. This satisfied the agency's legal obligation to evaluate the publicly available scientific evidence and determine whether, based on the totality of that evidence, there is significant scientific agreement among qualified experts that a health claim for sodium and hypertension is supported. Since the primary data tapes from the INTERSALT study are not publicly available, the agency did not review that evidence. The agency does not have the authority to compel the release of these data.

15. One comment objected to the findings of the TOHP Collaborative Research Group study (Ref. 145) (see section VIII.A.5. of this document), which reported significant average decreases in blood pressure (1.7 millimeters of mercury (mm Hg) SBP; 0.9 mm Hg DBP) with average daily reductions in sodium of 55.19 millimoles (mmol) or 1,270 mg in 2,182 normotensives over an 18-month period. The comment suggested that the study methodology was flawed because the sodium reduction intervention group was compared with unmasked nonintervention controls, because the sodium reduction group was compared with a subset (417 subjects) of the "usual care" control group (589 subjects), and because the authors failed to explain the drop in blood pressure of the control group, which was two-thirds of the decrease noted in the sodium reduction intervention group.

FDA disagrees. As the authors noted, achieving sodium reduction via dietary changes requires active and conscious cooperation of the intervention participants in changing shopping, cooking, and food selection behaviors. Therefore, it would not have been feasible to blind the study participants to the dietary changes necessary to reduce sodium intake. In addition, it would have been impractical to follow free-living participants who are blinded to sodium intake for an 18-month period. Most importantly, the study included blinding at the critical point, blood pressure measurement, that is, trained, certified observers, who were blinded to the dietary sodium status of the participants, took the blood pressure measurements of participants at 3, 6 12, and 18 months. In addition, the success of the dietary sodium intervention and possible confounding factors were independently monitored at 6, 12, and 18 months by collecting 24-hour urine samples for sodium analysis, and weighing participants. With regard to the number included in the control group systematically and randomly assigned, the total cumulative number of controls was 589 generated as a result of conducting three separate intervention studies. Furthermore, as noted in Figure 1 in the article, the number of control subjects available for respective comparisons varied due to stratification by clinic and body mass index, and as noted on page 1,214 of the article, in clinics where both weight reduction and sodium reduction were

studied, a higher number of subjects were assigned to the control group to provide sufficient high-weight controls for comparison with the weight reduction intervention. Thus, it is inaccurate to conclude that 172 controls were excluded, since none of the three intervention groups had a control group of all 589 controls. Finally, although both the sodium reduction intervention and the control group experienced decreases in blood pressure, the sodium reduction intervention group's decrease in blood pressure relative to the control group was statistically significant. Furthermore, although the control group was not specifically instructed in ways of reducing sodium intake, the independent measures indicated that, at 18 months, the sodium intake of the control group had decreases by 11.33 mmol (260 mg) sodium as compared with 55.19 mmol (1,270 mg) in the sodium reduction intervention group. This reduction in sodium could account for some of the decrease in blood pressure observed in the control group. In conclusion, the epidemiologic study design was rigorous. The study results provide important insight into the relationship between sodium intake and blood pressure in a normotensive population and also into the long-term impact of sodium reduction on both blood pressure and the development of hypertension over time.

16. One comment objected to FDA's definition of normotension, SBP below 140 mm Hg and DBP below 90 mm Hg, arguing that this implies that blood pressures below 90 mm Hg are without risk. The comment noted that those with DBP between 80 and 90 mm Hg account for one third of cardiovascular disease response. The comment suggested that labels state that blood pressure should ideally be no more than 120 mm Hg SBP and 80 mm Hg DBP.

FDA disagrees. In the proposed rule, the agency acknowledged that the definitions of hypertension and normotension are based on correlations with risk of heart disease and stroke, differ by organization and purpose (Refs. 4, 17, 27, and 38), and are currently under review by the Joint National Committee of the National Heart, Lung, and Blood Institute at the National Institutes of Health. The definitions were changed in 1984 (Ref. 23) based on Public Health Service recognition that there is substantial risk associated with blood pressure levels between 140 and 160 mm Hg SBP and between 90 and 95 mm Hg DBP. These definitions will continue to be monitored; however, it would be very confusing to consumers if various government agencies used different definitions of hypertension and normotension. Consequently, FDA adopted the current Public Health Service definitions.

IV. Statement of the Significance of the Sodium and Hypertension Relationship

17. A few comments argued that the general population should be considered to be the general normotensive population, and that studies on hypertensives would, therefore, not be relevant. The comments suggested also that the data on normotensives are sparse, heterogeneous, and short-term, and that there is no clear, persuasive scientific evidence that healthy people in the general population would benefit from sodium reduction or that sodium increases the risk of hypertension in the general population. The comments concluded that the data do not support a recommendation that 200 million normotensives should reduce their daily sodium intake by half.

FDA disagrees with this assessment. Under new § 101.14(b)(1), set out in the final rule on general requirements for health claims, published elsewhere in this issue of the **Federal Register**, to qualify for a health claim a "substance must be associated with a disease or health-related condition for which the general U.S. population, or an identified U.S. population subgroup (e.g., the elderly) is at risk." The general population is at risk for hypertension, and sodium consumption is associated with hypertension. One third of the adult, U.S. population is hypertensive (Ref. 85) and many of these are expected to benefit from sodium reduction. Furthermore, many normotensives are likely to benefit as well, because even in the range of normal blood pressures, mortality risk from stroke and heart disease decreases as blood pressures drop (Refs. 68, 69, and 114).

18. One comment opposed the sodium/hypertension claim, arguing that high blood pressure affects a large segment of the population, but that only a minority are salt sensitive and that this fact should be stated if claims are permitted. Other comments argued that there is wide variation among individuals in salt sensitivity, that many patients are not responsive to sodium, and that health claims should not be allowed because only 12.5 percent of the population, the salt-sensitive hypertensives, would benefit. Another comment said that sodium restriction would benefit a large portion of the population, 20 to 40 percent, and one comment argued that FDA should change its statement to indicate that "many" people, rather than "some," would be likely to benefit. One submitted study (Ref. 143) reported that 13 of 30 well-established hypertensive patients (DBP greater than 90 mm Hg) could control their blood pressure (DBP below 90 mm Hg) on a low salt diet (2 g salt or 780 mg sodium per day). The blood pressures of the remaining patients were reduced as well (SBP: from 173.3 to 164.1 mm Hg; DBP: 102.9 to 98.2 mm Hg) but not enough to return to normotensive levels. The FASEB report (Ref. 138) noted that, "[al]though it is clear that there is a marked heterogeneity of blood pressure responses to alterations of dietary NaCl in both the experimental animal and in man, currently, there is not a uniform definition of salt sensitivity of blood pressure." The report concluded that, "until more information is available, caution is recommended before arbitrarily classifying individuals as NaCl sensitive or NaCl resistant."

FDA recognized in its proposed rule that not all persons may be sensitive to salt. However, all salt-sensitive individuals, those with high blood pressures as well as those with normal blood pressures, are likely to benefit from sodium reductions, since mortality risk from stroke and heart disease drops as blood pressures decrease. Even within the range of normal blood pressures, the lower the blood pressure, the lower the risk (Refs. 68, 69, and 114).

Recognizing that the response varies widely between individuals and that not all people are likely to benefit, FDA originally proposed that health claims indicate that a low sodium diet is associated with lower blood pressure in "some people" (proposed § 101.74(c)(2)). Upon reconsideration, the agency agrees with the comment that suggests that more than "some" individuals are likely to profit from reducing sodium intake. The word "some" may erroneously lead consumers to believe that only a small percentage of the population will benefit and may discourage many people from following this dietary goal. Some scientists have estimated that 30 to 60 percent of hypertensives and 15 to 45 percent of normotensives are salt sensitive (Ref. 116) and would thus benefit from sodium reduction. Taken together, this represents a significant segment of the U.S. adult population. FDA is persuaded that these numbers may not be accurately conveyed by noting that "some" people may benefit from sodium reduction. The agency has therefore dropped the use of the qualifier from the regulation. The agency believes that requiring the use of "may" or "might" (new

§ 101.74(c)(2)(i)(A)) to describe the relationship between sodium intake and blood pressure conveys the meaning that not all individuals respond to sodium restriction with lower blood pressure levels. The statement of the significance of sodium in relation to high blood pressure now includes the following sentences at new § 101.74(b)(1): "The scientific evidence indicates that reducing sodium intake lowers blood pressure and associated risks in many but not all hypertensive individuals. There is also evidence that reducing sodium intake lowers blood pressure and associated risks in many but not all normotensive individuals as well." Consistent with other health claim regulations, the final rule specifically permits the inclusion in a claim of information on the number of people in the United States who have high blood pressure.

19. A few comments contended that moderate reductions of less than 100 mmol sodium (2,300 mg) sodium would have limited impact. A couple of these comments noted that the relationship between sodium and hypertension in the INTERSALT study was significant when all 52 centers were included, but not when only 48 centers were considered. The comment considered the sodium intake range in the 48 centers to be comparable to sodium intakes of Western diets, and argued that since the results were not significant in this group, sodium intake changes in this range would not have any significant effect. A few comments also stated that no populations with free access to salt voluntarily choose such low levels. A few comments suggested that reducing sodium intake significantly was not feasible in Western populations. Others disagreed. One comment noted that the public health benefit could be substantial because food habits are linked to preventable diseases. Another comment extrapolated its clinical findings to the total population and estimated that FDA's reference value of 2,400 mg for sodium could result in cost savings of $2.1 billion per year by reducing costs of hypertension medications for patients who can control their blood pressure by diet alone. They further noted that additional cost savings could be expected through reductions in medication dosages, medication side effects, hospitalization, and costs associated with stroke, heart disease, and kidney disease.

FDA agrees with the comments that suggest sodium restriction will have a significant impact. Average estimates of the effect of a reduction in sodium intake of 100 mmol (2,300 mg) per day on SBP range from 2.2 mm Hg (Ref. 37) to 5 to 10 mm Hg (Ref. 106). Since these are population averages and therefore composite figures, the individual impact for many people will be greater than average. Furthermore, estimates suggest that over a 30-year age span (i.e., 25 to 55 years of age), this reduction of 100 mmol per day corresponds to a reduction in mortality rate of 16 percent for heart disease and 23 percent for stroke (Refs. 69 and 114). Other estimates indicate that a 1,150 mg daily change in sodium intake over a 10-year age span (i.e., 50 to 59 years of age) would result in a 26 percent reduction in stroke and a 15 percent reduction in heart disease in Western populations (Ref. 107).

FDA agrees that there is significant potential benefit if moderate sodium intakes in the U.S. population can be achieved and maintained. This is a feasible goal, because it has been estimated that 90 percent of dietary sodium is from salt added during food processing and manufacturing (75 percent) and during food preparation and consumption (15 percent). Thus, only 10 percent of sodium is naturally occurring in food. The agency notes that populations that voluntarily choose to consume high levels of sodium also have high prevalence of hypertension and greater increases of blood pressure with age. FDA continues to believe that encouraging reductions in sodium intake will benefit millions of Americans.

20. One comment objected to health claims listing ways of reducing sodium without noting that the majority (75 percent) is added to foods in processing, and the most effective strategy to reduce sodium intake is to avoid high-sodium, processed foods.

In the proposed rule, FDA included ways to reduce sodium intake as part of the significance statement, § 101.74(b): "In order to reduce sodium intake, individuals can choose foods with less sodium and salt, reduce the amount of sodium and salt used in food preparation and cooking, and reduce the amount of salt added at the table." This information has been deleted from the final rule in order to make it consistent with the final rules authorizing other health claims. However, the same information is included in "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 85). This information is truthful and correct, and manufacturers may provide this or similar information as long as it is presented in a truthful and nonmisleading manner. Furthermore, FDA agrees that most sodium is added in manufacturing and processing; however, the agency has restricted sodium/hypertension health claims to foods naturally low or processed to be low in sodium and salt.

V. Requirements

FDA received many comments about its proposed disqualifying criteria for sodium and hypertension health claims. Some of these comments supported and some opposed the concept of disqualifying criteria, the selected nutrients, the proposed levels, and the per 100-gram (g) criterion.

FDA has made several changes that affect disqualifying criteria, and these changes are discussed more fully in the final rules on general requirements for nutrient content claims, general requirements for health claims, Reference Daily Intakes (RDI's) and Daily Reference Values (DRV's), and serving sizes, which are published elsewhere in this issue of the **Federal Register**. FDA has retained sodium, fat, saturated fat, and cholesterol as disqualifying and disclosure nutrients, but the levels have changed due to changes in serving sizes, in the caloric basis for DV's (from 2,360 to 2,000 kilocalories), in the cutoff percentage for disqualifying nutrients (from 15 percent to 20 percent of the DV), and in the density criteria for disqualifying nutrients (from per 100 g to per 50 g for foods with reference amounts of 30 g or less or two tablespoons or less). As discussed below, these changes have resulted in additional foods qualifying for sodium/hypertension health claims.

The requirement that foods meet the "low sodium" content claim requirements was inadvertently removed from the proposed regulation and a notice to that effect appeared in Corrections to Proposed Regulations (57 FR 8180, March 6, 1992). It has been added to the final rule as new § 101.74(c)(2)(ii).

21. Several comments supported FDA's requirement that, in order to qualify for sodium/hypertension health claims, foods must meet the qualifying criterion for "low sodium" foods. Comments also favored allowing health claims only on foods that make a nutritional contribution to the diet. One comment supported requiring foods to meet the "very low sodium" (35 mg sodium) rather than the "low sodium" (140 mg sodium) criterion before being allowed to bear sodium/hypertension health claims. It argued that this would be consistent with prior FDA practices and with scientific evidence that only primitive societies with sodium intake levels at or below this level can avoid developing hypertension. The comment further argued that the only appropriate

target population for sodium/hypertension health claims is individuals on medically restricted diets, that the medical evidence suggests that only salt-sensitive hypertensives would benefit from sodium restriction, and that the INTERSALT (Ref. 37) data showed no effect for diets between 2,300 mg and 4,600 mg sodium per day. The comment concluded that 15 to 26 servings of "very low sodium" foods would provide a daily intake of only 525 to 910 mg sodium, and that this intake level corresponds to the intakes of low sodium populations that had little or no hypertension, and would, therefore, be low enough to have an impact on blood pressure.

FDA disagrees with these comments and contends that restricting sodium/hypertension health claims to "low sodium" foods is consistent with prior agency initiatives that emphasized developing and maintaining policies appropriate for the general public (47 FR 26580, June 18, 1982; and 49 FR 15510, April 18, 1984). The agency does not agree that the only appropriate target population is individuals on medically restricted diets. Furthermore, as discussed in comments 17 and 18 of this document, FDA disagrees that only hypertensives would benefit from reduced sodium intakes. Estimates suggest that 15 to 45 percent of normotensives are likely to benefit from salt (sodium) reduction (Ref. 116). Even within "normal ranges," lower blood pressures are generally associated with reduced mortality risk for the normotensive population as well as for the hypertensive population (Refs. 68, 69, and 114). In addition, 15 to 26 servings of "low sodium" foods would provide from 2,100 to 3,640 mg sodium per day. This is consistent with the DV for sodium of 2,400 mg, published elsewhere in this issue of the **Federal Register**. This is also consistent with FDA's policy that health claims are intended for the general population. Conversely, requiring foods bearing health claims to meet requirements for "very low sodium" could result in a sodium intake from 525 to 910 mg sodium per day, a value more appropriate for therapeutic diets than for diets for the general population. FDA is encouraging the entire population to moderate sodium intake, but the goal for the United States is not to try to reach the sodium intake levels of primitive societies. Although the INTERSALT data cited in the comment on the relationship between sodium and blood pressure were generally inconclusive when the four populations with the lowest sodium intakes were excluded, the data on the relationship between sodium intake and trends in blood pressure with age remained positive and significant.

The definition of "low sodium" requires that foods contain less than 140 mg sodium per reference amount and per 50 g for foods with reference amounts of 30 g or less or 2 tablespoons or less. The "per 50 g" criterion is a change from the proposed criterion of "per 100 g," and this change is discussed in further detail in the final rule on general requirements for nutrient content claims, which is published elsewhere in this issue of the **Federal Register**.

In the companion document on general requirements for health claims, FDA is also prohibiting claims on foods lacking naturally occurring nutrients (i.e., in order to bear health claims, foods must naturally contain a minimum of 10 percent of the RDI or DRV for one of six specified nutrients: Protein, fiber, vitamin A, vitamin C, calcium, and iron). The changes in the qualifying criteria for "low sodium," in the disqualifying levels for fat, saturated fat, and cholesterol, and in the restrictions to foods with naturally occurring nutrients have resulted in the qualification of some additional foods for sodium/hypertension health claims and the disqualification of foods lacking significant naturally occurring nutrients. Examples of foods that may bear sodium/hypertension claims include several additional fish and shellfish products, egg substitutes, and a few skim milk cheeses. Examples of foods that would have qualified for health claims under the proposed rules but no longer qualify include beverages such as carbonated soft drinks, coffees, and teas; most candies, cookies, baked goods, and icings; margarines and salad dressings; sweeteners; most jams and jellies; a few canned fruits; and a few canned and raw vegetables.

22. One comment argued that foods allowed to bear sodium/hypertension health claims should have a calorie restriction, since obesity is a risk factor for high blood pressure.

FDA disagrees. Sodium/hypertension health claims are intended for the general population and not merely for those who need to restrict their caloric intake. It would be a disservice to restrict health claims to low calorie foods, since many people who are at risk for high blood pressure and can benefit from consuming foods that are low in sodium may not need to consume foods low in calories. In addition, although everyone is encouraged to consume a diet low in sodium, individuals can select a variety of foods with different sodium and calorie contents to meet their dietary needs.

23. Some comments approved of the model health claim message. Others expressed concern that, by including too much information, claims would become overly burdensome and ineffective and would discourage manufacturers from using them and consumers from reading them. One comment suggested a simpler claim: "A low sodium diet can help to lower blood pressure in some people with high blood pressure."

FDA appreciates the concern about long and burdensome messages and has discussed this issue in the final rule on general requirements for health claims published elsewhere in this issue of the **Federal Register**. Upon reconsideration, the agency has made several changes that will simplify claims and limit the amount of required information, while assuring that claims are clear and nonmisleading to consumers. The proposed regulation would have imposed the following requirements on health claims: "The health claim states that a low sodium diet is associated with or related to lower blood pressure in some people. Alternatively, the health claim can state that a high sodium diet is associated with or related to higher blood pressure in some people" (proposed § 101.74(c)(2)); and "The health claim identifies the populations at greatest risk of developing high blood pressure as being the elderly and those with family histories of high blood pressure and states that other dietary risk factors associated with high blood pressure include alcohol consumption and excess weight" (proposed § 101.74(c)(3)).

These requirements have been simplified to require that claims use the words "may" or "might" (§ 101.74(c)(2)(i)(A)) (see comment 18 of this document); that the disease and nutrient terms be "high blood pressure" (§ 101.74(c)(2)(i)(B)), and "sodium" (§ 101.74(c)(2)(i)(C)), respectively (this is consistent with the proposed rule); and that claims not state any degree of risk reduction (§ 101.74(c)(2)(i)(D)) (see comment 26 of this document). The agency believes that simplifying the relationship statement will make the message shorter and easier for consumers to understand. In order to be consistent with other regulations, FDA has used wording associating diets low in sodium "to reduced risk of high blood pressure" rather than the wording suggested in the comment "to lower blood pressure." This phrasing more accurately captures the relationship

between sodium intake and high blood pressure than the proposal, which would have permitted claims to note the "association" or "relation" of sodium to blood pressure. In addition, as discussed in comment 18 of this document, the wording "in some people" has been deleted.

24. One comment opposed identifying specific risk populations in health claims and argued that other populations would assume they do not need to be concerned. Others argued that the inclusion of risk populations and dietary risk factors made claims too long and burdensome. Still others provided data on other dietary factors, such as the potassium, calcium, magnesium, or chloride ion content or the ratio of sodium to potassium (Refs. 15, 19, 21, 24, 26, 28, 32, 36, 39, 61, 65, 66, 67, 73, 77, 86, 88, 101, 110, and 115) or suggested that these other dietary factors should be discussed and acknowledged in health claims as dietary risk factors.

FDA recognizes that high blood pressure is a multifactorial disease and that research has indicated that other nutrients may be associated with high blood pressure. However, in the 1990 amendments, Congress directed the agency to evaluate, within a short period of time, the relationship between sodium and hypertension. Thus, FDA's present assessment of the scientific evidence is limited to this relationship. References in a sodium/hypertension health claim to other specified nutrients would constitute a health claim for these nutrients and would not be allowed unless authorized through the petition process set out in the final rule on general requirements for health claims, published elsewhere in this issue of the **Federal Register**.

FDA is concerned that allowing the unrestricted listing of risk factors for high blood pressure other than sodium intakes could result in risk factors of little relative importance or with minimal scientific support being included on labels. Depending on the context in which they are discussed, information on risk factors other than sodium can be misleading. However, the agency is also concerned that consumers could be misled into overemphasizing the impact of sodium on blood pressure or into believing that high blood pressure can be controlled by sodium restriction alone. Proposed § 101.74(c)(3) would have required health claims to include information identifying populations at greatest risk of developing hypertension and other risk factors associated with high blood pressure.

Upon reconsideration, FDA has chosen to limit the mandatory health claim requirement for sodium and hypertension to a short statement containing the minimum essential information and to allow additional information on an optional basis. Under the final regulation, claims must indicate that the development of high blood pressure depends on many factors. This requirement is intended to prevent consumers from being misled that sodium intake alone is connected with high blood pressure. However, in order to permit shorter claims, the final regulation dose not require that specific risk factors be identified. FDA has listed major risk factors for which there is general scientific agreement in § 101.74(d)(1). Under that section, a claim "may identify one or more of the following risk factors for development of high blood pressure in addition to dietary sodium consumption: family history of high blood pressure, growing older, alcohol consumption, and excess weight." FDA encourages manufactures to provide useful and accurate information on risk factors, but advises that, if specific information about disease risk is included in health claims, then the information must of course be presented in a truthful and nonmisleading manner.

VI. Optional Information

25. One comment supported encouraging 2,400 mg sodium as a maximum intake recommendation for the public at large, and another agreed that current intakes of sodium are well in excess of need and recommendations. Another comment strongly opposed including a statement that sodium intake should not exceed 2,400 mg, indicating that this value is a reference level, not a maximum intake level.

In response to comments urging the agency to shorten health claims and to provide more consistent regulations, FDA has decided to retain this information, but to move it to the significance statement. While most people should target their sodium intakes within the 500 to 2,400 mg range, a very few individuals may need more than the minimum because of excessive sweat losses, and some high calorie consumers may find 2,400 mg impossible to meet. Section 101.74(d)(2) will permit the inclusion of information from the significance statement in a health claim. Consequently, proposed § 101.74(d)(1) has been deleted, and the following sentence has been added to the significance statement in § 101.74(b)(4): "Sodium is an essential nutrient, and experts have recommended a safe minimum level of 500 mg sodium per day and a upper level of 2,400 mg sodium per day, the FDA Daily Value for sodium."

26. Comments from both health professionals and trade associations strongly supported requiring that sodium/hypertension health claims contain a statement that individuals with high blood pressure should consult their physicians for medical advice and treatment. There were no comments opposing this statement or requesting that it remain optional, as proposed, although some comments expressed general objections to the length of health claims.

In the proposal, FDA expressed concern that some people might attempt to use the ready availability of sodium labeling, and in particular sodium/hypertension health claims, to self-medicate or treat their hypertension without consulting a physician, especially since many people are aware of the dangers of hypertension (Ref. 56) and can easily learn their blood pressure levels by visiting a health professional or using "do it yourself" machines in grocery stores or shopping malls. Requiring the statement about physician consultations as part of the health claim might give consumers the erroneous impression that there is no benefit in making recommended dietary changes unless they have been identified as hypertensive. On the other hand, FDA remains concerned about hypertensives foregoing needed medical diagnosis and treatment. Specifically, definitions of hypertension or normotension in terms of blood pressure readings could encourage self-diagnosis, and information relating specific sodium intakes to specific reductions in blood pressure could encourage self-treatment. To decrease the likelihood of self-diagnosis or treatment based on health claims, in new § 101.74(c)(2)(i)(D) FDA has specifically prohibited claims from including any information on the degree of risk reduction for high blood pressure associated with sodium reduction. The agency has also has removed the following quantitative statements from the significance statement in new § 101.74(b):

> Estimates suggest that reducing sodium intake by 100 millimoles (mmol) per day (2,300 mg of sodium or approximately one rounded teaspoon of salt) would correspond to an average lowering of blood pressure of approximately 2.2 mm Hg systolic and 0.1 mm Hg diastolic. Because these are population-wide estimates, the magnitude of the effect for sensitive individuals would be greater. Estimates suggest that, for the age range from 25 to 55, a 100 mmol per day (2,300 milligrams (mg) per day) lower lifetime intake of sodium would correspond to a reduction in mortality rates of

approximately 16 percent for coronary heart disease and 23 percent for stroke.

FDA has decided to limit the information required in health claims to that which is essential. Therefore, the agency has retained the physician consultation statement as optional information, § 101.74(d)(7). However, should manufacturers choose to include information that could increase the likelihood of consumers self-diagnosing or self-treating their hypertension, that information must be presented in a clear and nonmisleading manner. For example, claims should not overemphasize the importance of sodium in reducing blood pressure. In addition, should manufacturers include specific information that would assist consumers in self-diagnosing their hypertension, such as definitions of either high or normal blood pressure, then the physician consultation statement would be mandatory, and this requirement has been included in new § 101.74(d)(7):

The claim may state that individuals with high blood pressure should consult their physicians for medical advice and treatment. If the claim defines high or normal blood pressure, then the health claim must state that individuals with high blood pressure should consult their physicians for medical advice and treatment.

Because high blood pressure is a serious disease that often has no outwardly observable symptoms, FDA encourages manufacturers to include a physician referral statement as a public service, and requires it when health claims include information that could encourage self-diagnosis or treatment.

27. The agency proposed to permit the optional use of the term "salt" in addition to the term "sodium" in health claims. However, because of recent studies, and the increasing body of evidence identifying sodium chloride rather than sodium alone as the active substance in affecting blood pressure, the agency specifically requested comments regarding the appropriateness of selecting sodium rather than sodium chloride as the specified nutrient and on allowing the term "salt" in addition to the term "sodium" in health claims. One comment objected to allowing the term "salt" in addition to the term "sodium," arguing that FDA policies have been based on sodium, that the 1990 amendments specify sodium, that it would be arbitrary and capricious to indicate sodium chloride without providing a scientific basis, that consumers would consider the two interchangeably, and that it would undermine previous education efforts. Other comments provided data on sodium salts other than sodium chloride and argued that the effect of sodium on blood pressure was due not to sodium alone but rather to sodium in combination with chloride. One comment noted that only studies involving sodium as the chloride salt have resulted in demonstrable increases in blood pressure. The comment urged the agency to permit salt/hypertension health claims and not sodium/hypertension health claims. The FASEB report (Ref. 138) concluded that "the impact of dietary sodium on blood pressure depends on the provision of sodium as the chloride."

After considering the comments and data submitted in response to the proposed rule, FDA has concluded that these issues are very complex. Salt or sodium chloride is the major source of sodium in foods, and over the years most of the studies investigating the effect of sodium on blood pressure have involved either increasing or decreasing sodium chloride intake (56 FR 60825, Table 2, Refs. 44, 45, 80, 109, 121, 122). Many dietary guidance discussions, policies, and recommendations refer to both sodium and salt (Refs. 43, 62, and 85), and the use of the term "salt" would make claims more understandable to many people. For these reasons, the agency has decided to make final its proposal to permit the optional use of the term "salt" in addition to "sodium."

FDA acknowledges that some studies and reviews indicate that sodium chloride and other sodium salts have distinct effects on blood pressure (Refs. 31, 43, 48, 79, 87, and 92). The agency recognizes that, if it is true that "salt" and not "sodium" is implicated in high blood pressure, products containing other sources of sodium may be incorrectly considered to promote high blood pressure. At present, however, there is not significant scientific agreement that only sodium chloride affects blood pressure, as evidenced by the fact that authoritative documents have not limited their recommendations to salt. Limiting health claims to "salt" would represent a significant policy change and would have implications for many other regulations. FDA has therefore concluded that a thorough review of all the data and an opportunity for public comment are required before such a shift. If concerned parties believe that, based on the totality of the publicly available scientific evidence, there is significant scientific agreement that sodium chloride, and not just sodium, is associated with high blood pressure, they should petition the agency for a change in the regulation.

28. No comments were received regarding FDA's tentative decision to allow the term "hypertension" in addition to the term "high blood pressure." Consequently, FDA has retained this provision in the optional information section of the regulation, although the numbering has changed from § 101.74(d)(4) to (d)(5).

29. Comments to the public docket on sodium and hypertension strongly supported Consumer Summaries. One comment recommended developing additional summaries to target specific audiences. A few comments suggested specific changes in the wording provided in the proposed rule. However, comments to the public docket for the general requirements for health claims generally opposed Consumer Summaries.

FDA acknowledges the interest expressed by comments in the consumer summaries. However, the agency has been persuaded by the comments received overall relative to health claims (See the general requirements for health claims final rule published elsewhere in this **Federal Register**). FDA notes that considerable educational efforts are planned and Consumer Summaries as part of the preamble and not in the codified language had limited utility.

VII. Model Health Claims

30. Several comments approved the model health claim for sodium and hypertension. Others objected to its length or to specific required information, and these comments have been addressed in comments 18, 23, 24, and 27 of this document. FDA has provided new model health claims to illustrate changes made in the proposed regulations.

VIII. Additional Scientific Data

To assure that significant new evidence had not become available subsequent to the proposal, FDA updated its review of the scientific evidence with human studies that were directly relevant to the proposed rule or became available after publication of its proposal (see Table).

A. Review of Scientific Studies and Data

1. Relationship of sodium intake to blood pressure

Pavek and Pavek (Ref. 146) conducted an intervention study in 35 mild, untreated hypertensives (15 males, 20 females) to determine the blood pressure sensitivity to 72-hour salt depletion achieved through a low salt diet consisting of unprocessed rice, potatoes, fruits, vegetables, and 2 liters (L) of tap water. Oscillometric,

auscultatory, and ambulatory blood pressure measurements were taken, and sodium intake was determined by 24-hour urine collections. Average 24-hour urinary sodium decreased by 17.5 mmol (400 mg), and average body weight by 3.1 percent. Average SBP decreased significantly (Oscillometric: 147.3 to 134.8 mm Hg; Auscultatory: 148.0 to 134.4 mm Hg; and Ambulatory Oscillometric: 138.6 to 130.4 mm Hg). Average DBP changed little, and only oscillometric measurements were statistically significant. Determination of individual salt sensitivity varied greatly and depended on the type of blood pressure measurement considered.

Dustan and Kirk (Ref. 125) investigated the effect of sodium depletion (9 meq or 210 mg sodium diet) followed by sodium loading (9 meq or 210 mg sodium plus 3.88 meq or 90 mg sodium per kilogram (kg)) in 51 normotensive white (19 male, 32 female), 18 normotensive black (7 male, 16 female), and 21 hypertensive black (5 male, 16 female) patients and the effect of sodium loading followed by sodium depletion in 11 normotensive white (2 male, 9 female), 16 normotensive black (6 male, 10 female), and 19 hypertensive black (4 male, 15 female) patients. The order of sodium loading and depletion did not affect mean arterial pressure in normotensive white patients (blood pressure did not vary) or in hypertensive black patients (blood pressure rose during sodium loading and fell during sodium depletion). Mean arterial pressure in normotensive black patients did not vary when sodium depletion was followed by sodium loading, but when the order was reversed, mean arterial pressure fell during sodium depletion and rose during sodium loading.

A study by Elliott et al. (Ref. 126) analyzed data collected as part of a random sample of 58 subjects aged 40 or above (29 male, 29 female) from a North London population that included diabetics (6 subjects) and individuals taking antihypertensive medication (5 subjects) or diuretics (3 subjects). SBP was significantly and positively related to 24-hour urinary sodium excretion and remained significant after adjustment for age, sex, and body mass index. DBP was significantly related to 24-hour urinary sodium excretion; however, the significance was borderline after adjustment for age and sex and insignificant after additional adjustment for body mass index. The reliability of complete 24-hour urine collection was monitored by para-aminobenzoic acid, and the significance of the results was greater in the subgroup identified as having the most complete urine collections. The within-individual variation in sodium intake was estimated from data on 11 subjects who completed two 24-hour collections. A reduction of 50 mmol (1,150 mg) sodium was associated with lower SBP and DBP of 5.3 and 1.4 mm Hg, respectively.

Khaw and Barrett-Conner (Ref. 128) examined the relationship between blood pressure and sodium estimated from dietary recall data in upper middle class white Southern Californian subjects (584 men and 718 women). Age-adjusted SBP and DBP correlated significantly with dietary sodium intake in men but not in women and with the sodium/potassium ratio in both men and women. The relationship persisted over the entire range of blood pressures and dietary intakes. The authors concluded that the results support the hypothesis that dietary sodium and potassium are related to blood pressure within a population.

He et al. (Ref. 139) investigated the relationship of 4 dietary ions, including sodium, to blood pressure in 4 population groups of Southern Chinese men from the Sichuan Province: 119 Yi farmers from remote villages in the high mountains, 114 Yi farmers from lower elevation, mountainside villages, 89 Yi people who had migrated to the county seat, and 97 Han people who were native residents of the county seat. Dietary and urinary sodium were significantly and positively correlated with SBP and DBP, even after controlling for age, body mass index, heart rate, alcohol, and total energy intake. Analysis at the individual level confirmed these results.

Forte et al. (Ref. 132) studied the effect of a health education program on salt reduction and blood pressure response in two matched rural Portuguese communities (150 of approximately 800 subjects studied in each community) with initially high daily salt intakes (360 mmol or 8,300 mg sodium). The health education program in the intervention community emphasized adding less salt in the kitchen, eating less cod fish and fewer sausages, and adding less salt to home-baked bread. In addition, local bakers were asked to reduce the salt added to bread by 50 percent during the 2-year trial. Mean sodium intake fell in the intervention community (364 mmol or 8,370 mg to 202 mmol or 4,640 mg) and rose slightly in the control community (352 mmol or 8,100 mg to 371 mmol or 8,530 mg). In the intervention community, average blood pressure decreased (SBP: decrease of 3.6 mm Hg at one year and 5.0 mm Hg at 2 years, DBP: decrease of 5.0 mm Hg at 1 year and 5.1 mm Hg DBP at 2 years); however, in the control community, average SBP rose and DBP remained constant.

2. Risk factors for high blood pressure

Beretta-Piccoli (Ref. 134) studied total exchangeable sodium in 62 normotensive (SBP < 130 mm Hg, DBP < 90 mm Hg) Swiss males with and without a family history of hypertension (31 subjects each, matched by age, height, and weight) on a normal daily sodium intake (150 mmol or 3,400 mg) and, in a subgroup of 23 subjects (13 with and 10 without a family history of hypertension), Beretta-Piccoli studied the adaptation of exchangeable sodium to variations in dietary sodium intake (low urinary sodium of 17 mmol or 390 mg versus high urinary sodium of 270 mmol or 6,200 mg). In the first, matched study, blood pressures tended to be higher in the group with a family history of high blood pressure. In the second, subgroup study, blood pressures increased with sodium intake in all subjects, but the magnitude of increase was greater in subjects with a family history of hypertension (SBP: 119 to 126 mm Hg, DBP: 76 to 80 mm Hg) than in those without (SBP: 112 to 113 mm Hg, DBP: 69 to 71 mm Hg).

3. Hypertensives versus normotensives

In addition to the Dustan study (Ref. 125) considered above, two additional studies investigated differences in responses for hypertensives and normotensives. Gill et al. (Ref. 127) investigated various hormonal changes in response to various dietary sodium levels. The study classified 19 patients with normal renin idiopathic hypertension as salt-sensitive (mean arterial pressure increases of 8 to 14 percent) (8 patients) or salt-resistant (mean arterial pressure changes from −7 to +7 percent) (11 patients) as compared with 5 normotensive subjects (mean arterial pressure changes from −3 to +7 percent). Subjects were fed a constant isocaloric diet supplemented with sodium chloride to provide 3 dietary levels of sodium intake: 9 meq (200 mg), 109 meq (2,500 mg), and 249 meq (5,700 mg). Average mean arterial blood pressures on the low sodium relative to the high sodium diet changed from 79 to 83 mm Hg in the normotensive subjects, from 104 to 114 mm Hg in the salt-sensitive hypertensive patients, and remained balanced at 114 mm Hg in the salt-resistant hypertensive patients.

Weinberger and Fineberg (Ref. 141) conducted 3 studies in Indiana. The first investigated the reproducibility of determining salt-sensitivity in 28

normotensive (BP < 140/90) and hypertensive (antihypertension therapy or BP ≤ 140/90 on at least 3 occasions) subjects. Salt-sensitivity was defined in terms of response to sodium chloride infusion (change from 2 L of 0.9 percent sodium chloride to 10 mmol or 230 mg sodium per day) where mean arterial blood pressure responses of 10 mm Hg or greater, of 5 mm Hg or less, and of 6 to 10 mm Hg were classified as salt-sensitive, salt-resistant, and indeterminant, respectively. The authors reported that the majority (18 of 28) were consistent in their responses. The second study investigated the influence of age on blood pressure response to the salt-sensitivity procedure described above in 430 normotensive and 230 hypertensive subjects. Sodium sensitivity increased progressively with age in hypertensive subjects but not in normotensive subjects until they reached 60 years of age and older. The third study assessed changes in blood pressure over 10 or more years in subjects classified initially using the salt-sensitivity procedure described above: 13 hypertensives (10 salt-senstive, 3 salt-resistant) and 18 normotensives (6 salt-sensitive, 12 salt-resistant).

4. Salt sensitivity

In addition to the Gill study (Ref. 127) and the Weinberger study (Ref. 141) considered above, two other studies investigated the salt sensitivity issue. Sullivan et al. (Ref. 130) studied 65 borderline hypertensive (DBP generally below 90 mm Hg but greater than 90 mm Hg on at least 3 occasions) and 92 normotensive subjects to investigate different characteristics of sodium-sensitive and sodium-resistant individuals. Many parameters were studied while subjects followed their usual diets, 10 meq (230 mg) sodium/60 meq potassium diets, and 200 meq (4,600 mg) sodium per 60 meq potassium diets. Sodium sensitivity was defined as a 5 percent increase in blood pressure between the low sodium and the high sodium states; the prevalence of sodium sensitivity was higher in blacks (27 percent of normotensives and 50 percent of borderline hypertensives) than in whites (15 percent of normotensives and 29 percent of borderline hypertensives). Sodium depletion and repletion had a variable effect on blood pressure, and mean blood pressure rose 6.5 percent in those identified as sodium sensitive as compared with 0 percent in those identified as sodium resistant.

Espinel (Ref. 143) conducted a 3-phase dietary salt intervention trial to characterize the response of 30 well-established adult hypertensive patients (DBP greater than 90 mm Hg) to dietary salt. The unrestricted-salt phase certified the presence of hypertension and documented the customary salt intake. The restricted-salt phase (2 g salt) (<34 mmol salt or 780 mg sodium) identified 13 patients, who were considered salt-sensitive, who could control their DBP (below 90 mm Hg) on a salt-restricted diet containing less than 2 g salt per day (SBP: from 177.1 to 145.1 mm Hg; DBP: from 105.4 to 82.0 mm Hg). The blood pressures of the remaining patients were reduced as well (SBP: from 173.3 to 164.1 mm Hg; DBP: from 102.9 to 98.2 mm Hg) but not enough to return to normotensive levels. In the salt-step phase, salt was added to the diet established during the restricted-salt phase in a stepwise manner (increases of 1 g salt or 390 mg sodium; each step lasting at least 3 days) to determine the level of salt that triggered hypertension in individual patients. This level was termed the Salt Hypertension Threshold for that patient and in the 13 patients ranged from 3 to 16 g salt (1,200 to 6,200 mg sodium) per day. The test was repeated between 2 months and 1 1/2 years later and the results remained stable and reproducible.

5. Long-term effect

The results of an 18-month trial on normotensives, the TOHP Collaborative Research Group study abstract (Ref. 123) was included in the proposed regulation, and the final study results are summarized here (Ref. 145). The TOHP Collaborative Research Group study included 7 nonpharmacologic interventions, 3 life-style changes (weight reduction, sodium reduction, and stress management), and 4 nutritional supplements (calcium, magnesium, potassium, and fish oil) in 2,182 normotensive (DBP from 80 to 89 mm Hg) subjects (70 percent male). The sodium-reduction intervention emphasized shopping, cooking, and food selection behavior aimed at reducing sodium intake, and at 18 months had achieved average daily reductions of 55.19 mmol sodium (1,270 mg) as compared to 11.33 mmol sodium (260 mg) in the control group from initial baseline values of 154.6 mmol (3,550 mg) and 156.4 mmol (3,600 mg) in the two groups, respectively. Statistically significant average decreases in blood pressure were reported in the intervention group as compared with the control group for both DBP (decrease of 0.9 mm Hg) and SBP (decrease of 1.7 mm Hg).

Joosens and Kesteloot (Ref. 147) reanalyzed data from 3,328 subjects collected as part of 6 Belgian surveys conducted between 1967 and 1986. Six of the surveys included blood pressure data and five included 24-hour sodium excretion data. Between 1967 and 1986, the mean standardized sodium excretion decreased from 265 to 160 mmol in men (6,100 to 3,700 mg) and from 208 to 160 mmol in women (4,800 to 3,700 mg). Mean SBP decreased from 169 to 142 mm Hg in men and from 171 to 147 mm Hg in women. The prevalence of hypertension (SBP > 159 mm Hg) decreased from 51 to 21 percent in men and from 66 to 22 percent in women, and severe hypertension (SBP > 220 mm Hg) nearly disappeared. During the same period, body mass index increased 1.1 kg/m^2 in men and was unchanged in women. Since increased weight is associated with increases in blood pressure, the observed decreases in blood pressure could not be ascribed to changes in weight. The proportion of subjects receiving treatment for hypertension increased from 10 to 36 percent in men and from 18 to 41 percent in women. The increased treatment would account for some of the observed decreases in blood pressure, but the authors concluded that treatment alone could not account for all of the observed changes in blood pressure. The authors used the correlation between sodium intake and blood pressure from the INTERSALT study (Ref. 37) and the observed decrease in sodium intake in Belgium from 1967 to 1986 in order to estimate the expected corresponding decrease in SBP. Considered together, the increase in treatment and the decrease in sodium intake were considered sufficient to explain the observed decreases in blood pressure. Methodologies in the six studies were similar but not identical, adding to the uncertainties.

6. Sodium chloride versus other sodium salts

Shore et al. (Ref. 129) conducted a randomized, crossover study to investigate the blood pressure response of six hypertensives (DBP between 90 to 110 mm Hg) on low sodium diets of 10 mmol (230 mg) sodium and 80 mmol potassium with the addition of either sodium chloride (120 mmol or 2,760 mg total daily sodium) or sodium potassium (122 mmol or 2,800 mg total daily sodium). Urinary sodium excretion was similar during both periods. However, blood pressures increased when sodium chloride was added to the diet, but not when sodium phosphate was added.

7. Effect on medication requirements

Weinberger et al. (Ref. 131) investigated whether free-living

hypertensive patients could reduce their medication by individualized dietary counseling aimed at moderately reducing their dietary sodium intake. Only 98 of the original 114 individuals completed the study and maintained significant reductions in mean sodium intake for 30 weeks. Those who achieved the 80 mmol (1,800 mg) sodium goal were more likely to have a reduction in a number of medications than those not reaching the goal.

In an observer-blind, controlled trial, Little et al. (Ref. 140) compared the effect of a low sodium, low fat, high fiber diet against the individual components of the diet in reducing the amount of antihypertensive medication required by 196 patients with established hypertension. Medication reductions were 64 percent and significant on the combination diet, 45 percent and insignificant on the low sodium diet, and 33 percent on the control diet; 57.5 percent of patients on the combination diet stopped all medication as compared with 24 percent on the control diet.

8. Effect of sodium intake on medicated patients

Carney et al. (Ref. 136) used a randomized, double-blind, crossover study design to investigate the effect of 100 mmol (2,300 mg) of sodium chloride on blood pressure control in 11 patients with mild to moderate hypertension successfully treated with various hypotensive agents. No significant changes in supine or erect blood pressure were observed in these medicated patients.

9. Studies in children

An intervention study by Ellison et al. (Ref. 148) involved reducing the sodium intake of students by 15 to 20 percent through changes in food purchasing and preparation practices in two boarding high schools. Each school served alternately as the control or the intervention school for one school year. Early in the year, blood pressures increased above baseline; however, as the year progressed blood pressures in the intervention school dropped and remained below baseline. The average SBP and DBP, adjusted for sex and initial blood pressure, were reduced by 1.7 and 1.5 mm Hg, respectively, on the low sodium diet when measured from the beginning to the end of the school year. Changes in sodium intake were calculated from 24-hour food diaries completed periodically during the year, and no independent measurements were made to document changes in sodium intake.

A longitudinal study by Geleijnse et al. (Ref. 149) collected blood pressure and electrolyte data annually from 233 Netherlands children ranging in age from 5 to 17 years old (108 boys, 125 girls) for an average period of 7 years in order to investigate the association between sodium and potassium intake and the change in blood pressure over time. No significant association between sodium intake and the change in blood pressure over time was observed. Mean 24-hour sodium intakes were calculated values and were based on six timed, overnight urine collections.

Miller et al. (Ref. 150) conducted an intervention study in Indiana with 64 male and 84 female white, normotensive children to determine if modest dietary restriction in childhood results in heterogeneous changes in blood pressure response. Families received instruction to assist them in restricting their dietary sodium to 60 mmol (1,380 mg) per day. Average sodium decreased from 112.9 mmol (2,600 mg) to 53.4 mmol (1,230 mg) in boys and from 91.1 mmol (2,090 mg) to 41.1 mmol (940 mg) in girls. Changes in SBP were not significant for either boys or girls, but girls showed a decrease in DBP ($p<0.05$) and in mean arterial pressure.

Rocchini et al. (Ref. 133) studied blood pressure changes in 60 obese and 18 nonobese adolescents (10 to 16 years of age) on high salt diets (> 250 mmol or 5,700 mg sodium) per day and low salt diets (< 30 mmol or 700 mg sodium) per day with the caloric content held constant. In the obese adolescents, there was a statistically significant decrease in blood pressure on the low sodium diet (mean arterial pressure change from 92 to 80 mg Hg), but no significant change was observed in the nonobese adolescents (mean arterial pressure change from 76 to 77 mm Hg). The study was repeated on 51 of the obese adolescents after 20-week weight loss program. The 36 subjects who lost at least 1 kg of body weight (average weight loss 7.5 kg) had a reduced sensitivity of blood pressure to sodium (mean arterial pressure change from 82 to 81 mm Hg) as compared to the 15 subjects who lost less than 1 kg of body weight (mean arterial pressure change from 89 to 79 mm Hg).

B. Conclusions from Scientific Studies and Data

In assessing the new scientific evidence, FDA has considered whether the evidence significantly challenges any of its tentative conclusions presented in the proposed rule.

The agency has determined that, although one study was inconclusive (Ref. 125), the scientific evidence continues to support a relationship between sodium and hypertension in adults (Refs. 123, 126, 127, 128, 132, 134, 139, 141, 146, and 147). In particular, the 3-year study on nonpharmacologic interventions (Ref. 145) strengthens previously limited evidence on the benefits of long-term sodium reduction in reducing blood pressure. In addition, the Espinel study (Ref. 143) demonstrates the wide variability in blood pressure response to sodium and the long-term individual reproducibility. The studies on children sometimes showed an effect (Ref. 148), sometimes showed no effect (Ref. 149), and sometimes showed an effect in certain population subgroups but not in others (Refs. 133 and 150). The one study involving a nonchloride sodium salt (Ref. 129) showed an effect for sodium chloride but not for sodium phosphate, which supports the contention that sodium chloride and not sodium per se is important in blood pressure response (see comment 27 of this document).

In conclusion, the new scientific evidence strengthens the conclusion reached in the proposed regulation that, based on the totality of the scientific evidence, there is significant scientific agreement that the evidence supports health claims that diets low in salt and sodium may help lower blood pressure in many people.

IX. Conclusions

FDA has responded to all comments received in response to the proposed sodium/hypertension health claim regulation. In addition, the agency has reviewed all additional scientific studies received in comments or independently identified and has determined that the new studies strengthen the conclusions reached in the proposed regulation. After considering the comments and the new scientific studies, the agency concludes that health claims for sodium and hypertension should be authorized.

The agency has decided that the regulations for the authorized health claims are most useful if they follow a consistent format and require only information that the agency considers essential. Therefore, the agency has made a number of editorial changes in the proposed codified material of the sodium and hypertension health claim to make it more consistent with other authorized claims.

X. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole,

would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

XI. Environmental Impact

The agency has determined that, under 21 CFR 25.24(a)(11), this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6, of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.74 is added to subpart E to read as follows:

§ 101.74 Health claims: sodium and hypertension.

(a) *Relationship between sodium and hypertension (high blood pressure).* (1) Hypertension, or high blood pressure, generally means a systolic blood pressure of greater than 140 millimeters of mercury (mm Hg) or a diastolic blood pressure of greater than 90 mm Hg. Normotension, or normal blood pressure, is a systolic blood pressure below 140 mm Hg and diastolic blood pressure below 90 mm Hg. Sodium is specified here as the chemical entity or electrolyte "sodium" and is distinguished from sodium chloride, or salt, which is 39 percent sodium by weight.

(2) The scientific evidence establishes that diets high in sodium are associated with a high prevalence of hypertension or high blood pressure and with increases in blood pressure with age, and that diets low in sodium are associated with a low prevalence of hypertension or high blood pressure and with a low or no increase of blood pressure with age.

(b) *Significance of sodium in relation to high blood pressure.* (1) High blood pressure is a public health concern primarily because it is a major risk factor for mortality from coronary heart disease and stroke. Early management of high blood pressure is a major public health goal that can assist in reducing mortality associated with coronary heart disease and stroke. There is a continuum of mortality risk that increases as blood pressures rise. Individuals with high blood pressure

are at greatest risk, and individuals with moderately high, high normal, and normal blood pressure are at steadily decreasing risk. The scientific evidence indicates that reducing sodium intake lowers blood pressure and associated risks in many but not all hypertensive individuals. There is also evidence that reducing sodium intake lowers blood pressure and associated risks in many but not all normotensive individuals as well.

(2) The populations at greatest risk for high blood pressure, and those most likely to benefit from sodium reduction, include those with family histories of high blood pressure, the elderly, males because they develop hypertension earlier in life than females, and black males and females. Although some population groups are at greater risk than others, high blood-pressure is a disease of public health concern for all population groups. Sodium intake, alcohol consumption, and obesity are identified risk factors for high blood pressure.

(3) Sodium intakes exceed recommended levels in almost every group in the United States. One of the major public health recommendations relative to high blood pressure is to decrease consumption of salt. On a population-wide basis, reducing the average sodium intake would have a small but significant effect on reducing the average blood pressure, and, consequently, reducing mortality from cardiovascular disease and stroke.

(4) Sodium is an essential nutrient, and experts have recommended a safe minimum level of 500 milligrams (mg) sodium per day and an upper level of 2,400 mg sodium per day, the FDA Daily Value for sodium.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met.

(2) Specific requirements. (i) *Nature of the claim.* A health claim associating diets low in sodium with reduced risk of high blood pressure may be made on the label or labeling of a food described in paragraph (c)(2)(ii) of this section, provided that:

(A) The claim states that diets low in sodium "may" or "might" reduce the risk of high blood pressure;

(B) In specifying the disease, the claim uses the term "high blood pressure";

(C) In specifying the nutrient, the claim uses the term "sodium";

(D) The claim does not attribute any degree of reduction in risk of high blood pressure to diets low in sodium; and

(E) The claim indicates that development of high blood pressure depends on many factors.

(ii) *Nature of the food.* The food shall meet all of the nutrient content requirements of § 101.61 for a "low sodium" food.

(d) *Optional information.* (1) The claim may identify one or more of the following risk factors for development of high blood pressure in addition to dietary sodium consumption: Family history of high blood pressure, growing older, alcohol consumption, and excess weight.

(2) The claim may include information from paragraphs (a) and (b) of this section, which summarizes the relationship between dietary sodium and high blood pressure and the significance of the relationship.

(3) The claim may include information on the number of people in the United States who have high blood pressure. The sources of this information must be identified, and it must be current information from the National Center for Health Statistics, the National Institutes of Health, or "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Health and Human Services (DHHS) and U.S. Department of Argiculture (USDA), Government Printing Office.

(4) The claim may indicate that it is consistent with "Nutrition and Your Health: U.S. Dietary Guidelines for Americans, DHHS and USDA, Government Printing Office.

(5) In specifying the nutrient, the claim may include the term "salt" in addition to the term "sodium."

(6) In specifying the disease, the claim may include the term "hypertension" in addition to the term "high blood pressure."

(7) The claim may state that individuals with high blood pressure should consult their physicians for medical advice and treatment. If the claim defines high or normal blood pressure, then the health claim must state that individuals with high blood pressure should consult their physicians for medical advice and treatment.

(e) *Model health claims.* The following are model health claims that may be used in food labeling to describe the relationship between dietary sodium and high blood pressure:

(1) Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.

(2) Development of hypertension or high blood pressure depends on many factors. [This product] can be part of a low sodium, low salt diet that might reduce the risk of hypertension or high blood pressure.

Dated: December 17, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

Note: The following table will not appear in the annual Code of Federal Regulations.

BILLING CODE 4160-01-F

TABLE

Sodium/Hypertension

Study	Study Design	Subjects	Methods	Results	Comments
Beretta-Piccoli (1990) (Ref. 134)	Survey of exchangeable body sodium (Na) in normotensive men with and without a family history of hypertension Study done in Switzerland	62 healthy, normotensive males (SBP < 130 mm Hg, DBP < 90 mm Hg) (31 with a family history of hypertension, 31 without a family history of hypertension) Subjects matched by age, height, and weight Subgroup of 23 (13 with and 10 without a family history of hypertension)	Mean total exchangeable Na was measured by isotope dilution The study of exchangeable Na in the total group was carried out with subjects on a normal Na intake (150 mmol or 3,400 mg per day) The adaptation of exchangeable Na to variations in dietary Na intake, carried out in the study subgroup, involved taking measurements at the end of a 7-day low-salt phase (17 mmol or 390 mg per day) and of a 7-day high-salt phase (270 mmol or 6,200 mg per day)	Investigation of 62 subjects on normal Na intake: Blood pressure (BP) was higher in the group of normotensive men with a family history of hypertension ($p < 0.005$), but age, urinary Na excretion, plasma renin activity, and aldosterone levels or creatine clearance were comparable Exchangeable Na did not differ significantly between the two groups and was unrelated to arterial pressure or to plasma renin activity Investigation of subgroup of 23 subjects varying the Na intake: At the end of the low-Na phase, there was no significant difference in BP, heart rate, body weight, exchangeable Na, plasma Na and potassium, or creatinine clearance between subjects with and without a family history of hypertension The change from a low-Na diet to a high-Na diet resulted in significant and comparable rises in body weight and exchangeable Na in the two groups, comparable values for Na-dependent suppression of renin, angiotensin II, aldosterone, and plasma catecholamines, and no changes in heart rate, plasma Na and potassium, or creatine clearance Supine SBP and DBP increased with Na intake in all subjects but more in subjects with a family history of hypertension (SBP: from 119 to 126 mm Hg, DBP: from 76 to 80 mm Hg) as compared to those without a family history of hypertension (SBP: from 112 to 113 mm Hg, DBP: from 69 to 71 mm Hg)	Findings suggest that exchangeable body Na is normal and adapts normally to variations in dietary Na intake in normotensive subjects with familial predisposition to hypertension The authors concluded that exchangeable body Na depletion in early hypertension appears to be a secondary rather than a primary event

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Carney (1991) (Ref 136)	Randomized double-blind crossover study to evaluate the effect of additional sodium chloride (NaCl) compared with a placebo on BP control over a 6 week period before changing to the other trial arm for an additional 6 week period	11 patients with mild to moderate essential hypertension satisfactorily treated with diverse hypotensive agents (BP stable and well controlled for at least 6 months with no evidence of renal, cardiac, hepatic, or endocrine disease) (5 men, 6 women) Age range: 30 to 65 years	Patients were kept on normal diets and randomly assigned to 6 week periods of additional Na (100 mmol or 2,300 mg slow Na (10 NaCl tablets per day) or a placebo with a subsequent crossover Body weight, pulse, and supine and erect BP (mean of two readings) were measured at 1, 2, 4, and 6 weeks of each trial arm Blood collections and 24-hour urine collections were taken at study commencement, and 1, 6, 7, and 12 weeks	Tablet compliance was excellent There were no significant changes in mean supine or erect BP with increased NaCl in patients on various hypotensive drugs	Findings suggest that excess dietary Na does not jeopardize BP control in patients on various hypotensive drugs
Dustan (1988) (Ref. 125)	Intervention study to investigate the quantitative importance of Na balance to arterial pressure changes produced by changes in Na intake Conducted at the University of Alabama Hospital	Protocol 1: 51 normotensive white patients (19 males, 32 females) 18 normotensive black patients (7 males, 11 females) 21 hypertensive black patients (5 males, 16 females) Protocol 2: 11 normotensive white patients (2 males, 9 females) 16 normotensive black patients (6 males, 10 females) 19 hypertensive black patients (4 males, 15 females)	Protocol 1: A 3-day control period (150 meq or 3,400 mg Na intake per day) followed by 4 days of salt depletion (SD) (low-Na diet of 9 meq or 210 mg Na per day) and furosemide (1 mg/kg given on the first day) followed by 3 days of salt loadingPABA (SL) (low-Na diet continued plus 25 mL/kg of isotonic NaCl solution or 3.88 meq or 90 mg per kg per day) given intravenously Protocol 2: Same as Protocol 1 except the sequence of Na intake changes was reversed For both protocols, Na balance was calculated by subtracting urinary Na excretion from Na intake and expressed in meq per Kg, either positive or negative	Protocol 1: Mean arterial pressures of the two normotensive groups were comparable in the control period and varied little during SD and SL Mean arterial pressures of the hypertensive group fell during SD and returned toward control values during SL Na balance data were comparable for the three groups, except the hypertensives lost more Na during SD than the normotensives Protocol 2: Mean arterial pressures of the normotensive white group varied little during SD and SL Mean arterial pressures of both the normotensive and the hypertensive black groups fell during SD and rose during SL Na balance data were comparable for the two normotensive groups; the black hypertensives retained less Na during SL and did not lose more Na during SD than the normotensives Spearman correlation coefficients indicated that there was no significant relationship between arterial pressure changes and Na losses during SD or Na retention during SL in either protocol or any group	The authors noted that group averages obscured the heterogeneity of the BP responses Spearman correlations suggest that salt-sensitive (SS) hypertension results not from the magnitude of Na retention, but from the pressor mechanisms evoked

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Elliott (1988) (Ref. 126)	Data collected as part of a 1983 to 1984 survey in North London, England Random sample of survey population selected for study of Na versus BP	58 subjects (29 men, 29 women) Age: 40 years and above Age range: 41 to 87 years Mean age: 57.9 years Diabetics (6 subjects) and people taking antihypertensive medication (5 subjects) and diuretics (3 subjects) were included in the study	Na determined by 24-hour urinary Na excretion BP determined as the average of 2 measurements, 1 at each of 2 visits an average of 8 1/2 months apart	SBP significantly related to 24-hour Na excretion, and results remained significant after adjustment for age, sex, and body mass index DBP significantly related to 24-hour Na excretion, and results were borderline after adjustment for age and sex and not significant after adjustment for age, sex, and body mass index Para-aminobenzoic acid (PABA) was used to monitor reliability of complete 24-hour urine collection and the statistical significance was greater for the subgroup of "complete collectors" as monitored by PABA	Eleven subjects provided two 24-hour urine collections to estimate the within-individual variability Only 50% of subjects were classified as "complete collectors" by PABA excretion
Ellison (1989) (Ref. 148)	Nonrandomized, concurrently controlled, longitudinal study Application of intervention in two boarding high schools Each school served alternatively as the control or the intervention school for 1 school year	BP monitored among 341 subjects during control years and 309 subjects during intervention years	The Na intake of students was reduced by 15 to 20% through changes in food purchasing and preparation practices Students were not asked to change their usual eating habits Changes in Na intake were determined by 24-hour food diaries which the students completed periodically during the study BP determined weekly as the average of 2 of 3 measurements	Average SBP reduced by 1.7 mm Hg (95% confidence intervals (CI) = -0.6, -2.9, p=0.003) on low-Na diet Average DBP reduced by 1.5 mm Hg (95% CI = -0.6, -2.5, p=0.002) on low-Na diet Values were adjusted for gender and initial BP	There was no control for possible differences in exercise levels among students at two schools There was no independent measurement of urinary Na excretion from the beginning to the end of the year to document changes in Na intake BP increased above baseline early in the year and then fell and remained below baseline later in the year

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Espinel (1992) (Ref. 143)	Three-phase dietary salt intervention trial to characterize the response of hypertensive patients to dietary salt	30 well-established adult hypertensives (DBP > 90 mm Hg on 3 visits)	Salt-Step Test in three Phases (medications and substances that might alter BP or salt balance were discontinued during the three phases) Phase 1: Unrestricted-salt phase: No restrictions on salt intake to certify the presence of hypertension and to document customary salt intake Phase 2: Restricted-salt phase: Low salt diet (2 g salt per day, i.e. < 34 mmol or 780 mg Na per day) to identify SS patients who could maintain DBP < 90 mm Hg on 2 g salt per day Phase 3: Salt-step phase: Diet established in Phase 2 (2 g salt per day) continued and salt added stepwise (each step lasting at least 3 days) in 1 g increments (390 mg Na) to determine the level of salt that triggered hypertension in individual patients (Salt Hypertension Threshold)	The 13 patients classified as SS (DBP < 90 mm Hg on salt-restricted diet) experienced large BP decreases between Phases 1 and 2 (SBP: from 177.1 to 145.1 mm Hg; DBP: from 105.4 to 82.0 mm Hg) The Salt Hypertension Threshold for the 13 SS patients ranged from 3 to 16 g salt (1,200 to 6,200 mg Na) per day, and the results, which were repeated in 11 patients at intervals between 2 months and 1 1/2 years later, remained stable and reproducible (i.e., they agreed for each patient within 2 g salt or 780 mg Na per day) The remaining 17 patients experience smaller BP decreases between Phases 1 and 2 (SBP: from 173.3 to 164.1 mm Hg; DBP: from 102.9 to 98.2 mm Hg) Body weight decreased in all but 2 patients in the restricted-salt phase and increased in all patients until thresholds were reached	The independent contribution of weight changes was not evaluated, thus, it is not clear whether the observed BP changes are the result of lower salt intake, lower weight, or a combination of the two The author noted that the individuality of responses and the broad range of thresholds could explain why some patients respond to fixed salt dosages and others do not and concluded that the Salt-Step Test may be useful in providing specific, individualized guidelines for dietary salt restriction
Forte (1989) (Ref. 132)	Study to evaluate the effect of a health education program on salt reduction and BP in two matched rural communities in Portugal Initial salt intake was high (about 360 mmol or 8,300 mg Na per day) and 30% of individuals were hypertensive (DBP = or > 95 mm Hg)	2 villages, each with about 800 inhabitants A stratified random sample of 150 people was drawn from each village, comprised of 25 subjects of each gender in each of 3 age groups (15 to 34, 35 to 54, and 55 to 69 years)	In the intervention community there was a vigorous health education effort to reduce salt intake Duplicate BP readings were obtained from each individual at the beginning of the study, at 12 months, and at 24 months	In the intervention community, average SBP and DBP fell by 3.6 and 5.0 mm Hg, respectively, at 1 year and by 5.0 and 5.1 mm Hg, respectively, at 2 years In the control community, average SBP rose and DBP remained stable	The authors noted that the difference in trends between the two communities was highly significant and seemed to indicate that, at least in this high-intake population, a decrease in salt consumption seemed to have resulted in a sizeable decrease in average BP

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Study	Study Design	Subjects	Methods	Results	Comments
Geleijnse (1990) (Ref. 149)	Longitudinal study of a cohort of children in a suburban town in the Netherlands to assess the association between Na and potassium intake and BP	233 children (108 boys, 125 girls) Age range: 5 to 17 years at entry Randomly selected from participants in an epidemiological population survey for determining risk factors for cardiovascular disease Children with established hypertension were excluded	At least 6 yearly examinations were made during an average followup period of 7 years Mean 24-hour Na and potassium was calculated from 6 timed overnight urine samples during the year, and the sodium/potassium ratio was calculated BP was determined at each visit as the average of 2 readings Individual slopes of BP over time were calculated by linear regression analysis	No significant association was observed between Na excretion and the change in BP over time Figures were adjusted for gender, initial age, change in height, change in body weight, and potassium intake Boys mean 24-hour Na ranged from 61.5 to 251.5 mmol (1,400 to 5,800 mg) Girls mean 24-hour Na ranged from 68.5 to 215.3 mmol (1,600 to 4,900 mg) The mean yearly rise in SBP for the whole group was 1.95 mm Hg	Dietary potassium and the ratio of dietary Na to potassium were related to the rise in BP in children, and the authors concluded that these values may be important in the early pathogenesis of primary hypertension Higher potassium levels were associated with lower mean SBP slopes over time Higher sodium/potassium ratios were associated with greater changes in SBP
Gill (1988) (Ref. 127)	Intervention trial in which patients with normal renin, idiopathic hypertension were compared with normotensive subjects after consuming Na intakes of 9, 109, and 269 meq (200, 2,500, and 5,700 mg) per day for 7 days	19 patients with normal renin idiopathic hypertension (antihypertensive medications discontinued) (14 women, 18 men) (20 to 75 years of age) 5 normotensive subjects without a family history of hypertension (3 women, 2 men) (20 to 62 years of age)	All subjects housed on a metabolic unit and fed a constant isocaloric diet containing 9 meq (200 mg) Na Supplements of NaCl were given as follows: 100 meq (2,300 mg Na) per day for 7 days (normal Na intake of 109 meq or 2,500 mg Na); no supplement for 7 days (low Na intake of 9 meq or 200 mg Na); and 240 meq (5,500 mg) per day for 8 days (high Na intake of 269 meq or 5,700 mg Na)	Hypertensive subjects were classified as SS (mean arterial pressure increases of 8 to 14%) or salt-resistant (SR) (mean arterial pressure changes of -7 to +7%) as compared with normotensive subjects (mean arterial pressure changes of -3 to +7%) in response to changes in Na intake Mean BP on the low-Na relative to the high-Na diet increased in the SS hypertensive subjects (from 104 to 114 mm Hg), and the normotensive subjects (from 79 to 83 mm hg), and remained balanced in the SR hypertensive subjects (114 mm Hg) (due to classification scheme in which BP increases and decreases were set to be equal)	The authors noted that supernormal Na retention and a failure to suppress adrenergic activity may explain, in part, the phenomenon of salt sensitivity of BP in SS patients and may also be factors in the pathogenesis of hypertension in this subset of individuals

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
He (1991) (Ref. 139)	Study to investigate the relationship of Na, potassium, calcium, and magnesium to BP in 4 groups of Southern Chinese men with a wide range of electrolyte intakes Study conducted in Puge County, Sichuan Province, People's Republic of China	4 groups of men: 119 high-mountain Yi farmers, 114 mountainside Yi farmers, 89 Yi people who had migrated to the county seat, 97 Han people who were native residents of the county seat	Four electrolytes were measured in the diet, blood serum, and urine	Na excretion was 73.9 mmol (1,700 mg) per 24 hours in high-mountain Yi farmers, 117.9 mmol (2,700 mg) per 24 hours in mountainside Yi farmers, 159.4 mmol (3,700 mg) per 24 hours in Yi migrants, and 186.0 mmol (4,300 mg) per 24 hours in the Han people In ecological correlation analysis, dietary and urinary Na were significantly and positively correlated with both SBP and DBP, whereas serum Na showed no relationship to BP Analysis at the individual level confirmed the results seen at the ecological level These findings persisted after controlling for age, body mass indices, heart rate, alcohol, and total energy intake In multiple regression analysis, an increase in Na intake of 100 mmol (2,300 mg) per day corresponded to an increase of 2.3 mm Hg SBP and 1.8 mm Hg DBP	The authors noted that the results are consistent with the view that a diet low in Na may prevent the development of hypertension

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Joossens (1991) (Ref. 147)	SBP data from 6 Belgian surveys conducted between 1967 and 1986 were reanalyzed	3,328 subjects 1967 study: 510 subjects 1972 study: 366 survivors of 1967 study 1973 to 1977 study: 143 subjects 1980 to 1984 study: 1,803 subjects 1979 to 1986 study: 344 subjects 1986 study: 162 subjects Range of mean ages of 6 groups: 70 to 81 years	All Na determinations from 24-hour urine samples were performed using the same methods and in the same laboratory used in the INTERSALT study (Ref. 37) Data were analyzed by age groups and the age groups used were the same as those used in the INTERSALT study	Values are for the change between 1967 and 1986: The mean standardized 24-hour Na excretion decreased from 265 to 180 mmol (6,100 to 3,700 mg) in men and from 208 to 160 mmol (4,800 to 3,700 mg) in women Mean SBP decreased from 159 to 142 mm Hg in men and from 171 to 147 mm Hg in women The prevalence of hypertension (SBP above 159 mm Hg) decreased from 51% to 21% in men and 66% to 22% in women, and severe hypertension (SBP > 220 mm Hg) nearly disappeared The proportion of subjects receiving treatment for hypertension increased from 10% to 36% in men and from 18% to 41% in women SBP was significantly and independently related to Na excretion in the 1967 and 1972 studies	Methodologies were similar but not identical between the studies, and differences would increase variability Only SBP was considered because DBP decreases with age in the elderly During the same period, body mass index increased 1.1 kg/m^2 in men and remained unchanged in women, therefore decreases in BP cannot be ascribed to changes in body mass index Treatment for hypertension increased, and Na intake decreased The authors calculated that the increase in hypertension treatment and the decrease in Na intake, taken together, could account for the observed changes in SBP, but that neither factor alone was sufficient The authors concluded that the decrease in SBP in Belgium was influenced by the combined effects of more and better treatment for hypertension and a decrease in Na intake

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Rhaw (1988) (Ref. 128)	Cross-sectional examination of the relationship between dietary Na and potassium intake and BP estimated from 24-hour dietary recall among members of a defined geographical region in Southern California	584 men and 718 women Age: 30 to 79 years Geographically defined, upper middle class, white population	A 24-hour dietary recall was obtained by a certified dietician The raw 24-hour dietary recall data were coded for nutrient intake by the Nutrition Coordinating Center, University of Minnesota, using their 1983 computerized data base	Age-adjusted SBP and DBP correlated significantly with dietary Na intake in men, but not in women, and with the sodium/potassium ratio in both men and women The relationship was apparent over the whole range of BP and dietary intakes A marked age gradient was apparent in men; the regression slope for BP versus sodium/potassium ratio increasing with increasing age, suggesting increasing sensitivity to dietary sodium/potassium ratio with age Adjustments for intakes of other dietary variables; including calories, protein, carbohydrates, saturated fat, alcohol, calcium, and fiber; did not alter the relationship. Adjustments for body mass index reduced the strength of the association in women but not in men	The authors noted that the results support the hypothesis that Na and potassium are related to BP within a population
Little (1991) (Ref. 140)	Observer-blind, controlled trial studying the effect of a low-Na, low-fat, high-fiber diet in allowing a reduction of antihypertensive medication as compared with the effect produced by the individual components of this diet Study conducted in the United Kingdom	196 patients with established hypertension (DBP > 95 mm Hg on at least 3 occasions)	Patients were allocated to the following groups, keeping the observer blind to group allocation: Group A (control): no change in diet (n=41) Group B (high-fiber diet): 40 to 45 g soluble and insoluble fiber per day (n=42) Group C (low-Na diet): 40 to 50 mmol (920 to 1,150 mg) Na per day (n=30) Group D (low-fat diet): 23 to 25% calories as fat per day with no change to the P/S or M/S ratios (n=43) Group E (combination low-Na, low-fat, high-fiber diet) 40 to 45 g fiber, 40 to 50 mmol (920 to 1,150 mg) Na, 23 to 25% calories as fat per day (n=40)	In the control group, a 33% reduction in medication was possible, with 24% of patients off medication altogether The low-fat, high-fiber, and low-Na groups showed larger reductions in medication (38%, 47%, and 45%, respectively, but the results were not significant when compared with the control group The combination group had the largest medication reduction (64%) and the difference was highly significant when compared with the control group, and significantly more patients in this group stopped their medication altogether (57.5%) when compared with the control group	The authors noted that the findings are significant because negative side effects of drug treatment may be reduced by lowering drug doses and making corresponding changes in diet

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Miller (1988) (Ref. 150)	Intervention study to determine whether modest dietary Na restriction in childhood results in heterogeneous changes in BP response Study conducted in Indiana	149 healthy, normotensive children (64 boys, 85 girls)	Baseline BP and 24-hour urinary Na were determined prior to Na restriction to serve as control data Families received instructions designed to aid them in restricting their dietary Na intake to a goal of 60 mmol (1,380 mg) per day Families were encouraged to maintain their usual dietary practices so that other dietary constituents (i.e. potassium and calories) would not be altered Dietary restrictions lasted for 3 months	Na excretion was decreased during the study period in both boys (from 112.9 mmol or 2,600 mg to 53.5 mmol or 1,230 mg) and girls (from 91.1 mmol or 2,090 mg to 41.1 mmol or 940 mg) Changes in SBP were not significant in either sex but females showed a decrease ($p < 0.05$) in DBP and mean actual pressures Because BP in children is correlated with age and body size, multiple linear regression was used to adjust BP levels for age and weight, and these analyses yielded small but significant decreases in SBP, DBP, and arterial pressures	The authors noted that the results suggest that compliance with modest Na restriction does not consistently lower BP in normotensive children
Pavek (1990) (Ref. 146)	Intervention study Objective measures of BP sensitivity to a 72-hour salt depletion were evaluated Salt-sensitivity was defined as a decrease in DBP after salt depletion and was estimated by both 24-hour ambulatory and office BP measurements Study conducted in Sweden	35 mild hypertensives (15 men and 20 women) Mean age: 48 years Mean body mass index: 25.2 Active, working patients with mild, untreated hypertension were recruited from a screening of public health service employees The duration of known increase of BP was 7.3 years	Salt depletion started with a morning furosemide (60 mg) tablet and continued for 72 hours with a low-salt diet consisting of unprocessed rice, potatoes, fruits, vegetables, and about 2 L of tap water Na determined by 24-hour urine collection BP determined before and after salt depletion; 24-hour ambulatory BP was recorded 3 times per hour on the left arm using an oscillometric monitor; and 6 pairs of sitting auscultatory and oscillometric pressures were recorded in random order in the mornings, at the start, and at the end of the 24-hour BP recordings	Average 24-hour Na decreased by 17.5 mmol (400 mg) Average body weight decreased by 3.1% Average SBP decreased significantly using all 3 types of BP measurements Average DBP changed little, and a statistically significant decrease was observed only by the oscillometric method.	Study duration was short (72 hours) Individual estimates of salt-sensitivity varied widely and were dependent on the type of BP measurement employed

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Study	Study Design	Subjects	Methods	Results	Comments
Rocchini (1989) (Ref. 133)	Study to measure BP response in obese and nonobese adolescents after successive 2-week periods of a high-salt diet and a low-salt diet, and to compare results for a subset of the obese adolescents before and after a 20-week weight-loss program	60 obese adolescents (10 to 16 years old) (Mean age: 13 years) 18 nonobese adolescents (10 to 16 years old) (Mean age: 12.5 4 years)	Sensitivity to Na was evaluated by giving all subjects a high-salt diet (> 250 mmol or 5,700 mg Na per day) for two weeks, followed by a low-salt diet (< 30 mmol or 700 mg Na per day) for two weeks The low-salt diet was formulated to contain the same caloric intake as the high-salt diet To assess compliance with the diets, 24-hour food records were reviewed and 24-hour urine samples were collected on the day before the outpatient testing A subset of the obese adolescents (51 subjects) were also studied before and after a 20-week weight-loss program	When changed from the high-salt to the low-salt diet, the obese group had a significant decrease in mean arterial pressure (from 92 to 80 mm Hg) relative to insignificant change in the nonobese group (from 76 to 77 mm Hg)($p < 0.001$) After the weight-loss program, the 36 subjects who lost more than 1 kg of body weight (average weight loss 7.5 kg) had a reduced sensitivity of BP to Na	The authors noted that the results support the hypothesis that the BP of obese adolescents is sensitive to dietary Na intake, and that this sensitivity may be due to the combined effects of hyperinsulinemia, hyperaldosteronism, and increased activity of the sympathetic nervous system that are characteristic of obesity
Shore (1988) (Ref. 129)	Randomized, crossover study to investigate the effect of supplementing a low-Na diet with either NaCl or sodium phosphate Study conducted in the United Kingdom	6 hypertensive outpatients (DBP between 90 to 110) with no history of, and no clinical, or biochemical evidence of renal or heart disease Patients had either received no antihypertensive medication or such medication had been withdrawn for at least 2 weeks prior to the study Patients had DBP between 90 and 110 mm Hg when receiving no medication	A low-salt diet (10 mmol or 230 mg Na and 80 mmol potassium) was provided After 5 days on the low-salt diet, the diet was supplemented with Na for an additional period of 5 days, followed by another 5-day period of the low-salt diet alone, and a second supplementation period of 5 days The Na load was given as NaCl (daily Na intake 120 mmol or 2,760 mg) or as Na in the presence of other anions, mainly phosphate (daily Na intake 122 mmol or 2,800 mg) Three patients received NaCl supplementation first	With both Na salts, urinary Na excretion increased The calculated amount of Na retained was similar for both the NaCl and the sodium phosphate periods Increases in BP occurred with the addition of NaCl to the low-salt diet; however, no change in BP occurred with the addition of sodium phosphate	Differences in the distribution of the retained Na may have contributed to the BP responses The authors noted that these findings suggest that the anion may be important in the BP response to Na loading in patients with essential hypertension

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Study	Study Design	Subjects	Methods	Results	Comments
Sullivan (1988) (Ref. 130)	Dietary intervention study to identify normotensive and borderline hypertensive individuals whose BP rose in response to increased dietary Na, to determine the hemodynamic mechanism causing the increase in BP, to identify other characteristics of the Na-or salt-sensitive (SS) individual, and to determine if the Na-induced increases in BP persisted with time	65 borderline hypertensive subjects (DBP generally < 90 mm Hg, but > 90 mm Hg on at least 3 occasions) 92 normotensive subjects	Subjects were studied while following their usual diets followed by 4 days of a 10 meq (230 mg) Na and 60 meq potassium diet, and again after 2 days of their usual diets followed by 4 days of a 200 meq (4,600 mg) Na and 60 meq potassium diet After examining the distribution of responses, a 5% increase in BP from the 230 mg Na to the 4,600 mg Na state was selected as a measure of SS A subset of normotensive subjects, chosen from the Na-resistant normotensive subjects who agree to participate, followed a daily diet containing about 200 meq (4,600 mg) Na and were followed for 12 months	The prevalence of SS was higher in blacks than in whites and greater in hypertensives than in normotensives Mean BP rose on the high-salt diet as compared with the low-salt diet in the SS population (increase of 6.5%) as compared with the Na-resistant population (0%) BP was not found to rise during the long-term study because total peripheral resistance fell proportionately	The authors speculated that there may be a genetic basis for the response to Na, because the observed changes resembled those reported in the Dahl SS rat
Trials of Hypertension Prevention (TOHP) Collaborative Research Group (1992) (Ref. 123)	Randomized control, multicenter trials	2,182 normotensive (DBP: 80 to 89 mm Hg) subjects (70% men) Age: 30 to 54 years Average age: 43 years	Three life-style change groups (weight reduction, Na reduction, and stress management) were each compared with unmasked nonintervention controls over 18 months Four nutritional supplement groups (calcium, magnesium, potassium, and fish oil) were each compared singly, in double-blind fashion with placebo controls over 6 months The primary outcome measure was change in DBP from baseline to final followup, measured by blinded observers Secondary outcome measures were changes in SBP and intervention compliance measures Na reduction interventions focused on shopping, cooking, and food selection behaviors aimed at reducing intake of Na No recommendations regarding Na were given to weight reduction participants	In the Na-reduction and weight-reduction groups, both DBP and SBP were consistently reduced in the active intervention groups when compared to the controls In the Na-reduction group, the mean decrease in Na excretion was constant at about 55 to 60 mmol (1,300 to 1,400 mg) per 24 hours at 6, 12, and 18 months At the end of the study, the BP decreases in the Na-reduction group were 0.9 mm Hg DBP ($p<0.05$) and 1.7 mm Hg SBP ($p<0.01$), while in the weight reduction group, they were 2.3 mm Hg DBP and 2.9 mm Hg SBP ($p<0.01$ for both) Changes in BP for stress management were small and inconsistent in direction	Compliance with the three life-style interventions was satisfactory, both in terms of attendance at counseling sessions and in reaching specific goals The authors concluded that the magnitude of the BP reductions with changes in body weight and Na intake could have a substantial benefit in reducing the incidence of hypertension, and on cardiovascular morbidity and mortality

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TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Weinberger (1991) (Ref. 141)	Three studies to classify subjects as SS or SR, to evaluate the relationship of SS and SR to age, and the evaluate the changes in BP over time of individuals classified as SS or SR Used a Na and volume expansion and contraction protocol in making both cross-sectional and longitudinal observations Study conducted in Indiana	Study 1: 28 hypertensive (antihypertensive medication or BP > 140/90) and normotensive (BP < 140/90) subjects Study 2: 230 hypertensive and 430 normotensive subjects Study 3: 13 hypertensive (10 SS, 3 SR) and 18 normotensive (6 SS, 12 SR)	Rapid Na-sensitivity test described: Comparison of BP response after rapid increase in extracellular fluid volume and Na balance using an intravenous infusion of 2 L saline (0.9%) over 4 hours versus Na and volume depletion induced by intake of 10 mmol or 230 mg Na and furosemide over 1 day A SS response was defined as a decrease in mean arterial pressure of 10 mm Hg or greater, and a SR response was defined as a change in mean arterial pressure of 5 mm Hg or less Study 1: The BP response was studied twice within a 12-month period Study 2: The BP response was studied to evaluate the influence of age Study 3: BP changes over a period of 10 years or more were studied	Study 1: The BP response was reproducible in 28 individuals who were tested twice within a 12-month period ($r=.56$; $p < 0.002$) Study 2: Salt-sensitivity of BP increased significantly with increasing age in the entire population ($n=660$; $r= -0.38$; $p < 0.001$) and was more striking in hypertensive subjects in whom a progressive increase in SS with decades was seen than in the normotensives in whom SS was not seen until the sixth decade Study 3: SS subjects had a significantly greater increase in SBP and DBP over time than SR subjects	The authors noted that salt-sensitivity appears to be a reproducible phenomenon that is related to the age-associated increase in BP which is characteristic of industrialized societies The authors noted that salt-sensitivity can be shown to be a predictor of subsequent, age-related BP increase

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 101, 102, 130, 135, 136, 137, 139, 145, 146, 150, 152, 155, 156, 158, 160, 161, 163, 164, 166, 168, and 169

[Docket No. 90N-0361]

RIN 0905-AD08

Food Labeling; Declaration of Ingredients

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its food labeling regulations to make ingredient labeling more useful for consumers. The agency is also responding to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), which amended the Federal Food, Drug, and Cosmetic Act (the act) by requiring the listing of the common or usual names of: (1) All ingredients in standardized foods and (2) all color additives required to be certified by FDA.

In addition, this document will: (1) Permit inclusion of the food source in the names of the sweeteners defined by the food standards in §§ 168.110 and 168.111 (21 CFR 168.110 and 168.111) (i.e., "corn sugar anhydrous" and "corn sugar monohydrate" would be permitted in addition to names already provided for in § 168.110(b) ("dextrose anhydrous" or "anhydrous dextrose") and § 168.111(c) ("dextrose monohydrate" or "dextrose")); (2) require the declaration of all protein hydrolysates (hydrolyzed vegetable protein and others), including the identification of the food source, e.g., "hydrolyzed corn protein," in the list of ingredients; (3) require identification of a caseinate (e.g., sodium caseinate) as a milk derivative when used in foods that claim to be nondairy foods; (4) provide a uniform format for voluntary declaration of percentage ingredient information; (5) require label declaration of sulfiting agents that have a functional effect in a standardized food or that are present in a standardized food at a detectable level of 10 parts per million (ppm) or more; and (6) provide certain exemptions from the requirements for listing the specific common or usual names of preservative coatings on fresh fruits and vegetables. Elsewhere in this issue of the **Federal Register**, the agency is publishing a final rule under the provisions of section 701(e) of the act (21 U.S.C. 371(e)) to establish and amend the ingredient labeling requirements within the standards of identity for dairy products (parts 131, 133, and 135 (21 CFR parts 131, 133, and 135)) and maple sirup (syrup) (§ 168.140 (21 CFR 168.140)). Also in this issue of the **Federal Register**, the agency is publishing a proposed rule to: (1) Amend the ingredient labeling requirements within the standard of identity for canned tuna (§ 101.190); (2) amend the common or usual name regulations for protein hydrolysates (§ 102.22) to require the term "contains glutamate" as a part of the common or usual name of autolyzed yeast extracts and certain hydrolyzed proteins; and (3) amend the food labeling regulations in § 101.22 (21 CFR 101.22) to allow "and/or" labeling for the declaration of sweeteners in soft drinks.

DATES: The effective date of the provisions in this final rule for ingredient listing of standardized foods and declaration of certified color additives is May 8, 1993 (§ 101.4(a) and (b)(2)(i), § 101.22(k), and parts 130 through 169). The effective date of all other provisions in this regulation is May 8, 1994. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of a certain publication at 21 CFR 130.9, effective May 8, 1993.

FOR FURTHER INFORMATION CONTACT: Betty Campbell, Center for Food Safety and Applied Nutrition (HFS-155), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5229.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 21, 1991 (56 FR 28592), FDA published a proposed rule (hereinafter referred to as the June 21, 1991, proposal) to implement amended sections of the act in accordance with section 7 of the 1990 amendments (Pub. L. 101-535) to require the listing of the common or usual names of all ingredients in standardized foods and of all color additives required to be certified by FDA under section 706(c) of the act (21 U.S.C. 376(c)) that were used in the food.

In response to written and oral comments received on an advance notice of proposed rulemaking (ANPRM) published in the **Federal Register** of August 8, 1989 (54 FR 32610), FDA also proposed in the June 21, 1991, proposal to: (1) Require that when more than one sweetener is used in a product, all sweeteners be listed together in the ingredient list under the collective term "sweeteners"; (2) permit inclusion of the food source in the names of the sweeteners defined by the food standards in §§ 168.110 and 168.111; (3) require the declaration of protein hydrolysates used for flavor-related purposes, including the identification of the food source in the list of ingredients; (4) require identification of caseinate as a milk derivative when used in a food that claims to be a nondairy food; (5) require that label statements explain that the list of ingredients is arranged in descending order of predominance; (6) provide a uniform format for voluntary declaration of percentage ingredient information; and (7) permit certain exemptions from requirements for listing the specific common or usual names of preservative coatings on fresh fruits and vegetables.

FDA also reproposed labeling requirements for sulfiting agents in standardized foods that it had first proposed in the **Federal Register** of December 19, 1988 (53 FR 51062). In 1988, FDA proposed to require that any sulfiting agent (or combination of sulfiting agents) that is present in a standardized food and is functional and provided for in the standard of identity, or that is present in the finished food at a detectable level of 10 ppm or more, must be declared on the label of the food by its common or usual name. Under the proposal, label declaration of sulfites meeting these criteria would be required regardless of whether the sulfite is directly added or indirectly added to the food via one or more of the ingredients of the food. The preamble to the December 19, 1988, proposal was incorporated in the June 21, 1991, proposal. In this final rule, FDA is responding to the comments received on the proposal and on the reproposal.

The agency received over 700 letters about the June 21, 1991, proposal. Each letter contained one or more comments. The letters were from a wide range of sources, including consumers, consumer organizations, professional associations, State and local government agencies, industry, and industry trade associations. Many comments generally supported the proposal or various provisions of the proposal. Other comments addressed issues outside the scope of the proposal (e.g., nutrition labeling, State petitions for exemption from preemption) and will not be discussed here. Many of the comments suggested modifications, revisions, or revocations of various provisions of the proposal. A summary of the comments, the agency's responses to the comments,

and a complete discussion of the agency's conclusions with respect to ingredient labeling, follow.

II. Ingredients of Standardized Foods

Before the 1990 amendments were enacted, FDA had authority under section 403(g) of the act (21 U.S.C. 343(g)) to require the declaration of optional ingredients in standardized foods. The act did not make any provision, however, for the declaration of mandatory ingredients (21 U.S.C. 343(g) and (i)). In the absence of statutory authority, FDA could not require the complete listing of all ingredients in standardized foods. However, the 1990 amendments revised section 403(i) of the act to treat standardized foods like all other foods and require the listing of all ingredients.

In addition, section 8 of the 1990 amendments removed most rulemakings on food standards from the coverage of section 701(e) of the act. Thus, they are subject to section 701(a) of the act. Actions for the amendment or repeal of food standards for dairy products and maple sirup, however, remain subject to section 701(e) of the act, which prescribes formal rulemaking procedures for the issuance, amendment, or repeal of regulations. Under formal rulemaking procedures, there is an opportunity to object to a final rule and to request a public hearing based upon such objection. Such an opportunity is not provided as part of the notice-and-comment rulemaking procedures followed by the agency under section 701(a) of the act. The agency is publishing the regulations set forth below under section 701(a) of the act. Elsewhere in this issue of the **Federal Register**, the agency is amending the standards of identity for dairy products in parts 131, 133, and 135 and for maple sirup in § 168.140 under the formal rulemaking provisions of section 701(e) of the act.

A. General Labeling of Standardized Foods

To make its ingredient labeling regulations consistent with the 1990 revision of section 403(i) of the act that pertains to standardized foods, FDA proposed in the June 21, 1991, proposal, to add new § 130.3(e) (21 CFR 130.3(e)). The proposed paragraph specified that all mandatory and optional ingredients of standardized foods must appear on food labels in accordance with the requirements of part 101 (21 CFR part 101), except that where a definition and standard of identity contains a specific provision with respect to the declaration of optional ingredients, the optional ingredients may be declared in accordance with that provision. FDA also proposed to amend all the standards of identity to require that all ingredients be declared on the label in accordance with the applicable sections of part 101 and part 130 (21 CFR part 130).

1. International Implications

1. Two comments from foreign governments opposed the declaration of mandatory ingredients of standardized foods. These comments maintained that listing mandatory ingredients would place an undue burden on the manufacturer without a noticeable advantage to the consumer and would cause confusion among foreign manufacturers, because in most other countries, manufacturers are required only to provide optional ingredient labeling in standardized foods. These comments argued that this regulation would require foreign companies to use separate labels just for the U.S. market, consequently increasing costs and discouraging free trade. They further maintained that consumer education would be more beneficial than ingredient declaration because standardized foods are prepared according to regulations.

The agency advises that foreign companies that market their products in the United States will have to comply with this requirement. The agency does not have the authority to provide a general exemption from this statutory provision for foreign manufacturers. The 1990 amendments amended section 403(i) of the act to require that the labeling of products marketed in the United States declare all ingredients used to make a food including a standardized food. Congress adopted this amendment with full recognition that it would eliminate a significant exception to the mandatory ingredient labeling requirements in section 403 of the act. See 136 Congressional Record H5842 (July 30, 1990). Consequently, FDA finds that there is no basis to make any changes in the regulations that it proposed in response to these comments.

2. Declaration of Noncharacterizing Optional Ingredients

2. Some comments, objecting to the proposed revocation of § 101.6, requested that provisions in § 101.6(d) be retained. This provision exempts manufacturers who declare all of the ingredients in a standardized food in the ingredient list from declaring certain optional ingredients on the principal display panel or wherever the name of the standardized food appears on the label, as required by certain individual standards. These comments asserted that without this provision, a 1"double declaration" of certain optional ingredients would be required which would overemphasize the optional ingredients, overcrowd the label, and may be confusing and misleading to the consumer.

These comments also responded to the question raised in the June 21, 1991, proposal on the need for the requirement in some standards of identity that certain optional ingredients be declared in conjunction with the name of the food wherever it appears on the label (e.g., the principal display panel), and that the declaration be so conspicuous as to be easily seen under customary conditions of purchase. The comments recommended that declaration of these ingredients in this manner be voluntary because all ingredients will now be required to be declared on the information panel.

The agency agrees with the comments. In most cases, the declaration of certain optional ingredients in conjunction with the name would be duplicative and unnecessary now that the 1990 amendments require that all ingredients of standardized foods be declared in the ingredient list. It is not the agency's intent to require dual declaration of noncharacterizing optional ingredients. However, the agency notes that in some instances, the optional ingredients provided for in the individual standards of identity are characterizing in the food. In such instances, the optional ingredient must be declared in accordance with the provisions of the specific standard, as required by § 101.3(f) and new § 130.11.

With regard to retaining § 101.6, the agency recognizes that, in the absence of § 101.6, several of the standards of identity (e.g., Macaroni products (21 CFR 139.110)) would require that all optional ingredients in the food, whether characterizing or not, be declared wherever the name of the standardized food appears on the label. The agency considers such dual declaration of noncharacterizing optional ingredients in standardized foods to be unnecessary and inappropriate. Nonetheless, the agency finds that it is not appropriate simply to retain § 101.6(d).

Section 101.6(d) includes guidance on the voluntary listing of ingredients in standardized foods. Such guidance is no longer necessary under the new ingredient listing requirements. The agency finds that rather than retaining § 101.6(d), it is more appropriate to establish general provisions regarding label declaration of optional ingredients

of standardized foods in part 130, where the other general regulations for food standards are set forth.

Accordingly, the agency is revoking § 101.6 and establishing new § 130.11 to prescribe requirements for the declaration of characterizing ingredients and an exemption from such requirements for noncharacterizing ingredients. The requirements in new § 130.11 are intended to provide manufacturers the same options regarding declaration of noncharacterizing ingredients of standardized foods that were provided by § 101.6(d). The basic difference between new § 130.11 and § 101.6(d) is that the requirements in the latter section were based on voluntary declaration of all ingredients in standardized foods, whereas new § 130.11 reflects the requirements that all ingredients in standardized foods must be declared, as provided in the 1990 amendments.

The agency finds that the adoption of new § 130.11 in this final rule is a logical outgrowth of the proposal. The proposed revocation of § 101.6 created ambiguity between the agency's position not to require dual declaration of certain optional ingredients and the requirements of some of the existing standards of identity. Thus, the agency is adopting new § 130.11 to remove this ambiguity.

3. Ingredients of Standardized Juices

3. One comment requested that the agency provide an exemption under § 101.100(a)(3)(ii)(b) for naturally occurring constituents or components of fruit juice from ingredient declaration requirements. The comment expressed the opinion that substances that are ingredients of standardized foods, and thus subject to the new ingredient listing requirements, should be differentiated from those that, in the comment's view, are naturally occurring constituents of the raw food from which the standardized food is made and that, therefore, should not be subject to these requirements. The comment maintained that the distinction between "ingredients" and "constituents" is clearly recognized by the act, and that the distinction is made clearer in § 101.100(a)(3)(ii)(b), which provides for an exemption from ingredient declaration for processing aids that are "substances that are added to a food during processing, are converted into constituents normally present in the food, and do not significantly increase the amount of the constituents naturally found in the food."

The comment noted that several of the standards of identity for various forms of orange juice and grapefruit juice in part 146 (21 CFR part 146) require that all "optional ingredients" be listed on the label in the statement of ingredients. The comment further stated that each of the standards that refers to "optional ingredients" uses the term to apply to added ingredients such as sweeteners or concentrated juice products. The comment also noted that these standards provide for the removal, addition, and adjustment of certain naturally occurring constituents or components of the juice, such as the oil, pulp, and essence.

FDA does not agree with this interpretation of § 101.100(a)(3)(ii)(b). The exemption from ingredient declaration provided by § 101.100(a)(3)(ii)(b) pertains to "incidental additives," substances that are present in a food at insignificant levels and that do not have any technical or functional effect in that food. Oil, pulp, and essence are not incidental additives under this definition for the following reasons:

First, fruit oils, pulp, and essence are added to fruit juice products to accomplish specific technical functions in the manufactured juice products and are, therefore, not processing aids. These constituents are added to the juice to replace constituents or components (oil, pulp, and essence) of the juice that are intentionally or unavoidably removed during processing. Their addition enables manufacturers to adjust the organoleptic characteristics of the juice as needed because of natural variations in the fruit from which it is derived and to achieve uniform quality and organoleptic properties in the finished products from lot to lot and season to season (Ref. 44).

Secondly, the level of use of the added ingredients is not insignificant. For example, in the manufacture of frozen concentrated orange juice, most of the pulp of orange juice is removed to facilitate concentration. Pulp, obtained from oranges, is later added to the concentrate in amounts sufficient to yield levels in the finished product that are comparable to the pulp levels of the raw juice. Therefore, these ingredients cannot qualify as incidental additives or as processing aids under § 101.100(a)(3)(ii)(*b*).

However, FDA notes that when these naturally occurring constituents (oil, pulp, and essence) are removed from the juice for purposes of efficient processing, and these constituents, from the same types of fruit provided by the standard (including any limits on fruit species) are added to the juice later in the manufacturing process, there is no need to declare these constituents as "ingredients" under section 403(i)(2) of the act. The agency believes that this approach is reasonable because when the constituents of the juice are added to the juice, in the same proportions as in the original juice, the basic composition of the juice is not changed. Further, FDA believes that it may be misleading to consumers if these constituents are listed in the ingredient statement of the juice when their addition has not altered the basic composition of the juice. Consumers might be led to believe that the juice has been fabricated from the individual juice components, or that the juice contains substantially higher levels of these constituents than would be the case if the ingredients had not been added.

Thus, FDA advises that only if pulp, oil, or essence are added at levels significantly in excess of those found in the raw juice from which the juice is derived, or if they are obtained from an extraneous source, i.e., from sources other than the fruit from which the juice is obtained (e.g., produced synthetically or purchased through a flavor supplier for artificially adding flavor or texture to the juice), would they be ingredients subject to the ingredient labeling requirements for standardized foods, as set forth in part 130.

4. One comment expressed the opinion that orange juice from different species of orange should continue to be permitted to be declared as "orange juice" on the label. The comment noted that the standards of identity for pasteurized orange juice (§ 146.140), canned orange juice (§ 146.141), orange juice from concentrate (§ 146.145), and frozen concentrated orange juice (§ 146.146) provide that the finished juices are made from the juice of oranges of the species *Citrus sinensis*, with up to 10 percent of the juice from the species *C. reticulata* or hybrids thereof. Similarly, the comment noted, the standard of identity for grapefruit juice (§ 146.132) provides for juice from the species *C. paradisi Macfadyen*, with up to 10 percent of the juice coming from mature hybrids of grapefruit.

In this context, FDA notes that the standard for frozen concentrated orange juice (§ 146.146) also provides for the addition of up to 5 percent of the juice of mature oranges of the species *C. aurantium*. By cross-reference to this standard, the standards of identity for orange juice from concentrate (§ 146.145), reduced acid frozen concentrated orange juice (§ 146.148), concentrated orange juice for manufacturing (§ 146.151), and frozen concentrated orange juice with

preservative (§ 146.153) also provide for the juice of oranges of *C. aurantium*.

FDA agrees with the comment that juice from different species of orange (*C. sinensis*, *C. reticulata*, and *C. aurantium*) may be declared as a single food. The labeling regulations in part 101 (§ 101.4(a)) require that food ingredients be declared by their common or usual names. There is no requirement that the scientific species names be used on the food label.

In addition, FDA recognizes that the need to blend juices, as well as juice constituents, will vary depending on the quality of the oranges used and the desired characteristics of the finished juice product. For example, the juice of mandarin oranges (*C. reticulata*) or sour oranges (*C. aurantium*) may be blended with the juice of the sweet oranges (*C. sinensis*) to adjust the color or degree of sweetness to compensate for differences arising from seasonal variations or the lack of availability of specific varieties. Such variations in formulation of the processed orange juice products could require multiple labels for products with essentially the same composition and organoleptic properties. The agency believes that in such cases, requiring multiple labels for the same juice product is impractical and needlessly burdensome. FDA, therefore, is not requiring that the specific orange species or varietal names be listed in the ingredients statement of orange juice products when manufacturers comply with the limits on the species of orange specified in the standards of identity in part 146. FDA takes the same position for standardized grapefruit juice products.

4. Addition of Water to Tomato Concentrates

5. One comment opposed the current exemption in § 155.191(a)(3)(iv) (21 CFR 155.191(a)(3)(iv)) for label declaration of water added to adjust the tomato soluble solids content of tomato concentrates within the range of soluble solids levels permitted for these foods. The comment stated that some manufacturers make tomato concentrate with an approximate Brix value of 31° and, at a later date and typically in a geographically different location, add 2.5 to 3.5 parts water to 1 part tomato concentrate to make a tomato product with a significantly lower Brix value. Thus, the comment asserted that water added to tomato concentrates is an ingredient and should be required to be declared in the ingredient statement.

The intent of this exemption was to allow for the adjustment, within the range of concentrations for the particular finished tomato product being made, of the soluble solids content of the tomato concentrate products during the production of these tomato products from fresh tomatoes. For example, if the product being manufactured is tomato puree, and the resulting tomato concentrate has a soluble solids content in the range provided by the standard of identity for tomato puree, i.e., not less than 8 percent but less than 24 percent, manufacturers would be allowed to add water to the puree to adjust the tomato soluble solids content within the standardized range and not have to declare the added water. Similarly, manufacturers of tomato paste would be allowed to add water to a tomato concentrate containing more than 24 percent soluble solids without having to list the added water as an ingredient, as long as the finished tomato paste contained at least 24 percent soluble solids as required by the standard.

FDA provided the labeling exemption codified in § 155.191(a)(3)(iv) in response to an industry comment (49 FR 15071, April 17, 1984). The exemption was intended to eliminate confusion as to whether, for example, a manufacturer of a tomato puree of 12.0 percent soluble solids that is prepared from a tomato puree of 18 percent soluble solids would have to state "tomato concentrate and water" in the ingredients statement.

Differences in raw ingredients and difficulty in obtaining a precise endpoint during the evaporation process in manufacturing tomato concentrates justify addition of the water to adjust the soluble solids level. The addition of water enables manufacturers to obtain a uniform product concentration from batch to batch and facilitates production of products that are designed to meet specific needs and that fall within the ranges provided by the standard. Therefore, FDA has not deleted the current exemption in § 155.191(a)(3)(iv).

However, when tomato paste is converted to tomato puree, by the addition of water, the label of the puree, and of any food in which that puree is used, must show the ingredients used, namely, tomato paste and water (Refs. 45 and 46). This result is required by section 403(i)(2) of the act, which states that when a food is fabricated from two or more ingredients each such ingredient must be declared by its common or usual name, except that spices, flavorings, and color not required to be certified under section 706(c) of the act may be declared as such without naming each. In addition, it would be false and misleading to make a food (tomato puree) from two ingredients (water and tomato paste) and not disclose that fact on the label. It is true that both tomato paste and tomato puree are provided for in the general standard for tomato concentrates (§ 155.191). However, this fact does not mean that a manufacturer can transform one food with an established common or usual name into another without disclosing that fact on the label.

With regard to labeling standardized and nonstandardized tomato products made by diluting previously processed tomato concentrates with 2.5 to 3.5 parts of water, one comment contended that consumers and purchasers of these tomato products need a label statement on the principal display panel to disclose when that tomato product has been "made from concentrate" because consumers do not take time to read ingredient statements. The agency has also received several letters in support and in opposition to the position stated in this comment.

The intent of this rulemaking is to deal with ingredient issues, not how reconstituted products should be labeled. This issue was not raised in the proposal, nor can it be viewed as the logical outgrowth of any issues that were. Therefore, these comments are outside the scope of this rulemaking.

5. Optional Ingredients of Canned Tuna

6. One comment suggested that the optional ingredients listed in the standard of identity for canned tuna in § 161.190(a)(6) (21 CFR 161.190(a)(6)) need only be declared in the ingredient statement. The comment asserted that these optional ingredients are "minor" and "noncharacterizing." Therefore, the comment continued, the agency should not require that they be declared wherever the name of the standardized food appears on the label.

FDA disagrees that all of the optional ingredients listed in § 161.190(a)(6) are noncharacterizing in canned tuna. In many instances the optional ingredients, provided for in this paragraph on how the food may be flavored and seasoned, will in fact, be characterizing, depending upon the level and specific conditions of use of the ingredient in the food.

For example, added to canned tuna at low levels, lemon flavoring, one of the optional ingredients provided for in § 161.190(a)(6), would not impart any characteristic flavor of its own but would merely subtly alter the flavor profile of canned tuna. However, above a certain level, this ingredient would contribute a distinctive lemon flavor to the canned tuna.

In the former case, the agency requires that the optional ingredient be declared only in the ingredient statement as "natural flavor." Such ingredients need

not be declared in conjunction with the name of the standardized food on the label because they are not significant characterizing ingredients in the food (see § 130.11).

In the latter situation, because "lemon flavoring" would be a significant characterizing ingredient, it would need to be declared on the food label, in accordance with the provisions of § 101.3 and § 102.5(c) (21 CFR 102.5(c)), as a characterizing ingredient to distinguish lemon-flavored canned tuna from other types of canned tuna. Therefore, in this instance, in addition to the declaration of "flavoring" in the ingredient statement on the food label, the words "lemon flavored" or "with lemon flavoring" would need to appear in conjunction with the name of the standardized food as required by new § 130.11 and by new § 161.190(a)(8)(vi) and (a)(8)(viii).

When FDA proposed the revocation of § 101.6 in the June 21, 1991, proposal, the agency did not intend to alter its policy concerning the naming of canned tuna on the food label. As previously discussed, FDA is revoking § 101.6 and establishing new § 130.11 as a replacement for § 101.6(d). The latter action will correct the unanticipated effects that the revocation of § 101.6 would have had on the naming of canned tuna and other standardized foods. In accordance with new § 130.11, an optional ingredient listed in the standard of identity for canned tuna will have to be declared wherever the name of the food appears on the label only if the use of the optional ingredient in the food significantly distinguishes the food from the same standardized food that does not contain the optional ingredient as a significant characterizing ingredient.

7. One comment stated that vegetable broth used in canned tuna is a flavoring and falls under the definition of flavoring ingredients in § 101.22.

In claiming that vegetable broth is a flavoring, this comment is pointing to the fact that vegetable broth contains vegetable extractives that may provide flavor to the canned tuna. However, this effect may be outweighed by the flavor-enhancing effect that this ingredient may have in canned tuna. Flavor enhancers are used to supplement, enhance, or modify the original taste or aroma of a food without imparting a characteristic taste or aroma of their own (§ 170.3(o)(11) (21 CFR 170.3(o)(11)), while flavoring agents and adjuvants impart or help impart a taste or aroma in food (§ 170.3(o)(12)).

According to information available to FDA, vegetable broth used in canned tuna may serve to enhance the basic flavor of the tuna and to make it appear less bland when it is packed in water, as in dietetic packs where it supplements the flavor of the product, without imparting a flavor of its own (Refs. 47, 48, and 49). It also aids in suppressing the bitter flavors that may develop during the canning operation (Ref. 47). Because vegetable broth is not generally used at levels at which it would impart a characteristic flavor or aroma of its own to the tuna, FDA concludes that flavor-enhancement may be a significant function of vegetable broth in canned tuna.

Flavor enhancers are not exempt from the ingredient declaration requirement in section 403 of the act. Therefore, they must be listed by their common or usual names in the ingredient statement on the food label. Where vegetable broth functions to enhance the basic flavor of the tuna, it must be declared by its common or usual name in the ingredient statement of the food label, even though it may, at certain levels of use and depending on the flavoring potential of vegetable sources used in making the broth, also act as a flavoring in the food.

Where the effect of the addition of vegetable broth is such that it adds a characterizing flavor to the tuna, the standard of identity, in new § 161.190(a)(8)(vi) and (a)(8)(viii), requires that the term "seasoned with vegetable broth" appear in close proximity to the name of the standardized food wherever that name occurs on the principal display panel of the label. In this situation, the vegetable broth would be properly declared in the ingredient statement as "flavoring" provided that it does not serve a flavor enhancing function in the food. Where the vegetable broth serves both as a flavor enhancer and a flavor, it must be declared by it common or usual name in the ingredient statement, as well as in conjunction with the name of the food when it serves as a characterizing ingredient, in accordance with new § 161.190(a)(8)(vi) and (a)(8)(viii).

8. One comment stated that, traditionally, the individual vegetable extractives used in the preparation of vegetable broth have not been declared on the label of canned tuna. This comment interpreted the agency's implementation of the 1990 amendments to mean that FDA will require the listing of each vegetable that is in the vegetable broth in order of predominance parenthetically following the term "vegetable broth" in the ingredient statement on the label of canned tuna. The comment stated its opposition to this approach. In support of its position, the comment pointed out that this method of listing the ingredients comprising vegetable broth in canned tuna would "intensify label crowding" and "create confusion as to whether or not whole pieces of vegetables are contained therein." This comment also stated that if FDA requires the listing of the components of vegetable broth in canned tuna, then the agency should generate an alternative labeling scheme that would be flexible, economically feasible, and protective of trade secrets.

FDA agrees that the listing of each ingredient comprising vegetable broth on the label of canned tuna could be lengthy and cumbersome. New § 130.3(e) provides that:

> All ingredients must be listed in accordance with the requirements of part 101 of this chapter, except that where a definition and standard of identity has specific labeling provisions for optional ingredients, optional ingredients may be declared in accordance with those provisions.

The standard of identity for canned tuna permits the optional ingredient defined in renumbered new § 161.190(a)(6)(v) to be called "vegetable broth" on the label of canned tuna, as specified in new § 161.190(a)(8)(vi). Hence, the optional ingredient vegetable broth may be listed as "vegetable broth" in the list of ingredients on the label of canned tuna. The new regulations do not require full declaration of all of the ingredients of which the vegetable broth is comprised.

However, for reasons discussed in another document that appears elsewhere in this issue of the **Federal Register**, the agency is proposing to amend the standard of identity for canned tuna to require the declaration of soybeans when the ingredient vegetable broth contains soybean extractives. If the agency adopts this proposal, the ingredient will have to be listed as "vegetable broth (includes soybeans)."

9. Although the agency did not receive any other comments with respect to canned tuna, FDA, as set forth in new § 161.190(a)(6)(ii), is amending the standard of identity for this food to eliminate the term "purified" in conjunction with "monosodium glutamate" (MSG) for consistency with the terminology for MSG in the food additive regulation in 21 CFR 182.1 and in the food labeling regulation in § 101.22(h)(5). The term "purified" had been used in the name in § 101.35 to distinguish between three types of ingredients, "monosodium glutamate," "hydrolyzed proteins," and "hydrolyzed proteins with reduced monosodium glutamate content." Elsewhere in this document (See section VIII. of this document), FDA is revoking

§ 101.35 because the regulation is obsolete and does not include many of the protein hydrolysates used in foods.

In addition, consistent with the establishment of new § 102.22, as set forth below, to provide for the declaration of protein hydrolysates by a common or usual name that is specific to the ingredient and that identifies the food source from which the protein was derived, the agency is amending the standard of identity in new § 161.190(a)(6)(iii) to require labeling of the source of protein in the optional ingredient "hydrolyzed protein."

Furthermore, to reflect the agency's decision to revoke § 101.35, the agency is amending the standard of identity for canned tuna in new § 161.190(a)(6) to remove "hydrolyzed protein with reduced monosodium glutamate content" from the list of optional ingredients permitted in canned tuna. As discussed in the June 21, 1991, proposal (56 FR 28592 at 28600 et seq.), all hydrolyzed protein contains MSG, and this MSG is not itself an ingredient that is subject to the ingredient declaration requirements of the act. In that document, FDA stated that after carefully considering the information available concerning the safe use of protein hydrolysates and whether the presence of MSG is a material fact that needs to be disclosed on the label for health reasons, it tentatively concluded that the information does not provide an appropriate basis to require declaration of MSG as a component of protein hydrolysates. However, for the reasons discussed in another document elsewhere in this issue of the **Federal Register**, the agency has reconsidered this issue and is proposing to require the declaration of glutamate as part of the common or usual name when a component of certain hydrolyzed proteins. Therefore, it will no longer be necessary to distinguish between "hydrolyzed protein" and "hydrolyzed protein with reduced monosodium glutamate content" in the manner currently provided for in this standard.

Accordingly, new § 161.190(a)(6)(i) through (a)(6)(ix) have been renumbered to reflect the elimination of "hydrolyzed protein with reduced monosodium glutamate content" from the list of optional ingredients permitted in canned tuna. "Hydrolyzed protein" will be retained in the list of optional ingredients, as specified in § 161.190(a)(6) below (see section VIII. of this document).

6. Other Related Actions

10. The agency did not receive any comments that objected to its proposal to require that the ingredient declaration for fruit butter in § 150.110 conform to the regulations in part 101. Thus, the agency is removing § 150.110(e)(2)(ii) (21 CFR 150.110(e)(2)(ii)), which states that if sugar or invert sugar is the sweetener used, the term "sugar" may be used, and if the sweetener used is derived from corn, the term "corn sweetener" may be used. The agency is also requiring that the ingredient declaration for fruit butter conform to the regulations in part 101. In this rule, the agency is terminating the rulemaking to permit the use of the terms "sugar" and "corn syrup" as collective ingredient designations. The agency has determined that declaration of specific names for sweeteners within these collective categories is practicable. Consistent with this action, the agency has concluded that declaration of the specific names of sweeteners is also practicable for standardized foods and is deleting the requirements of § 150.110(e)(2)(ii).

The agency is also deleting the requirements in the standards for mixed nuts and peanut butter in §§ 164.110 and 164.150 (21 CFR 164.110 and 164.150) that provide for the use of the term "hydrogenated vegetable oil" or "vegetable oil" with the optional use of the name of the vegetable source, and the requirement in § 164.110 for label declaration of chemical preservatives. Required label declarations for these types of ingredients are clearly delineated in §§ 101.4(b)(14) and 101.22(j), respectively. Moreover, the "and/or" labeling exemption in § 101.4(b)(14) should effectively eliminate the need for collective names for vegetable oils on these standardized foods.

The agency did not receive any other comments with respect to proposed changes to specific standards of identity. Thus, the agency is finalizing the amendments to the individual standards as proposed.

In the July 21, 1991, proposal on Declaration of Ingredients, FDA withdrew the proposed amendment to § 101.4 (formerly § 1.10) pertaining to the establishment of the terms "sugar" and "corn syrup" as collective ingredient designations that was published in the **Federal Register** of June 14, 1974 (39 FR 20888); terminated the rulemaking proceeding initiated by that proposal; and denied the petitions commenting on that proposal from the Canada Dry Corp. (June 27, 1975—Docket No. 75P–0144), the Canners League of California (January 19, 1977—Docket No. 77P–0051), the Independent Bakers Association (September 22, 1977—Docket No. 77P–0357), the California Milling Corp. (June 19, 1978—Docket No. 77P–0051 CP0002), the Orth Co. (July 31, 1978—Docket No. 77P–0357), and L. Karp & Sons, Inc. (August 11, 1978—Docket No. 77P–0357 CP0003).

B. Labeling of Sulfites in Standardized Foods

In the **Federal Register** of December 19, 1988 (53 FR 51062), FDA published a proposed rule to require that any standardized food that contains a sulfiting agent that has a functional effect or that is present at a level of 10 ppm or more is misbranded if the presence of the sulfiting agent is not declared on the label by its common or usual name. The agency proposed to codify this requirement in new § 130.9. The agency also solicited comments regarding sulfite-sensitive consumers' ability to recognize and avoid foods labeled with the six common or usual names for sulfites (sulfur dioxide, sodium sulfite, sodium and potassium bisulfite, and sodium and potassium metabisulfite). In addition, the agency requested comments on whether any final rule should contain a requirement that the common or usual name of a labeled sulfiting agent should be followed by the term "sulfiting agent." The comments received on these and other aspects of this part of the proposal, and the agency's response, follow.

11. The majority of comments from consumers and industry supported adoption of § 130.9. These comments stated that sulfite labeling of standardized foods would decrease allergic type reactions by increasing consumer awareness, while allowing the vast majority of consumers, who are not sensitive to sulfites, to continue to consume foods containing sulfiting agents. A few consumers' comments, however, requested that all unnecessary uses of sulfites be banned, or, in the alternative, that principal display panel warnings be required. Citing the large number of people adversely affected by sulfites, the comments asserted that there was no established safe threshold for sulfites, and that they are one of the few food ingredients known to cause anaphylactic shock and death.

The agency recognizes that sulfites present a significant health problem for a small segment of the population, particularly some asthmatics. However, sulfiting agents do not appear to present a problem for most people, and the declaration of sulfiting agents in the list of ingredients will provide sufficient information for those people who need or want to avoid unexpected exposure to these ingredients. Thus, FDA does not believe that it is necessary to require

a warning statement on food labels or to ban all uses of sulfites. In addition, the comments did not provide any data to support banning current uses of sulfites.

The agency believes that the action that it is taking in this final rule will afford more effective protection for sulfite-sensitive individuals than is currently provided. This provision for label declaration of sulfites for standardized foods is consistent with the provisions for label declaration of sulfites for nonstandardized foods in § 101.100(a).

Thus, FDA is adopting new § 130.9, as proposed, in this final rule. As a result, all foods containing sulfiting agents that are functionally active or present at 10 ppm or more in the finished food are now required to declare the presence of the sulfiting agent in the ingredient statement.

12. Some comments expressed the opinion that the term "sulfiting agent" should be used instead of the common or usual name of the particular substance because it is more recognizable by consumers. None of these comments, however, offered any data to show the extent of consumer knowledge about the common or usual names for sulfiting agents.

Lacking data, and reflective of the small number of comments from consumers on this issue, FDA is not persuaded that requiring a descriptive or collective term to be used with the common or usual name of the sulfiting agent is necessary because the declaration of the sulfiting agent by its common or usual name will adequately inform the consumer of its presence.

Furthermore, sulfite sensitive consumers know to look for sulfiting agents in the ingredient statement. However, the agency will not object if manufacturers choose to make this dual declaration.

Moreover, the agency is not persuaded that the term "sulfiting agent" should be used in place of the common or usual name for sulfiting agents added directly to the standardized food or for sulfiting agents that have a technical or functional effect. FDA addressed this issue with respect to label declaration of sulfites in nonstandardized foods in the **Federal Register** of July 9, 1986 (51 FR 25012). At that time the agency adopted § 101.100(a)(4) which requires sulfiting agents present at 10 ppm or more in a nonstandardized food be declared on the label. Furthermore, sulfiting agents that are directly added to, or that have a technical or functional effect in, food should be declared by the name of the specific sulfiting agent. However, the agency also established the policy that sulfiting agents that are indirectly added to a food, and that have no technical or functional effect in the food, could be declared by a collective term. FDA considered the term "sulfiting agent" to be the most accurate and informative collective term. The agency still believes that this position is appropriate for nonstandardized foods and is also appropriate for standardized foods. Thus, when indirectly added sulfiting agents remain in a standardized food in a significant amount, but no longer have a technical or functional effect, they may be declared by the term "sulfiting agents."

FDA also continues to hold that if a food contains a sulfiting agent that has a technical or functional effect in the standardized food and that is declared in the list of ingredients by its common or usual name, as required by § 130.9(a), any nonfunctional sulfiting agents present in the standardized food need not be declared separately in the list of ingredients. In such circumstances, sulfite sensitive individuals will be alerted to avoid the food by the declaration of the former sulfiting agent. However, FDA emphasizes that this flexibility applies only if the sulfite does not perform a technical or functional effect in the standardized food.

13. Several comments from industry and trade associations objected, for various reasons, to the use of the Monier-Williams method of sulfite analysis. These comments requested that firms should have the freedom to choose between "state-of-the-art" methods and the Monier-Williams method in determining the amount of sulfite present.

FDA has selected the Monier-Williams method as the method that it will use for enforcement of the sulfite labeling requirements because this method is an official method of the Association of Official Analytical Chemists and is the standard against which the accuracy of new procedures has been judged. Moreover, this method will measure the free sulfite plus a reproducible portion of the bound sulfites in the food. However, the agency advises that processors and food manufacturers are under no obligation to use the Monier-Williams method for quality control or any other purpose. Processors are free to, and frequently do, determine the correlation between the official FDA-designated enforcement method, i.e., the Monier-Williams method, and their method of choice. They may then use their method of choice as they see fit, recognizing that FDA will rely on the Monier-Williams method in any enforcement action.

14. A few comments suggested that the concentration of the sulfite should be declared on the label, thereby allowing the consumer to decide whether to purchase the product based on this information. The comments stated that this would absolve the manufacturers of liability, as long as the product did not exceed the limit.

The agency rejects this suggestion. Although the agency is aware that limited studies have been performed on sulfite-sensitive individuals to determine dose response reactions, the agency finds that the available evidence does not establish that a threshold level exists for sulfite-sensitive individuals. Furthermore, the agency does not believe that sulfite-sensitive individuals should be expected to determine their tolerance levels. Therefore, FDA finds that, given currently available information, there is no reason to require manufacturers to declare the concentration of sulfites on the label. Declaration of the sulfiting agent in the ingredient list will adequately inform all individuals who are sensitive to sulfites that sulfites are present in the food.

15. One comment asked for clarification of the "written agreement" exception to the labeling requirement as it applies to bulk shipment of ingredients that will be further processed into consumer products by other manufacturers. The comment stated that it is impractical for ingredient manufacturers of sulfiting agents to enter into written bilateral contracts with each customer. The comment proposed an alternative such as a "pure food" guarantee, indicating that the food is not adulterated or misbranded within the meaning of the act (e.g., a letter of guarantee from the manufacturer that the product contains less than the maximum residual limit of sulfites that is consistent with the generally recognized as safe (GRAS) regulations or the inclusion of information on an invoice that specifies the maximum residual level of sulfites contained in the product).

Section 101.100(d) provides an exemption from the labeling requirements for foods shipped in bulk when there is a written agreement between the shipper and the consignee. The written agreement must, among other things, contain specifications for the processing, labeling, or repacking of the food by a designated establishment that will ensure that the food will not be adulterated or misbranded within the meaning of the act. The exemption provided in § 101.100(d) applies to all foods shipped under the prescribed provisions without full labeling and not just those foods containing sulfites.

Furthermore, § 101.100(d) is not a subject of this rulemaking. In addition, sulfite manufacturers have not provided reasons to persuade the agency that they should be treated differently from manufacturers of other ingredients. The alternative proposed in the comment is welcome additional information but is not a substitute for written agreements for interstate shipment of partially labeled food for further processing.

III. Label Declaration—Statement that *Ingredients are Listed in Descending* Order of Predominance by Weight

FDA proposed in the June 21, 1991, proposal to adopt proposed § 101.4(a)(3) to require that food labels bear a statement explaining that the list of ingredients is in descending order of predominance by weight. The proposed requirement was in response to comments received on the 1989 ANPRM that suggested that consumers were not aware of the requirement in new § 101.4(a)(1) that ingredients be declared in descending order of predominance by weight. FDA cited, as an example of an appropriate statement: "Ingredients (in descending order of predominance by weight): ————————, ————————, and ————————."

16. Although a few industry and consumer comments on the June 21, 1991, proposal supported proposed § 101.4(a)(3), the majority of industry comments requested that it be deleted from a final rule. Industry comments maintained that consumers have been made aware that ingredients are declared in descending order of predominance by weight through the food industry's advertisements. According to these comments, such advertisements highlight ingredient statements when comparing the quantity of various ingredients among competitive products. The comments said that, therefore, an explanatory statement would be demeaning to many consumers. These comments further argued that the proposed model statement, "Ingredients (in descending order of predominance by weight)," uses sophisticated terminology unlikely to be understood by those consumers who remain unaware of the listing requirement. These comments suggested that this issue could be more appropriately addressed through public education efforts by FDA and the food industry.

Other opposing comments on this issue emphasized that the labeling exemption in proposed § 101.4(a)(2) for ingredients that are present in amounts of 2 percent or less by weight allows listing the ingredients without regard to order of predominance. These comments maintained that the proposed statement would contradict the 2 percent rule and lead to consumer confusion.

Some comments further stated that the parenthetical statement, as proposed, would use valuable label space, especially on small packages, and would add to label clutter without significant benefit to the consumer. Of particular concern was ingredient labeling for chewing gum packages. Comments from the chewing gum industry stated that the addition of this statement on the ingredient label in conjunction with all of the other labeling changes required by the 1990 amendments and proposed by FDA could require the development of new packaging.

Comments from foreign governments stated that there was no requirement to include such a statement in their countries. They contended that if FDA established the requirement for such a statement, additional labeling difficulties and costs would be borne by both United States and foreign food manufacturers wishing to use a single label for both markets. These comments stressed that any additional costs would ultimately be passed on to consumers.

The agency has carefully considered all of the comments and has been persuaded to reconsider its position. The agency agrees that in some cases, educational efforts by the industry and FDA may better inform the public that ingredients are listed in descending order of predominance by weight than requiring the statement on the label. The agency also recognizes that with the implementation of other labeling requirements mandated by the 1990 amendments, label space, especially on smaller packages, may be limited. Finally, comments from consumers demonstrated little support for the proposal. Accordingly, the agency is not requiring that food labels bear a statement explaining that the list of ingredients is in descending order of predominance by weight and is deleting proposed § 101.4(a)(3) from this final rule. However, the agency encourages manufacturers to provide this information voluntarily when practicable.

IV. Declaration of Sweeteners in the Ingredient List

A. General

The June 21, 1991, proposal discussed several issues regarding labeling of sweeteners. Consumers had complained of not being able to determine the relative amounts of added sweeteners because sweeteners are listed at various positions throughout the ingredient list. In response, the agency proposed that all sweeteners be grouped together parenthetically following the term "sweeteners" when more than one sweetener is present in a product and be declared in the ingredient list in the order of predominance appropriate for the sum of all sweeteners in the product. The agency also withdrew a previous proposal, published in the **Federal Register** of June 14, 1974 (39 FR 20888), to establish the term "sugar" as a collective ingredient designation for sucrose and invert sugar and "corn sweeteners" as a collective ingredient designation for sweeteners derived from corn. With this action, the agency denied several industry petitions requesting the use of these collective terms.

17. One consumer comment strongly disagreed with allowing the ingredient sucrose to be labeled as "sugar" while other caloric sweeteners are labeled by their proper names. This comment also expressed the belief that manufacturers mislead consumers by using the term "No sugar added" when the product is sweetened by a caloric sweetener other than sucrose. The comment urged that all sweeteners be labeled by their proper names, and that the term "sugar" be prohibited.

FDA has traditionally held that the term "sugar" in an ingredient list refers to sucrose as defined in § 184.1854 (21 CFR 184.1854). Although the agency proposed in 1974 to permit the term "sugar" to also include invert sugar, the agency never acted on that proposal and subsequently withdrew it in the June 21, 1991, proposal. In addition, the agency believes that sucrose is the only sweetener that has traditionally been referred to as "sugar" by industry and consumers, and that the use of this term in the ingredient list is not misleading. Thus, the agency is not granting the request to prohibit the use of the term "sugar" as defined in § 184.1854. To promote greater consumer awareness of § 184.1854, FDA has specifically referenced it in new § 101.4(b)(20) (§ 101.4(b)(22) in the proposed rule).

With regard to the statement "no sugar added" when sweeteners other than sucrose are used in a food, the agency's position (21 CFR 105.66) has been that label declaration claims such as "no sugar added" may reasonably be expected to convey to consumers that the food contains no added nutritive sweeteners, such as high fructose corn syrup, malt syrup, or honey. Claims such as "no sugar added" refer not only to sucrose but to a class of sweeteners of which sucrose is just one. The agency addressed this issue in detail in its

proposal on nutrient content claims (56 FR 60421 at 60437, November 27, 1991). At that time, FDA proposed that claims for the absence of added sugars apply only to those foods to which sugar or other nutritive sweeteners have not been added directly or indirectly during processing or packaging. This issue is further addressed in the nutrient content claims final rule published elsewhere in this issue of the **Federal Register**.

18. Comments from consumers, consumer groups, and some State governments supported the agency's proposal that all sweeteners be listed together in the ingredient list under the collective term "sweeteners." They expressed the belief that current regulations permit manufacturers to hide the actual amount of added sweeteners in a product by dispersing them in the ingredient statement. In addition, several of these comments requested more complete information on the total amount of sugars present in a finished food and suggested that such information be required in nutrition labeling.

However, comments from industry opposed grouping sweeteners in the ingredient list. The comments questioned FDA's authority to require grouping sweeteners in the ingredient list and stated that there was no scientific or public health rationale for singling out sweeteners for distinctive treatment in the ingredient list. These comments argued that total sugars declaration is the function of the nutrition label and not the ingredient label. They further argued that sweeteners may be added to foods for other than sweetening purposes (e.g., as bulking agents, firming agents, cryoprotectants, and fermenting agents), and that grouping sweeteners in the ingredient list could obscure the intended function of the sweetener in the food, thereby generating consumer confusion. In addition, several comments raised concerns regarding labeling requirements of foods that: (1) Are themselves sweeteners, (2) contain a standardized multicomponent ingredient that had a sweetener as one of its ingredients, and (3) contained sweeteners that perform functions for which "and/or" labeling is permitted under current regulations (§ 101.4(b)(19)).

One comment from industry argued that inclusion of the term "sweeteners" in the ingredient list of food products that are themselves sweeteners is unnecessary. The comment asserted that a sweetener with two ingredients, both of which are "sweeteners," would have to list under this regulation "Ingredients: Sweeteners (dextrose, aspartame)," rather than a simpler and more straightforward listing of "Ingredients: dextrose, aspartame." This comment requested an exemption for products that are themselves sweeteners.

Other industry comments maintained that where manufacturers declare a multicomponent ingredient (e.g., a standardized or nonstandardized food for which there is a common or usual name and that is fabricated from two or more ingredients) of a food by its common or usual name followed by a parenthetical listing of the two or more ingredients in the multicomponent ingredient, sweeteners would either: (1) Have to be listed twice, first in the parenthetical list following the name of the multicomponent ingredient and second in the list of combined sweeteners contained in the finished food; or (2) have to be removed from the parenthetical list of the multicomponent ingredient and added to the parenthetical list of sweeteners. These comments contended that such a practice would be misleading because it would, in the first case, over-represent the amount of the sweetener by declaring it twice, or, in the second case, give the impression that the multicomponent ingredient is "sugar free."

The comments stated that, in the alternative, the parenthetical listing of the ingredients of the multicomponent ingredient, as provided in proposed § 101.4(b)(2)(i), would no longer be an option. Sweeteners would have to be removed from the multicomponent ingredient declaration and grouped with other sweeteners. The other ingredients in the multicomponent ingredient would then have to be dispersed in the ingredient list in descending order of predominance, as provided in proposed § 101.4(b)(2)(ii), without naming the multicomponent ingredient. As a result, common, readily identifiable multicomponent ingredient names such as "milk chocolate" or "marshmallows" would not appear in the ingredients statement, and the consumer would be misled.

Several other industry comments requested clarification regarding label declaration of sweeteners, such as sugar alcohols, that may be used as firming agents and that are currently declared parenthetically using "and/or" labeling following the collective term "firming agents." These comments asserted that manufacturers who may not adhere to a constant pattern of use of a particular firming agent that is a sweetener would be at a competitive disadvantage because of the additional expense of maintaining label inventories for every possible formulation.

Additional comments that opposed the grouping of sweeteners stated that consumers will avoid foods unnecessarily if the grouped sweeteners appear first or second in the ingredient list and thereby imply that such foods are "bad." These comments further stated that when low calorie or intense sweeteners are used, they would most likely be the only sweetening ingredient in a food and therefore would be exempt from this requirement because the group declaration of sweeteners is only triggered when more than one added sweetener is present. These comments asserted that consumers would be given the impression that a food containing an intense or low calorie sweetener contained less sugar and therefore, was more nutritious than a food that contained, for example, five sweeteners. In fact, the comment continued, the food containing five sweeteners may contain other essential nutrients not present in the food with the intense sweetener. Another comment asserted that the grouping of sweeteners in the ingredient list would lead to deceptive and unfair practices because manufacturers may manipulate formulations so that ingredients that are valued by consumers, such as honey and concentrated fruit juice, would appear to be more predominant when grouped with other sweeteners than they would under current labeling regulations.

Finally, two comments from foreign manufacturers that opposed grouping sweeteners in the ingredient list maintained that such a requirement would be a barrier for foreign trade because foreign manufacturers are not required to group sweeteners on labels. These comments further stated that foreign manufacturers would be required to use separate labels just for the U.S. market, consequently increasing costs and discouraging free trade.

The agency has carefully reviewed all of the comments and, as stated above, has been persuaded to reconsider its proposal to require grouping of sweeteners in the ingredient statement. As stated in the final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**, in response to section 403(q) of the act, FDA is requiring the declaration of total sugars in the nutrition label. The agency believes that information on the quantity of sugars in a finished food is more effectively conveyed as part of nutrition labeling, than ingredient labeling. The total amount of sugars, including both added and indigenous

sugars, is declared in the nutrition label, whereas the information on sugars content provided through ingredient labeling includes only added sweetening ingredients in order of predominance by weight. The ingredient label does not give information regarding the amounts of those sugars.

It is true that in the June 21, 1991, proposal, the agency stated that even if it were to require the declaration of total sugars, there was still a significant need for grouping sweeteners in the ingredient list to prevent consumers from being misled by the practice of dispersing sweetener names throughout the ingredient list. FDA has reconsidered this position, however, and concludes that from a nutritional standpoint, the placement of added sugars in the ingredient statement is not relevant.

For FDA to require the grouping of sweeteners in the ingredient list, it would have to find that listing them in order of predominance is false or misleading (section 403(a) of the act). Clearly, the applicable finding would have to be that the current method of listing sweeteners results in consumer deception, that is, as argued by the consumer and state government comments, by dispensing sweeteners throughout the ingredient list, manufacturers hide the total amount of sweetening ingredients added to a food. FDA has concluded, however, that this practice will not result in deception for two reasons.

First, because nutrition labeling will include a listing of total sugars, this practice will no longer provide a means of hiding the amounts of sweeteners added to the food. The consumer will be able to determine if a product has a high amount of sugars by looking at the nutrition label.

Secondly, from a nutritional standpoint, the amount of added sugars is not significant information when considering overall sugar content. It is the total sugars content that has nutritional importance. Again, this amount will be determinable from the nutrition label. Thus, FDA agrees with the comments that there is no scientific or public health reasons for singling out sweeteners for special treatment in the ingredient list. For these reasons FDA concludes that grouping of sweeteners is not necessary to prevent consumers from being misled and, therefore, FDA is not requiring such a step. Accordingly, FDA has deleted the proposed requirement for aggregate declaration of sweeteners (proposed § 101.4(b)(21)) from this final rule.

FDA points out that it has considered the other objections raised by industry to its proposal. As explained above, FDA clearly has authority under section 403(a) of the act to take the step it proposed. FDA advises that there would be alternative ways of addressing each of the other concerns that the industry comments raised. Because the agency has decided not to adopt proposed § 101.4(b)(21), however, it finds that there is no need to address each of those concerns in detail.

The agency received several other supporting and opposing comments addressing its definition of sweeteners (i.e., list of ingredients to be included in the definition of sweeteners for the purpose of this regulation) as discussed in the June 21, 1991, proposal (56 FR 28592 at 28608). Because the agency has reconsidered its position on the aggregate declaration of sweeteners in the ingredient statement, the issues raised in those comments are no longer pertinent and need not be addressed in this rulemaking.

19. Other comments recommended that FDA require the disclosure of artificial sweeteners on the principal display panel in addition to the ingredient list. These comments suggested that the label should read "Artificially sweetened" and should also bear warnings about artificial sweeteners being harmful to children and pregnant women. However, the comments did not provide information supporting their assertion that artificial sweeteners are specifically harmful to children and pregnant women.

The agency will not object to manufacturers voluntarily declaring on the principal display panel that the product is artificially sweetened. This voluntary declaration, however, only applies in those instances where "artificially sweetened" is not a part of the statement of identity of the food (e.g., artificially sweetened canned apricots) and, therefore, required to appear on the principal display panel. The agency is not aware of any evidence to support the assertion in the comments that artificial sweeteners are more harmful to children and pregnant women than to the general population. FDA has considered the safety of these ingredients as part of the food additive listing process. Where it has been presented with evidence that shows that it is necessary for the safe use of an artificial sweetener, FDA has required declarations. Such a declaration is provided for in 21 CFR 172.804, which requires that labels on foods that contain aspartame bear the statement "PHENYLKETONURICS: CONTAINS PHENYLALANINE." In addition section 403(o)(1) of the act requires that labels of foods containing saccharin bear the warning statement "USE OF THIS PRODUCT MAY BE HAZARDOUS TO YOUR HEALTH. THIS PRODUCT CONTAINS SACCHARIN WHICH HAS BEEN DETERMINED TO CAUSE CANCER IN LABORATORY ANIMALS." Both provisions require that such statements shall be located in a conspicuous place on the label as proximate as possible to the name of the food and shall appear in conspicuous and legible type in contrast to other printed matter on the label. As other artificial sweeteners are permitted for use in foods, the agency will prescribe the conditions under which those sweeteners may be safely used, including labeling or packaging requirements if deemed necessary by the agency to ensure the safety of such use. See section 409(c)(1)(A) of the act (21 U.S.C. 348(c)(1)(A)).

B. Lactose Labeling

In the June 21, 1991, proposal, the agency restated its policy on the declaration of lactose and advised that ingredient labeling regulations require the listing of lactose whenever it is used as an ingredient of food (56 FR 28592 at 28608).

20. One comment supported FDA's position against requiring label declaration of lactose when present as a component of an ingredient (e.g., whey, nonfat dry milk), because lactose intolerant consumers know to avoid milk and milk products. Another comment requested the establishment of regulations to require labeling products as "lactose free." This comment stated that the high percentage of the population that suffers from lactose intolerance warrants such a requirement.

The agency does not agree that the requested statement is needed because lactose intolerant consumers know to avoid milk and milk products. Furthermore, the comment did not present data to substantiate that lactose intolerant consumers need a "lactose free" declaration to determine which foods they can safely consume. Such information would be necessary for FDA to require a statement that a product is "lactose free." Thus, FDA is not requiring a "lactose free" declaration on products that do not contain lactose. However, the agency advises that manufacturers may voluntarily label a food as "lactose free," provided, of course, that the statement is true. Any product labeled as "lactose free" must not contain lactose as an ingredient or as a component of an ingredient and

should adhere to the provisions of 21 CFR 105.62 on hypoallergenic foods.

V. Labeling of Fresh Fruits and Vegetables

A. Pesticides

21. The majority of comments, citing concerns about health risks and the consumer's right to know, requested that the agency require manufacturers to disclose preharvest and postharvest pesticide use on fresh fruits and vegetables at the retail level. The comments expressed concern that, in the absence of pesticide labeling at the retail level, growers, packers, repackers, or distributors may indiscriminately use pesticides that are not permitted or are permitted only on specific fruit and vegetable commodities.

As discussed in the preamble to the June 21, 1991, proposal (56 FR 28592 at 28611), section 403(l) of the act only requires declaration of postharvest pesticides on the shipping container. Moreover, section 403(l) of the act specifically precludes the agency from requiring declaration of postharvest pesticides at the retail level. The comments favoring disclosure of preharvest and postharvest pesticide use did not provide any information not considered by the agency at the time of the proposal, nor did they provide viable solutions to the many compliance and enforcement problems that would arise if the agency acquired statutory authority to require pesticide labeling at the retail level. Moreover, the agency advises that the indiscriminate use of pesticides is illegal. Only uses specifically permitted by the Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act of 1988 (7 U.S.C. 136a-1) are legal. Thus, FDA has concluded that it will not seek statutory authority to require pesticide labeling by the retailer at this time.

B. Wax or Resin Coatings

The agency proposed to permit retailers to use appropriate collective (generic) names for ingredient labeling of wax or resin coatings on fresh produce (56 FR 28592 at 28611). Section 403(i) of the act provides for exemption from specific ingredient labeling when such labeling is impracticable or results in deception or unfair competition. Because of the constant change of produce items in retail establishments, FDA tentatively concluded that specific ingredient labeling of waxes and resins was impracticable (56 FR 28592 at 28613). In addition, under the proposal, packers and repackers unable to adhere to a constant pattern of wax or resin use on produce would be permitted to use collective names in ingredient labeling. Also in the June 21, 1991, proposal, FDA responded to a citizen petition (Docket No. 90P–0404) requesting the agency to permit: (1) Collective labeling of fresh produce by shippers; (2) ingredient labeling on plastic bags; and (3) the term "may" in ingredient labeling of wax or resin coating on fresh produce.

22. Although a number of comments supported the agency's proposal, several comments requested specific wax or resin coating ingredient declaration at the retail level because of health and safety considerations and because of the right of consumers to know what is in the foods they eat.

The agency recognizes that consumers have expressed health and safety concerns as they relate to the consumption of waxes and resins. Waxes and resins used on fresh produce have been accepted as food grade and therefore are considered by the agency to be safe ingredients. If the agency becomes aware that a particular wax or resin may be harmful to consumers, it will take appropriate action to ensure safe use of the wax or resin.

The agency further acknowledges that some consumers desire specific ingredient declaration of waxes and coatings, and that such declarations are generally required under section 403(i) of the act. However, section 403(i) of the act does not provide a "right to know" the ingredients of every food. It qualifies the requirement that each ingredient be listed (section 403(i)(2) of the act) by saying that to the extent that compliance with that requirement is impracticable or results in deceptive or unfair competition, FDA is to establish exemptions from the requirement by regulation (section 403(i)(2)). The comments did not provide evidence regarding retail marketing practices that contradicted the agency's tentative conclusion that specific ingredient labeling at the retail level is impracticable. Therefore, FDA has not been persuaded to change its tentative finding that specific ingredient declaration is impracticable, at the retail level. Accordingly, the agency concludes that specific ingredient declaration of waxes and coatings on fresh produce is impracticable and that the proposed exemption permitting use of collective terms by the retailer is appropriate.

23. Some of the comments that requested specific wax or resin coating label declaration also requested declaration of the fungicides applied in the waxes or coatings. These comments asserted that information on fungicides is important for health and safety considerations.

As discussed above, section 403(l) of the act specifically precludes FDA from issuing regulations requiring retail labeling for postharvest use of pesticides. Fungicides that may be applied with or without waxes or coatings are included in the category of postharvest-use pesticides, as provided in section 201(q) of the act (21 U.S.C. 321a(q)) and therefore are exempt from required declaration at the retail level. As previously stated, the agency does not plan to seek statutory authority to require pesticide labeling by retailers.

24. Many comments requested that domestic and foreign packers and repackers be exempted from specific ingredient labeling and allowed to use collective (generic) terms without first having to determine whether there is a "constant pattern" of wax or resin use on the produce. Several of the comments asserted that seasonal variation, product variation, coating variability, product destination, cost and availability of wax or resin coating, and the practice of commingling lots of variously coated fresh fruits and vegetables from different suppliers occur so frequently that packers and repackers would rarely, if ever, adhere to a "constant pattern" of use.

In addition, the comments stated that the packer or repacker who adheres to a "constant pattern" of use, and, therefore, is required to use specific wax or resin coating ingredient declarations, is at a competitive disadvantage when compared to packers or repackers who do not adhere to a constant pattern of use. The comments contended that unfair competition results because of the labeling and inventory costs required to maintain specific ingredient labeling as well as collective ingredient labeling for those instances when the packer does not adhere to a constant pattern of use. The comments further stated that the ordinary practice in the packing industry is to use prestenciled shipping containers that are labeled before they are packed. Thus, packers and repackers who adhere to a constant pattern of use and are required to list individual wax or resin ingredients would have to maintain a separate inventory of boxes prestenciled with the required ingredient information. The comments argued further that most packers often run two or three shifts per day, each with multiple lines packing various types of produce simultaneously. These comments concluded that the packers who adhere to a constant pattern of use would not only have to increase their packaging costs and inventory space but also

would have to increase their workforce and reorganize the packing process.

Other comments stated that the requirement to list specific ingredients on shipping containers if a "constant pattern" of use is determined is at odds with the proposal to use collective names at retail. Such a requirement would compel retail store personnel to categorize the specific wax or resin coating, because retail establishments will always be able to use generic labeling. These comments further maintained that it is unreasonable to expect produce clerks and store managers to understand ingredient label classification of waxes and resins and to label accurately the products with the appropriate collective name. These comments also contended that requiring produce personnel to classify waxes and resins for labeling purposes may ultimately cause erroneous labeling, resulting in misbranding of the product and misleading the consumer.

The agency requires ingredient labeling for wax or resin coatings on both domestic and imported fresh fruits and vegetables. The agency finds, based on information provided in the comments regarding industry practices, that the loss of specific lot identification because of commingling of variously coated produce while in bulk storage at the wholesale distributor level makes specific ingredient declaration impracticable. Proposed § 101.4(b)(25) (redesignated as new § 101.4(b)(22) in this final rule) provided for the use of collective terms by packers and repackers when a "constant pattern" of wax or resin ingredient use is not practicable. In light of information regarding industry practice provided in several of the comments, the agency concludes that it is likely that the great majority of packers and repackers, both foreign and domestic, will satisfy the conditions of impracticability required for exemption from specific ingredient labeling for wax and resin coatings. The agency further concludes that the small number of manufacturers who adhere to a constant pattern of use of wax or resin coatings may be at a competitive disadvantage because they will incur additional labeling and inventory costs in order to provide specific wax or resin ingredient labeling for a variety of fruits and vegetables. Similar costs will not be borne by the majority of packers and repackers, who do not adhere to a constant pattern of wax or resin use.

Section 403(i)(2) of the act provides that, in cases where specific ingredient labeling would be impracticable or result in deception or unfair competition, the packer or repacker may be exempted from such labeling. Because of industry practices previously discussed, the majority of packers and repackers will meet the requirements for exemption from specific ingredient declaration because of impracticability. In the agency's opinion, however, the few packers and repackers that would not be exempt from specific ingredient declaration due to impracticability would be placed at a competitive disadvantage if required to comply with section 403(i) of the act. Accordingly, the agency is revising proposed § 101.4(b)(22) to exempt all packers and repackers from specific ingredient labeling of wax and resin coatings. In reaching this conclusion, FDA also considered that consumers would not be disadvantaged by any loss of information if packers and repackers use collective term labeling of waxes and resins because retailers are permitted to use collective terms. Therefore, specific ingredient labeling of waxes and resins by the packer or repacker would not be provided to the consumer by the retailer.

25. Several comments requested that the agency revise proposed § 101.4(b)(25) to include dairy-based waxes within the category of animal-based waxes, e.g., "animal-based or milk-based" or "coated with animal-based wax (may include dairy product-based wax)." The comments cited the possibility of allergic reaction to products containing small amounts of dairy products and religious, ethnic, or dietary restrictions as the reasons for the request.

The agency advises that dairy-based waxes are included in the animal-based wax category. The agency believes that consumers understand that dairy products are animal-based, and that any dairy-based ingredients in waxes or resins would be included in an "animal-based wax" declaration. The agency further believes that the prescribed term "coated with animal-based wax" is adequate to provide the requested information to consumers wishing to avoid dairy-based products. The comments did not provide any basis for finding that the use of the term "animal-based" is not adequate to advise consumers with all the information they would need to avoid the product. Accordingly, FDA has not made the requested revision of the regulation.

26. Some comments objected to the term "food grade," stating that all ingredients are food grade, and that this term may give the consumer the impression that other ingredients are not "food grade." These comments also objected to the optional use of functional phrases, e.g., "to maintain freshness," in conjunction with the words "wax" and "coatings," because the comments believed that such terms are misleading or redundant.

The agency points out that the term "food grade" is an optional term and concludes that it should remain as such. The agency is not convinced that consumers will perceive that ingredients not designated as "food grade" are not food grade. On the contrary, the agency believes that the use of the optional term "food grade" will assure consumers who are concerned about wax or resin coatings that these ingredients have been accepted by the agency as "food grade" and, therefore, are considered to be safe ingredients.

The agency disagrees that the phrase "to maintain freshness" is misleading. Waxes and coatings do perform a preservative function, and this phrase is an acceptable means of stating that fact. Although the agency is not requiring the phrase "to maintain freshness" to describe the preservative function of waxes and resins (FDA believes that consumers generally recognize that this function is associated with the terms "wax" and "resin;" thus, for produce, the terms "wax" and "resin" fulfill the requirements of new § 101.22(j) and section 403(k) of the act with respect to the declaration of the preservative function), the agency will permit the phrase to be included in the wax or resin ingredient declaration.

27. A few comments suggested that the term "no wax and/or resin coating" should be required instead of no labeling when no wax or resin coating is present, to assure the consumer that the absence of labeling is not the result of the retailer's failure to label the presence of wax or resin coating.

The agency has the authority to require declaration of the absence of an ingredient in cases where it is implied that the ingredient has been used when in fact it has not been used. In such instances the lack of specific information would be misleading under sections 403(a) and 201(n) of the act. However, the comment did not provide information to substantiate that in the absence of a wax or resin declaration, consumers would believe that a wax or resin coating had been applied. Thus, the agency does not have the authority, in this instance, to require a "no wax or resin" declaration. However, the agency will not object to use of a "no wax or resin" declaration but does require that the statement is factual in all respects. Furthermore, the agency expects that packers, repackers, and retailers will comply with the statutory requirements and correctly label wax or resin coated fresh fruits and vegetables.

28. Other comments requested that the agency revise proposed § 101.4(b)(25) to: (1) Establish shellac or lac-based coatings as a separate category of wax or resin coatings; (2) modify the term shellac with the phrase "a coating made up of a secretion of the lac insect" to alert strict vegetarians; and (3) combine the categories beeswax and shellac-based because they are both insect-derived.

The agency has not been persuaded by the comments that the prescribed terms are inadequate to inform the consumer about wax and resin coatings, or that an additional category should be established to alert a limited population of consumers. FDA selected the collective terms that it proposed in the June 21, 1991, proposal to assist the consumer in avoiding certain products for reasons of religious, cultural, or ethnic dietary restrictions. These collective terms allow consumers to avoid certain foods, while providing the flexibility needed by retailers in prevailing market conditions to comply with the ingredient labeling requirement. Thus, the agency is not creating an additional category for beeswax and shellac (or lac-) based waxes. However, should a packer, repacker, or retailer voluntarily choose to use a more narrow descriptive term such as "vegetable based" or "beeswax and shellac based," or to name the specific wax or resin coating, the agency will not object to such use but does require that the declaration be factual.

29. Some comments suggested use of the term "petroleum based" as opposed to "mineral based" because it is factual, it is understood by consumers, and the term "mineral" may be misleading if associated with vitamins and minerals, particularly if nutrition labeling is provided by the retailer.

The agency agrees with the comments. Currently, in part 172 (21 CFR part 172), there are at least four multipurpose direct food additives that may be applied to fresh fruits and vegetables as a protective coating, and that the agency considers to be in the category "petroleum based." These are: White mineral oil (liquid petrolatum), § 172.878; petroleum wax, § 172.886; synthetic petroleum wax, § 172.888; and petrolatum, § 172.880. With the exception of white mineral oil, all have the term "petroleum" as part of their common or usual name. Therefore, the agency concludes that the term "petroleum based" is more accurate and informative in describing the nature and source of the wax coating than the term "mineral," which may be associated with inorganic substances rather than organic substances. Accordingly, FDA has revised new § 101.4(b)(22) (formerly § 101.4 (b)(25)) to reflect this change.

30. Two comments expressed concern that growers, packers, and repackers may begin to use coatings derived from certain gluten containing foods (i.e., wheat, barley, rye, oats, or millet), and that the prescribed generic terms would not adequately inform persons who must avoid these foods. The comments further asserted that retailers should not be allowed to treat cut-up fruits or vegetables with a gluten-based coating to enhance color and preserve freshness without declaring the use of such coating.

The agency is not aware of any commercially used coating derived from wheat, barley, rye, oats, or millet that may contain gluten. However, should such a coating be developed in the future, FDA would decide what measures are necessary to adequately protect those consumers who need to avoid gluten and to ensure the safe use of the coating.

In addition, retailers who coat fruits or vegetables are required to declare such ingredients in accordance with the provisions of section 403(k) of the act and § 101.4(b)(22).

31. Some comments that supported the use of self-serve plastic bags to identify wax or resin coating ingredients saw no difference between prepacked plastic bags with ingredient labeling and those plastic bags to be used by consumers from a roll. Further, they argued that, as opposed to information on signs, the information on plastic bags would give consumers added time for review during shopping and after leaving the store. Other comments opposed the use of self-serve plastic bags to provide ingredient declaration of wax or resin coatings because: (1) The consumer would not have the information before making the purchase decision; (2) it is difficult to read print on bags in a roll; (3) the consumer may not use the plastic bags specific to the produce or to the actual waxes applied to the products being purchased; and (4) the practice is not ecologically sound.

The comments supporting use of self-serve plastic bags to declare wax or resin coatings on produce at retail have not persuaded the agency that self-serve plastic bags available in the produce department meet statutory labeling requirements for ingredient declaration, meet expressed consumer needs, or can reasonably be managed at the retail store. As stated in the June 21, 1991, proposal, ingredient information on plastic bags available in the produce department would not provide consumers with this information at the time they actually make purchase decisions (56 FR 28592 at 28614). Further, the agency doubts that consumers would notice ingredient information because the bags are usually distributed in rolls. Thus, because the ingredient information would not be placed conspicuously and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, the produce would be misbranded under section 403(f) of the act.

Furthermore, the agency believes that ingredient declaration on plastic bags could result in misleading consumers, especially when consumers may commingle different brands of the same produce or puzzle over which plastic bag to use for which produce. Unlike ingredient declaration on prepackaged fruits and vegetables, which is specific to the contents of that package, the agency cannot ensure that ingredient declaration placed on self-serve plastic bags would be used for the specific fruit or vegetable for which the bags were intended. Thus, FDA affirms its tentative finding and concludes that wax or resin coating ingredient labeling limited to self-serve rolls of plastic bags in the produce department does not meet the statutory requirement of section 403(f) of the act and, therefore, is not an acceptable alternative of ingredient declaration of waxes and resins.

32. Several comments requested that the agency reconsider its decision and permit retailers to use the term, "may have been treated with wax or resin coatings," on produce labels. The comments compared the concept to "and/or" labeling of fats and oils.

The agency believes that there is an inherent difference between the terms "may have been treated * * *," with its inherent suggestion that the food may or may not contain the wax, and "and/or." As discussed in the June 21, 1991, proposal, the suggestion that a food may contain a wax would be of virtually no use to consumers because it does not advise them whether the produce has a wax or resin coating or identify the coating used. On the other hand, "and/or" labeling informs the consumer that one or more of the ingredients declared is definitely present in the product. Thus, the agency is not granting the request to allow the term "may have been treated * * *" in the declaration of wax or resin coatings. However, the agency points out that it has allowed in new § 101.4(b)(22) for the use of "and/or" labeling in declaration of wax or resin coatings (e.g., "coated with vegetable-, petroleum-, beeswax-, and/or shellac-based wax or resin") because it

adequately informs the consumer of the generic category of wax or resin coating as well as provides the flexibility needed by industry. These prescribed terms are sufficiently general that if several different kinds of wax or resin coatings become commingled in different lots, the produce would still be factually and informatively labeled.

33. Several comments requested that the agency establish more rigid requirements with respect to format, terminology, and letter size for wax or resin label declaration. These comments expressed the belief that the proposed requirements were not adequate to inform the consumer.

The comments did not provide any evidence to support their claim that the requirements as proposed will not result in labeling that will adequately inform the consumer regarding wax or resin coating. Consequently, the agency disagrees with these comments and concludes that the requirement that labeling be displayed prominently and in a conspicuous manner with lettering at least one-fourth of an inch high is adequate to inform the consumer.

34. A few comments requested that FDA require that the sign for each commodity be placed next to the bin bearing that commodity. These comments contended that one sign in the produce department covering all affected produce would not adequately provide point-of-purchase information for the various items sold throughout the department. Comments opposing the requirement of individual signs next to each commodity stated that such a practice would ultimately lead to misbranding because of the retail practice of moving bins, rearranging produce displays, and the likelihood of consumers knocking down such signs.

In the June 21, 1991, proposal, the agency proposed in § 101.4(f) to require that ingredients that must be declared in labeling because there is no label for the food (display of written, printed, or graphic matter upon the immediate container of any article), be listed prominently and conspicuously by their common or usual name. The agency did not, however, propose requirements with regard to the number of signs or countercards or the placement of such labeling in produce departments because the arrangement and size of produce departments is not consistent from one retail establishment to another. In cases where the produce department is confined to a small area, one sign or counter card may be sufficient to adequately inform the consumer regarding the use of wax or resin coatings as produce ingredients. However, where the produce department covers a large area, one sign may not be adequate. The agency believes that retailers should be permitted to determine the appropriate placement of signs and counter cards to meet ingredient labeling requirements in each particular establishment. However, the agency advises that enforcement action may be taken against retail establishments where wax or resin ingredient declarations are not prominently and conspicuously displayed.

35. One comment stated that the agency should not specify the manner of labeling for wax or resin coated produce or set rigid type size requirements for sign lettering placed on bulk bins, i.e., one-fourth inch type size, as proposed in § 101.100(a)(2)(ii). The comment asserted that such rigid standards would stifle innovation and limit the creativity of grocers in finding new ways to provide useful information to consumers.

The agency disagrees with the comment that the proposed labeling requirements would stifle retail creativity. The proposed minimum type size requirement will help to ensure that consumers with a wide range of visual acuities will be able to read the written information. Moreover, such written information will comply with requirements provided under section 403(f) of the act. Further, the type size requirement does not preclude retailers from providing brochures, electronic signs, computer screen displays, or using other media and methods to inform consumers in addition to the sign required in § 101.100(a)(2).

36. One comment requested clarification on whether the minimum letter size requirement of one-fourth of an inch referred to upper case or lower case when both lettering types are used.

The agency advises that, as with other minimum lettering size requirements, the minimum size requirement of one-fourth of an inch for labeling of wax or resin coating ingredient labeling refers to the height of the lower case "o" when both upper and lower case lettering is used, as established in § 101.105(h)(2).

VI. Source Labeling

A. General

FDA stated in the June 21, 1991, proposal that declaration of the food source in the common or usual name of all foods would not be required.

37. Many consumer comments responding to the proposal requested that the agency reconsider its position and require that the specific source of an ingredient be declared as part of its common or usual name in the list of ingredients.

These comments repeated requests that the agency had already evaluated when developing the June 21, 1991, proposal and did not present new information. As previously discussed (56 FR 28592 at 28603), several of these comments expressed a desire to avoid certain ingredients (e.g., corn-derived sweeteners), while others stated that consumers should be fully aware of what is in the food they eat.

FDA appreciates consumer needs and concerns about source labeling and points out that source labeling is required as part of the common or usual name in instances where such information has a material bearing on the purchase of a food, where such information describes the basic nature of the food, or where consumers may be misled without such information (§ 101.4(a)(1) and 102.5(a)). For FDA to require declaration of the source of all ingredients, it would have to amend the common or usual name of those ingredients that do not currently include their source. As explained in the June 21, 1991, proposal (56 FR 28592 at 28603), such a requirement would require enormous resources, and the agency does not have such resources available. Moreover, many of these ingredients are so well known that most consumers understand the source of the ingredient from its name. Consequently, FDA reaffirms its conclusion that it is not feasible or necessary to establish a general requirement for source information in the common or usual names of all foods.

B. For Specific Foods—Gluten Labeling

38. FDA received several comments from consumers affected with celiac sprue, a medical condition that results in damage to the absorptive surface of the intestine when gluten (a protein fraction of cereal grains) is ingested. These comments strongly requested source declaration, particularly for all protein hydrolysates (i.e., flavor-related and nonflavor-related protein hydrolysates) and modified food starches produced from wheat, barley, rye, oats, and millet which commonly contain gluten. Alternatively, these comments requested that FDA establish regulations that would allow manufacturers to state that a product is "gluten free" without misbranding the food.

The agency acknowledges the desire of those individuals affected with celiac sprue to know what products contain gluten. As with other ingredients combined to make a finished food, declaration of gluten when added as an

ingredient to a food is required. Literature reviewed by the agency suggests that the two most commonly used forms of gluten are derived from corn and wheat (Ref. 45). Sections 184.1321 and 184.1322 (21 CFR 184.1321 and 184.1322) establish the terms "corn gluten" and "wheat gluten," respectively, as the common or usual names for declaration of these ingredients.

In this final rule, FDA is requiring source declaration in the common or usual name of all protein hydrolysates, including those that are made from sources that may contain gluten, because the source is essential to describe the basic nature of the ingredient. In the June 21, 1991, proposal, the agency advised that protein hydrolysates used for nonflavor-related purposes should also be declared by appropriate common or usual names in accordance with the provisions of proposed § 101.22(h)(7), which describes requirements for the declaration of protein hydrolysates used for flavor-related purposes (56 FR 28592 at 28600). For reasons discussed in section VIII.A. of this document, the agency is incorporating that position into the regulation. Therefore, the requirement for source declaration in the common or usual name of protein hydrolysates used for flavor-related purposes has been transferred from § 101.22(h)(7) to new § 102.22(a) and now applies to declaration of protein hydrolysates used for flavor-related as well as nonflavor-related purposes. The agency believes that this requirement will assist consumers who wish to avoid gluten.

With respect to modified food starch, the agency does not believe that source declaration is required to inform consumers about gluten content. Modified food starches (21 CFR 172.892) are products of the treatment of any of several grain- or root-based starches with small amounts of chemical agents, which modify the physical characteristics of the source starches to produce desirable properties. Corn starches are the dominant starches used in the United States (Ref. 50). As stated in the comments, consumers with celiac sprue must abstain primarily from gluten derived from wheat, oats, barley, millet, and rye. Corn as a source of gluten was not mentioned in the comments as one to be avoided.

More importantly, the starch component of the source food is separated from the protein (i.e., gluten) component through starch isolation techniques (Ref. 50). Once the starch has been isolated, it is modified and added to food as an ingredient. Therefore, irrespective of the source of the modified food starch, the gluten (protein) component is removed and therefore should not be a problem for gluten intolerant consumers. The comments did not provide evidence that modified food starch causes adverse health consequences as currently used. Therefore, the agency is not requiring source declaration for modified food starch.

The agency advises that even though it has not specifically defined "gluten free," this phrase can be used on foods provided that when as used it is not false or misleading. The term "gluten free" may be misleading when the food ordinarily contains no gluten (e.g., modified food starch). Further, it is the agency's understanding that "gluten free" foods labeled as such may be found in the special dietary sections of some food stores and on a very limited number of products more generally available. Therefore, the agency has advised (Refs. 51 and 52) that foods labeled "gluten free" that purport to be or are represented for special dietary use should adhere to the provisions for hypoallergenic foods in § 105.62 by declaring the common or usual name, and the quantity or proportion, of each ingredient (including spices, flavorings and noncertified color additives) when the food is fabricated of two or more ingredients. Additionally, under § 105.62(b), the name of the food or of its ingredients must be qualified to reveal clearly the specific plant or animal source of the food or ingredient. Moreover, an informative statement of the nature and effect of any treatment or processing of the food or any ingredient thereof must be declared if a change in the allergenic property results from such treatment or processing (§ 105.62(c)).

FDA will consider establishing a definition for "gluten free" if petitioned with sufficient information, including an adequate analytical methodology for food analysis.

C. Labeling of Foods Characterized as "Nondairy" that Contain Caseinates

In the June 21, 1991, proposal, the agency identified some food products that are marketed as dairy product substitutes and that bear labels that include the statement "nondairy," but that contain a caseinate milk derivative. FDA believes that the labeling of such products may lead consumers to think that the caseinates are not milk derived. Thus, the agency proposed in § 101.4(d) that wherever "nondairy" statements appear on the label of a product that contains a milk derivative, the source of the milk derivative must be declared in the ingredient statement.

39. The majority of comments that addressed this issue supported the agency's proposal. However, several comments recommended that the agency revise § 101.4(d) to require that the term "caseinate milk derivative" be declared after the term "nondairy" on the principal display panel, as well as in the ingredient list.

The agency disagrees with the latter comments. The agency does not believe that requiring the additional declaration on the principal display panel is justified. FDA believes that the proposed requirement to declare the source of the milk derivative in the ingredient list will adequately protect consumers who wish to avoid milk-derived ingredients. The comments in question did not provide evidence to show that the ingredient list declaration would not be adequate. Therefore, the agency is not requiring source declaration on the principal display panel.

40. One comment recommended that the source identification requirement of caseinates as milk derivatives in foods labeled as "nondairy" be extended to foods that do not bear a "nondairy" label. However, the comment offered no rationale for this recommendation.

The agency disagrees with the recommendation. In the absence of a "nondairy" label declaration, there is no basis to suggest that the consumer would be led to believe that the food was nondairy. The declaration of the specific name of the caseinate in the ingredient statement would not be misleading and complies with regulations for ingredient labeling. Thus, the agency is not requiring source information in the name of the caseinate if the product does not bear a "nondairy" claim.

41. Other comments recommended that State laws that require "nondairy" labeling of products with caseinates be preempted for health reasons.

The agency disagrees with this suggestion. The comments did not provide information on which the agency could make a finding that the term "nondairy" on products that contain caseinates would create health concerns if the products' labeling also declares, in the ingredient statement, that the caseinate is milk-derived. The latter statement would adequately inform consumers, wishing to avoid milk-derived products, of the presence of a milk-derived ingredient. Accordingly, the agency is requiring, as proposed, that products that bear a "nondairy" claim and contain caseinates, must declare in the ingredient statement that the caseinate is milk-derived.

D. Nomenclature for Sweeteners

42. One comment requested source labeling for sweeteners. This comment stressed that source labeling would allow persons with specific food allergies to avoid these ingredients in finished foods. This comment further stated that corn, specifically, is of concern to Jews observing dietary laws during Passover.

The evidence presented by the comment lacked supportive scientifically verifiable data and thus, has not persuaded the agency to modify its tentative finding that allergic reactions to sweeteners, particularly corn-derived sweeteners, do not represent a major health concern in the United States. In the absence of such evidence, the agency is not requiring inclusion of the food source in the names of sweeteners. However, the agency acknowledges the concern expressed by consumers about source labeling, particularly for corn sweeteners, for other than health reasons. Accordingly, as proposed, the agency is amending §§ 168.110(b) and 168.111(c) to provide for voluntary declaration of the food source in the naming of these sweeteners, as is currently allowed for glucose sirup (§ 168.120 (21 CFR 168.120)) and dried glucose sirup (§ 168.121 (21 CFR 168.121)). Because the agency is not requiring declaration of the food source in the naming of these sweeteners, it encourages consumers wishing to avoid certain sweeteners for religious or other reasons to familiarize themselves with the names of these sweeteners and look for these names in the ingredient lists.

43. Another comment requested clarification regarding nomenclature appropriate for commonly used nonstandardized sweeteners, such as corn sirups with varying degrees of sweetness intensity (dextrose equivalence) and in varying forms (dried, powdered, and liquid). The comment requested that names such as "corn sirup" and "corn sirup solids" be permitted instead of the common or usual name of the ingredient or the precise form in which the ingredient was incorporated into the food. The comment maintained that "corn sirup" and "corn sirup solids" would be better understood and more recognizable by consumers than the technical common or usual names.

The agency rejects this comment. The requested terms "corn sirup" and "corn sirup solids" are currently used as alternative names, designating source, for standardized sweeteners provided in §§ 168.120 and 168.121. They are specific to those ingredients and, therefore, not appropriate for collective declaration of nonstandardized sweeteners. Furthermore, consumers have consistently requested specific ingredient labeling information rather than the use of collective terms when asked to comment on several food labeling issues, including labeling of sweeteners.

Moreover, under section 403(i) of the act, a food that is fabricated from two or more ingredients is misbranded unless the label bears the common or usual name of each such ingredient. The act also states that the agency is to provide for exemptions if compliance with this requirement is impracticable or results in deception or unfair competition. The comment did not present evidence upon which FDA could make a finding that the declaration of nonstandardized sweeteners, by their common or usual names, would be impracticable or would result in deceptive or unfair competition. Accordingly, the agency is denying the comment's request to permit such names as "corn sirup" instead of the common or usual name of the nonstandardized sweetener. As discussed in the proposal, persons interested in further guidance on appropriate names for nonstandardized sweeteners should refer to parts 172, 180, 182, and 184 (21 CFR parts 172, 180, 182, and 184).

VII. Percentage Ingredient Labeling

FDA proposed in the June 21, 1991, proposal to codify in § 101.4(e) its voluntary percentage labeling policy, which permits manufacturers to declare voluntarily percentages of ingredients if the information is not misleading and is truthful in all respects.

44. Several industry comments acknowledged that in instances where an ingredient is prominently declared, either through identity or other label information, or where the ingredient has a market appeal or is used to make a claim, percent ingredient labeling should be required. However, these comments also suggested that voluntary percentage ingredient labeling has the potential to confuse and mislead the consumer because too much information can distract consumers from the more important nutrient content information now mandated for all food labels. These comments further stated that confusion could be generated if only some manufacturers declare ingredient percentages. These comments asserted that voluntary percent labeling is unnecessary in light of the new nutrition labeling regulations and is not important to consumers. One comment further expressed concern that percentage ingredient labeling will eventually become mandatory for all foods. This comment requested assurance from FDA that voluntary percentage ingredient labeling would not become mandatory.

The agency is not convinced that voluntary percentage ingredient declaration would lead to consumer confusion. FDA has permitted manufacturers to declare voluntarily the percentage of ingredients, and it does not have information to indicate that consumer confusion has occurred as a result of such declarations. In addition, the majority of comments on this issue stated that it was appropriate for FDA to establish a uniform method of declaration for those manufacturers who choose to use percent ingredient labeling.

Furthermore, the agency believes that this information could educate consumers as to the individual contribution of a particular ingredient in the finished food, thereby assisting them in planning their diets. Consumers have the ability to discern and understand labeling information that is presented in a uniform, clear, and concise manner. Therefore, the agency is issuing new § 101.4(e) to establish a uniform method for voluntary percentage declaration of ingredients.

FDA is not requiring general percentage labeling of all ingredients in all foods. Although the agency cannot give assurances regarding the future, it is not at this time seeking authority to require such percentage ingredient labeling. The agency emphasizes, however, that the percentage of characterizing ingredients must be declared, as provided in § 102.5(b), when the proportion of such ingredients has a material bearing on the price or consumer acceptance of the food, or when there may be an erroneous impression that the ingredients are present in an amount greater than is actually the case.

VIII. Flavors, Colors, and Spices

A. Label Declaration of Protein Hydrolysates

Protein hydrolysates, which include acid hydrolyzed and enzyme hydrolyzed proteins from plant and animal sources, and autolyzed yeast extracts, are used in many foods for a variety of functions, including as formulation aids, leavening agents, stabilizers, thickening agents, nutrient supplements, protein sources, flavorings, and flavor enhancers. Current regulations do not exempt protein hydrolysates from ingredient declaration when used for purposes other than flavoring. The practice

among some in industry has been to declare protein hydrolysates used for flavor-related purposes, such as flavor enhancement, as "flavorings" or "natural flavors."

In the June 21, 1991, proposal, the agency reached several tentative conclusions with regard to label declaration for protein hydrolysates used for flavor-related purposes. After reviewing available literature and technical data, FDA concluded that when protein hydrolysates are added to foods as flavorings, they also function as flavor enhancers. The agency pointed out that the act does not exempt flavor enhancers from required label declaration. Consequently, the June 21, 1991, proposal provided that any protein hydrolysate used in a food as a flavoring must be declared by its common or usual name.

As required by § 102.5(a), the common or usual name of a food should adequately describe its basic nature or characterizing properties or ingredients. The agency believes that some terms currently used for declaration of protein hydrolysates, e.g., "hydrolyzed vegetable protein" or "hydrolyzed animal protein," do not adequately describe their basic nature or characterizing properties because protein hydrolysates from different sources have different functional characteristics. Accordingly, in the June 21, 1991, proposal, FDA tentatively concluded that declaration of the protein source is necessary to describe accurately the nature of the protein hydrolysate, and proposed that it be included in the common or usual name. Furthermore, the agency stated that source declaration of protein hydrolysates is a material fact for consumers wishing to avoid certain foods for religious or cultural reasons.

In addition, FDA responded to the citizen petition submitted by the International Hydrolyzed Protein Council (the Council) in 1985. This petition requested that the agency revoke § 101.35 because the regulation is obsolete and does not include many of the protein hydrolysates presently used in foods. The agency agreed with the Council and proposed to delete § 101.35 from the regulations in the June 21, 1991, proposal.

FDA also tentatively found that there was no public health basis for requiring the declaration of free glutamates that occur as components of protein hydrolysates. However, comments on the June 21, 1991, proposal have raised other issues not related to public health concerning the declaration of glutamates. FDA did not consider these issues in the June 21, 1991, proposal. After evaluating the information presented in these comments, FDA has tentatively concluded that the phase "(contains glutamate)" is necessary to describe adequately the basic nature of certain protein hydrolysates and, thus, is proposing elsewhere in this issue of the **Federal Register** that this phrase be part of the common or usual name of certain protein hydrolysates. This action will, consequently, provide for the declaration of free glutamates as components of certain protein hydrolysates.

In the June 21, 1991, proposal, the agency did not include regulations for determining appropriate common or usual names for protein hydrolysates used for nonflavor-related purposes. Nevertheless, the agency did advise that protein hydrolysates used for nonflavor-related purposes should be declared in accordance with the provisions of proposed § 101.22. After reviewing the comments, however, the agency concluded that it is more appropriate to establish regulations that provide general requirements for the declaration of all protein hydrolysates and not just those used for flavor-related purposes. This will minimize confusion regarding appropriate common or usual names for the various kinds of protein hydrolysates. The agency also concluded that establishing general requirements for protein hydrolysates used for nonflavor-related purposes was a logical outgrowth of the June 21, 1991, proposal. Accordingly, the agency has transferred provisions of proposed § 101.22 regarding the common or usual name designation of protein hydrolysates used for flavor-related purposes to new § 102.22, and extended the requirements to include protein hydrolysates used for nonflavor-related purposes.

The agency has also concluded that highly hydrolyzed protein hydrolysates can be differentiated (as discussed below) from protein hydrolysates that may be mildly, lightly, or partially hydrolyzed (i.e., those types used for nonflavor-related purposes). Unlike highly hydrolyzed protein hydrolysates, protein hydrolysates that are not highly hydrolyzed may retain the functional effects and allergenic potential of the source protein because the source protein is still structurally intact to a substantial degree. Therefore, the agency has concluded that the inclusion of the protein source in the common or usual name of mildly, lightly, or partially hydrolyzed protein hydrolysates is also a material fact because this information is required by certain (allergic) individuals in order to make purchase decisions.

The agency's evaluation and summary of the comments received in response to the June 21, 1991, proposal follow.

45. The agency did not receive any comments objecting to the required ingredient declaration of protein hydrolysates when added to foods for flavor-related purposes. Therefore, as proposed, the agency is establishing in new § 101.22 a requirement for declaration of a hydrolyzed protein by its common or usual name in the ingredient list in order of predominance by weight when added to a food for flavoring or flavor-related functions. The agency points out, however, that provisions for specific declaration and acceptable names for protein hydrolysates have been transferred from proposed § 101.22(h)(7) to new § 102.22(a).

46. A number of comments requested more detailed source declaration, such as identification of milk-derived ingredients and specific origin of vegetable-derived protein hydrolysates. The two primary reasons cited in the comments for requesting source declaration were: (1) Religious or cultural dietary concerns; and (2) allergy, food intolerance, or sensitivity to the source protein. Other comments expressed the belief that the source of the protein should also be required in the declaration of the protein hydrolysate used for nonflavor-related purposes to protect those individuals who are allergic to certain source proteins. These comments stated that the potential for an allergic reaction is greater for nonflavor-related protein hydrolysates because these protein hydrolysates may be partially, mildly, or lightly hydrolyzed proteins. Unlike highly hydrolyzed proteins; partially, mildly, or lightly hydrolyzed proteins retain their capacity to induce allergic reactions because peptides from their source protein are significantly longer than those present in highly hydrolyzed proteins.

Several comments stated that source declaration should be limited to the terms "animal" or "vegetable," and that these generic terms would be sufficient for individuals wishing to avoid certain foods for religious or cultural reasons. These comments further stated that individuals wishing to avoid specific ingredients of animal or vegetable origin could do so by relying on the generic source declaration of "animal" or "vegetable."

The agency believes that the requirements set forth in §§ 101.22 and 102.22 are sufficient to inform consumers about the nature of the protein hydrolysate and, therefore, concludes that additional declarations

(e.g., milk-derived) are not necessary. However, the agency finds significant merit in those comments requesting that the source declaration be required for protein hydrolysates used for nonflavor-related purposes. The agency agrees with the comments that protein hydrolysates used for nonflavor-related purposes (i.e., partially hydrolyzed protein hydrolysates) may retain the allergenic potential of the source protein. Thus, the agency concludes that the inclusion of the name of the source in the common or usual name of the ingredient represents a material fact under section 201(n) of the act because individuals who are allergic to a specific food need to know when it is present as an ingredient in a food in order to make informed purchase decisions.

Furthermore, as the agency determined that source declaration as part of the common or usual name of highly hydrolyzed proteins is necessary to describe the basic nature of the ingredient because of inherent differences in the nature (amino acid profiles) of the source protein, it also finds that source declaration as part of the common or usual name of partially hydrolyzed proteins is necessary to describe the basic nature of the ingredient. Further, in order to provide additional guidance on the declaration of nonflavor-related protein hydrolysates, the agency is also advising that it is appropriate to use optional terms such as "partially," "lightly," or "mildly" in the declaration of protein hydrolysates that are not highly hydrolyzed. For example, the common or usual name of a protein hydrolysate that is not highly hydrolyzed may be declared as "hydrolyzed (source) protein" or "partially hydrolyzed (source) protein."

As stated in the June 21, 1991, proposal, the agency has advised that manufacturers should determine appropriate common or usual names for protein hydrolysates used for nonflavor-related purposes according to the provisions of proposed § 101.22. Upon consideration of the comments, however, the agency finds that it is necessary to establish regulations for the common or usual names of protein hydrolysates used for nonflavor-related purposes to ensure accurate, uniform, concise, and appropriate ingredient declarations for all protein hydrolysates. Accordingly, the agency has extended provisions for specific declaration and acceptable names for protein hydrolysates in proposed § 101.22 to cover all protein hydrolysates, and has transferred the provisions to new § 102.22.

With regard to the use of generic terms, the agency believes that generic terms like "animal" or "vegetable" do not adequately describe the basic nature or characterizing properties of the protein hydrolysate nor distinguish between the several types of source proteins in each general class of ingredients; therefore, they do not comply with § 102.5(a). As required by § 102.5(a), the common or usual name of an ingredient must describe, in as simple terms as possible, the basic nature of the food or its characterizing properties. As discussed in the proposal, hydrolyzed protein from wheat gluten and hydrolyzed protein from soy are different proteins, with significantly different amino acid profiles and functional properties. The amino acid profile, or composition, of the source protein describes the basic nature of the protein hydrolysate and determines the different levels of free amino acids released upon hydrolysis. In addition, the specific amino acids present in a source protein influence the flavoring ability of the protein hydrolysate at different stages of hydrolysis. Therefore, hydrolyzed wheat protein and hydrolyzed soy protein would not be distinguished accurately by a generic name.

Thus, generic source labeling using the terms "animal" or "vegetable" would not fully comply with § 102.5(a). The agency concludes that the declaration of the food source of a protein hydrolysate is essential to describe the basic nature of the protein hydrolysate, and that the food source is a significant determinant in the hydrolysate's eventual use in a food. Therefore, the food source should be a part of the common or usual name. The agency concludes further that the failure to identify the specific food source in the declaration of a protein hydrolysate causes the food to be misbranded because the declaration would not comply with the requirements of § 102.5(a) of the regulations and sections 201(n) and 403(a) of the act. The requirement for identification of the food source of a protein hydrolysate in proposed § 101.22(h)(7) is codified in new § 102.22(a).

47. One industry comment requested that FDA modify proposed § 101.22(h)(7) by providing that protein hydrolysates obtained from wheat gluten and other wheat sources be called "hydrolyzed wheat protein." The comment argued that once hydrolyzed, wheat gluten loses its specificity and is no longer wheat gluten because the carbon and nitrogen bonds holding the amino acids together are broken, leaving small peptides and amino acids. Therefore, the comment asserted, the term "hydrolyzed wheat protein" is more factual, adequately describes the nature of the ingredient, and is not misleading to consumers.

FDA recognizes that the hydrolysis of any protein source will produce small peptides and release certain amino acids, such that the hydrolyzed protein will not be identical structurally and functionally to the source protein. The amino acid profiles of the source protein and its hydrolyzed product, however, will be the same. Although wheat gluten is the principal protein component of wheat, there are other proteinaceous components of wheat that may not be defined specifically, as is gluten, but can serve as sources for hydrolyzed proteins. Furthermore, the agency believes that wheat gluten is generally accepted by consumers and industry as a differentiated wheat protein that meets the requirements of § 184.1322. Therefore, in the agency's opinion, when wheat gluten is used as a source of a hydrolyzed protein, the correct name of the ingredient is "hydrolyzed wheat gluten." Accordingly, the agency is not granting the comment's request. However, when other wheat components are used as sources of hydrolyzed proteins, the ingredient shall be declared as "hydrolyzed wheat protein."

48. Several comments asserted that source declaration for highly hydrolyzed proteins is not necessary because the source protein is so decharacterized in these products that its allergenic potential is no longer present.

The agency concurs with the comments' assertion that allergic, food intolerant, or sensitivity reactions are unlikely to occur from consumption of highly (acid) hydrolyzed proteins used in foods primarily for flavoring and flavor enhancement because the high degree of hydrolysis generally employed in the manufacture of these protein hydrolysates is likely to destroy the allergenic potential of the source protein (Ref. 4). Thus, the agency concludes that source declaration for highly hydrolyzed proteins is not necessary for the protection of individuals who are allergic, food intolerant, or sensitive to the source protein. However, as stated earlier, the food source of a protein hydrolysate is basic to describing the nature of the protein hydrolysate and, therefore, the agency is requiring the declaration of the food source as part of the common or usual name.

49. Many comments urged the agency to require declaration of the MSG (glutamate) component in protein hydrolysates for various reasons.

Because the agency is proposing, elsewhere in this issue of the Federal Register, to require, in specific situations, the declaration of glutamate as a component of protein hydrolysates, these comments and the agency's response will not be discussed here. However, a full discussion of this issue is presented in the above-referenced proposal.

50. In responding to the June 21, 1991, proposal, several comments indicated that differences exist among acid-hydrolyzed protein hydrolysates, enzyme-hydrolyzed protein hydrolysates, partially hydrolyzed protein hydrolysates, and autolyzed yeast extracts. These comments argued that the agency should make distinctions in the labeling of these different substances because some are used almost exclusively for flavor enhancement, sometimes substituting for MSG; others are primarily flavors rather than flavor enhancers but act in both capacities; and still others are neither flavors nor flavor enhancers but function as formulation aids, leavening agents, stabilizers, thickening agents, nutrient supplements, and protein sources. In conjunction with the nonflavor-related functions, some comments stated that the agency should address separately the labeling of a class of protein hydrolysates variously termed "partially," "mildly," or "lightly" hydrolyzed proteins, which primarily serve functions in food other than as flavor enhancers and/or flavorings.

The agency believes that the requirements in § 102.22 provide ample guidance for label declaration of protein hydrolysates in instances where confusion may have existed. As provided, the common or usual name of any protein hydrolysate will include the protein source. This requirement is necessary to describe the basic nature or characterizing property of the ingredient. The agency will also permit manufacturers to use such terms as "partially," "mildly," or "lightly" to describe protein hydrolysates that are not highly hydrolyzed. The agency believes that appropriate standards exist to allow it to distinguish between commercially-available highly hydrolyzed protein hydrolysates and those protein hydrolysates; variously termed "partially," "mildly," or "lightly" hydrolyzed; that are not used for flavor-related purposes. Highly hydrolyzed proteins can be defined as those whose ratio of α-amino nitrogen (AN) to total nitrogen (TN), determined by using the tests for "Acid Hydrolyzed Proteins" set forth in the "Food Chemicals Codex", 3d ed., 1st Supp. (1983), is greater than 0.62 (AN:TN > 0.62) (Ref. 53). Proteins that are not highly hydrolyzed would have an AN:TN ratio of less than 0.62 (AN:TN < 0.62) and may be declared by using such terms as "partially," "mildly," or "lightly" (e.g., "Partially hydrolyzed (source) protein"). The comments did not offer any analytical information or methodology, however, to assist the agency in distinguishing between partially, mildly, or lightly hydrolyzed proteins.

51. The agency did not receive any comments objecting to the proposed deletion of § 101.35, which provides guidelines for label declaration of MSG and other hydrolyzed vegetable proteins. Therefore, as proposed, the agency is deleting § 101.35 from its regulations.

B. Labeling of Other Flavors, Color Additives, and Spices

Before passage of the 1990 amendments, the act provided that flavorings, colorings, and spices could be declared collectively using the terms "flavorings," "colorings," and "spices." However, the 1990 amendments amended section 403(i) of the act to require that certified color additives be declared by their common or usual names and not be designated by the collective term "colorings." As a result of this change in the statute, each certified color additive used in or on a food must be declared by its common or usual name, but noncertified color additives may still be declared collectively. Congress did not revoke the exemption from required declaration for flavorings and spices.

In response to this new statutory authority, FDA proposed § 101.22(k) which details how color additives are to be declared in the ingredient list. The agency also proposed to permit the use of abbreviated names for certified color additives. Over the last several years, FDA has allowed manufacturers who voluntarily declare certified color additives to use abbreviated names. Although the agency believed that the common or usual names by which the color additives are listed in parts 74 and 82 (21 CFR parts 74 and 82) were the most appropriate names for identifying these color additives, it also felt that a provision that permitted the use of abbreviated names might encourage more manufacturers to voluntarily declare these color additives. The agency concluded that such a practice would provide more information to consumers than use of the collective term, which before the 1990 amendments, satisfied the requirements of the act.

On January 28, 1983, FDA issued an advisory opinion permitting the use of abbreviated names of certified color additives in response to a citizen petition submitted by the Grocery Manufacturers of America, Inc. (Docket No. 78P-0164). FDA subsequently proposed, in the **Federal Register** of June 6, 1985 (50 FR 23815), to incorporate that advisory opinion into its regulations. A final rule, however, has not yet published.

With the passage of 1990 amendments including the requirement that certified color additives used in foods be declared by their common or usual names FDA saw an opportunity to finalize the 1985 rulemaking. Given that under section 403(i)(2) of the act the listing of certified color additives will be required on food labels, the agency tentatively concluded that manufacturers should have the option to use abbreviated names for declaring the certified color additives. Accordingly, in the June 21, 1991, proposal, the agency proposed to continue the option to use abbreviated names because consumers have come to recognize and understand these names for color additives. Furthermore, the agency recognized that the use of abbreviated names has some advantage for industry because they consume less label space.

In the proposal, the agency solicited comments on whether certified color additive lakes should also be permitted to be declared using abbreviated names.

52. A comment from the Canadian government requested that the agency modify proposed § 101.22(k) to provide for the use of alternative names (such as tartrazine, allura red, erythrosine, sunset yellow FCF, brilliant blue FCF, indigotine, and fast green FCF) instead of the U.S. names (FD&C Yellow No. 5, FD&C Red No. 40, FD&C Red No. 3, FD&C Yellow No. 6, FD&C Blue No. 1, FD&C Blue No. 2, and FD&C Green No. 3, respectively) or to allow alternative names to be included in parentheses after the U.S. names. The comment stated that this approach would be consistent with provisions of the U.S. Canada Free Trade Agreement.

The agency believes that the common or usual names of certified color additives used in food, such as FD&C Blue No. 1 and FD&C Yellow No. 5, are recognized by consumers and broadly understood to be names of artificial colorings when they appear in an ingredient list. In addition, the certified color additives meet certain specifications, as provided in parts 74 and 82. The alternative names suggested in the comment may not represent the certified form of the specific color. For example, tartrazine may not be the U.S.

certified product, while FD&C Yellow No. 5 is the certified form of tartrazine.

Furthermore, the alternatives suggested in the comment have not been used in ingredient lists in the United States and are not recognized by FDA (part 74 (21 CFR part 74)) as the common or usual names of certified color additives. Accordingly, the agency is not persuaded that such names should be used at this time in place of common or usual names in the declaration of certified color additives.

However, the agency acknowledges the need, under the Free Trade Agreement, to accommodate Canadian labeling requirements where feasible. Declaration of both names for the U.S. certified color additives may facilitate familiarity with the alternative names for U.S. consumers. Therefore, manufacturers may voluntarily declare generally accepted alternative names, as suggested in the comment, in parentheses after the required U.S. name of the FDA certified color additive.

53. Another comment requested that the agency clarify that when several certified color additives are used in a food, they would have to be declared in descending order of predominance. The comment stated that proposed § 101.22(k) does not specifically address this issue. The comment was concerned that in instances where a combination of certified color additives and noncertified color additives is used in a food, the consumer would be confused because of the specific declaration of certified color additives and the use of a functional descriptor for noncertified color additives. The comment recommended that, when a combination of certified color additives and noncertified color additives is used in a food, the agency require both a functional descriptor and the listing of the specific names of all the color additives (certified and noncertified) in their order of predominance.

Declaration of certified color additives by their common or usual name must be done in a manner that complies with § 101.4. If more than one certified color additive is added to the food, the color additive present in the greatest amount must be declared first, unless the certified color additives are present at 2 percent or less and are, therefore, exempt from listing in order of predominance as provided in § 101.4(a)(2). With the exception of FD&C Yellow No. 5, current regulations have permitted collective declaration of certified and noncertified color additives, such that both "FD&C Yellow No. 5" and "artificial coloring" may appear on a food label. The agency has no evidence to indicate that consumers have been misled or confused by such a declaration. Consequently, the agency has no basis to conclude that declaration of certified and noncertified color additives as proposed would cause consumers confusion when both types of color additives are present in a food.

54. Another comment requested that FDA clarify whether dietary supplement manufacturers who comply with section 403(i) of the act, and have been permitted to list only those nutrients contained in the product for which a U.S. Recommended Daily Allowance (U.S. RDA) has been established, will be required to conform their ingredient listing to the regulation on color additives.

The agency acknowledges that a 1942 letter identified as TC-387 (Ref. 54) exempted "excipients, fillers, binders, and other fabricating ingredients" from complete ingredient declaration when used in manufacturing dietary supplements. Although TC-387 has not been officially revoked, the agency advises that its current policy, as stated in the **Federal Register** of August 2, 1973 (38 FR 20730), the **Federal Register** of March 16, 1979 (44 FR 16005), and in subsequent correspondence with industry (Refs. 55 and 56), is that the label for dietary supplements must contain a list of nutrients and a full statement of ingredients, except those exempted by section 403(i)(2) of the act, declared by the common or usual name. This policy is consistent with the ingredient declaration requirements for other types of products.

With regard to declaration of certified color additives, the 1990 amendments amended section 403(i)(2) of the act to require certified color additives be declared by their common or usual names. This requirement applies to all foods. However, in the Dietary Supplement Act of 1992, Congress imposed a moratorium on the implementation of the 1990 amendments with respect to dietary supplements with only very limited exceptions. Thus, FDA will not bring regulatory action against such products whose labels fail to declare the presence of certified color additives by their common or usual names until December 15, 1993.

55. Most comments responding to this issue strongly supported the use of abbreviated names for certified color additives. However, one comment maintained that certified color additives should be declared by their common or usual names as required in parts 74 and 82 and not by an abbreviated name unless there is a phase-in period of approximately 3 years during which both names would be used. The comment stated that this would allow consumers time to become familiar with the abbreviated name.

Because abbreviated names for certified color additives have been permitted and used by manufacturers since January 1983, the agency believes that consumers have a general understanding of these names, and are adequately informed about color additives. Consequently, an additional phase-in period is not necessary. Therefore, as proposed, the agency is providing the option to use abbreviated names for certified color additives in new § 101.22(k).

56. Several comments requested that the agency clarify the phrasing of the permitted abbreviated names. They pointed out that an FDA advisory opinion dated January 28, 1983, permitted the use of abbreviated names for color additives and the proposal of June 6, 1985 (50 FR 23815), permitted omission of not only "FD&C" but also "No." However, proposed § 101.22(k)(1) in the June 21, 1991, proposal only allowed the omission of the "FD&C" prefix from the declaration of a certified color additive in the ingredient list.

The agency acknowledges that proposed § 101.22(k)(1) in the June 21, 1991, proposal inadvertently omitted addressing the term "No." The agency intended to say that the abbreviated name need not include both "FD&C" and "No." FDA is revising new § 101.22(k)(1) accordingly.

57. The agency received several comments on the declaration of color additive lakes. Some of these comments recommended that abbreviated names should also apply to color additive lakes, so that their declaration would be consistent with that of certified color additives, e.g., "Blue 1 Lake." Other comments suggested that a single declaration (e.g., FD&C Blue No. 1) be used for both a certified color additive and its lake, or that the declaration of lakes of certified color additives follow the same requirements as certified color additives. These comments maintained that the difference between a certified color additive and its lake is one of technical functionality, and that consumers are unaware of the distinction. One comment argued that declaration of color additives and color additive lakes on the same information panel would lead to confusion and raise unnecessary questions in the consumer's mind. As an alternative, the comment recommended declaring lakes as dyes.

The agency agrees with those comments that stated that abbreviated names should also apply to certified

color additive lakes. Because this final rule provides for use of abbreviated names for certified color additives in foods, the agency finds that label declaration would be inconsistent and ultimately lead to consumer confusion if abbreviated names were not also allowed for certified color additive lakes. Accordingly, the agency is adopting, in § 101.22(k)(1), the option to declare the lake of a certified color additive using the abbreviated name of the certified color additive followed by the term "Lake." For example, a lake of FD&C Blue No. 1 would be "Blue 1 Lake."

The agency has no evidence to indicate that declaration of certified color additives and certified color additive lakes on the same information panel would lead to consumer confusion, and the comment did not present any evidence to substantiate this assertion. Furthermore, the agency believes that the use of the term "dye" for a lake would create an inappropriate distinction between a certified color additive and its lake by suggesting to consumers that certified color additive lakes are dyes, but that certified color additives are something other than dyes.

The agency is deferring rulemaking on the use of abbreviated names for color additives and lakes in drugs, cosmetics, and medical devices to separate action on the 1985 proposal.

58. One comment urged FDA to require that noncertified color additives be declared by name, so that consumers are provided with labeling information on noncertified color additives that is consistent with the labeling information on certified color additives. These comments asserted that noncertified color additives should also be declared by their common or usual names and not by collective terms, so that hypersensitive consumers can avoid foods to which they have chemical sensitivities.

Although the 1990 amendments modified section 403(i) of the act to require complete declaration of certified color additives, it did not revoke the exemption from ingredient labeling for noncertified color additives. Consequently, the agency does not have the authority to require specific declaration of noncertified color additives unless such declaration is necessary to ensure the safe use of the additive. Traditionally, the agency has encouraged manufacturers to list voluntarily, when practical, the specific names of all color additives following the functional descriptor. FDA has even provided guidance in new § 101.22(k)(2) for such a declaration.

The comment did not present any evidence to substantiate that there is a public health need for the specific declaration of all noncertified color additives. As with flavors and spices, FDA will consider requiring declaration of a noncertified color additive if such a need is demonstrated.

59. One comment stated that, although the proposal provided examples of specific declaration of noncertified color additives (e.g., caramel (color)), there appeared to be no reason to require the term "color" to be enclosed in parentheses. This comment requested clarification on whether parentheses were required, and if the term "caramel color" was an acceptable alternative.

The agency advises that the specific examples cited in the June 21, 1991, proposal for declaration of noncertified color additives were not intended to be all-inclusive. As discussed in the proposal, FDA will allow any informative term that clearly indicates to the consumer that a noncertified color additive has been added to the food. The agency advises that the term "caramel color" without parentheses adequately informs the consumer that caramel has been added to the food as a color additive.

60. Most comments generally supported FDA's recommendation, in proposed § 101.22(k)(3), for the voluntary declaration of all color additives in butter, cheese, and ice cream. These comments maintained that this practice would provide consumers with information for these three foods consistent with that now required for all other foods. No comments objected to this recommendation.

The agency is, therefore, finalizing its recommendation in new § 101.22(k) that when manufacturers add color additives to butter, cheese, or ice cream, they should voluntarily declare all color additives in the ingredient list.

61. Several comments from consumer interest groups requested that FDA require specific declaration of all flavors and spices on food labels. These comments contended that this information is important to individuals who have sensitivities to certain flavors and spices. The comments asserted that declaration of each spice and flavoring would enable these individuals to avoid foods that contain ingredients to which they are allergic.

Although the 1990 amendments required specific declaration of certified color additives, they did not amend the act to require specific declaration of flavorings or spices or of color additives that are not subject to certification. In the proposal, the agency tentatively concluded that, without such an amendment, it does not have the authority to generally require specific declaration of flavorings and spices. The comments summarized above were similar to the comments on the 1989 ANPRM that FDA reviewed when it was developing the June 21, 1991, proposal, and they did not provide any new information to justify their requests. However, if FDA determines that specific declaration of a flavor or spice is necessary to ensure its safe use, the agency will consider establishing requirements for label declaration of that flavor or spice by its common or usual name.

62. One comment requested clarification with respect to labeling of spices whose primary function is to color, e.g., paprika, a noncertified color additive. The comment argued that such an ingredient should not be labeled as a spice.

The agency encourages manufacturers to declare voluntarily specific spices and color additives they use in a food when practical. As for the label declaration of ingredients such as paprika (i.e., ingredients that have been declared GRAS as a spice and approved as a color additive), the agency expects manufacturers to declare such ingredients in a manner consistent with the ingredient's intended use in the food as provided in part 70 (21 CFR part 70). Section 70.3(f) provides that food ingredients that may contribute their own natural color when added to a food are not regarded as color additives, but when the ingredient is deliberately used as a color, it is a color additive. Therefore, if the intended use of an ingredient such as paprika is to color the food, it must be declared as an added color.

IX. Use of "And/Or" Labeling

FDA allows the use of "and/or" labeling in certain situations when manufacturers are unable to adhere to a consistent pattern of use of specific ingredients in their products (§ 101.4(b)). Such labeling provides a manufacturer with the flexibility to list together in the ingredient list of a food product all the ingredients of a particular type (e.g., fats or oils) that it sometimes uses to make the product, without having to specify the ingredients that are actually present in the product. To make clear that not all of the ingredients identified are actually present, the entry in the ingredient list must include the words "or," "and/or," or "contains one or more of the following." For example, the ingredient list on a package of crackers may include an entry, "partially

hydrogenated vegetable shortening (soybean oil, canola oil, and/or palm oil)."

In the June 21, 1991, proposal, FDA tentatively decided to continue to permit the use of "and/or" labeling for fats and oils. However, the agency requested any available scientific data on adverse reactions to fats or oils that would warrant a reconsideration of this decision.

The agency also discussed industry petitions that requested the use of "and/or" labeling of sweeteners, primarily for soft drinks (sodas) in the June 21, 1991, proposal. At that time, the agency denied the request for "and/or" labeling for sweeteners.

63. The majority of consumer comments addressing this issue opposed the continued use of "and/or" labeling for fats and oils for reasons already addressed in the June 21, 1991, proposal. These comments requested that the agency reconsider its position and revoke § 101.4(b)(14). These comments, however, did not offer any information that had not already been considered in developing the June 21, 1991, proposal.

In light of the 1990 amendments, which mandate declaration of the saturated fatty acid content of a food, and the revisions in nutrition labeling regulations proposed on November 27, 1991 (56 FR 60366), the agency does not believe that the potential benefits from requiring more specific labeling of fats and oils outweigh the possible impact of higher food costs that accrue when manufacturers are forced to change food labels in response to marketplace price fluctuations of fats and oils. In addition, the mandatory declaration of saturated fatty acid content grants the consumers' primary request regarding more information on saturated fats. Accordingly, FDA is not revoking § 101.4(b)(14).

It should be noted that § 101.4(b)(14) restricts "and/or" labeling to situations in which fats and oils are not the predominant ingredient. The agency is not changing this restriction.

64. One comment requested the option to use an "and/or" statement to list specific protein hydrolysates in canned tuna. The comment asserted that "and/or" labeling would give tuna processors the flexibility to select protein hydrolysates for use as flavor enhancers in canned tuna, based on cost considerations and the availability of these ingredients, without having to change labels.

FDA is not granting this request. Designation of the specific source of protein when protein hydrolysate is listed in the ingredient statement of the label alerts consumers to the exact identity of this ingredient. Such declaration of protein hydrolysates provides a tangible benefit to consumers who may be avoiding a particular protein source because of religious or cultural beliefs or other personal reasons. While FDA recognizes the need for flexibility in the selection of the protein hydrolysates used for flavor enhancing purposes in canned tuna, the agency believes that a provision for "and/or" labeling of the protein hydrolysate would defeat the purpose of this declaration.

As stated elsewhere in this document, FDA believes that consumers have a right to be able to choose between products on the basis of the ingredients contained in the foods. Disjunctive labeling on canned tuna, i.e., "and/or" labeling, limits consumers' choices because they must avoid all tuna products that may contain a certain protein hydrolysate when this ingredient is listed as one of several alternative protein hydrolysates on the label. Even though most protein hydrolysates used for flavor enhancement are highly hydrolyzed and unlikely to cause adverse reactions, FDA believes that manufacturers should continue to provide specific source information on protein hydrolysates to enable consumers to make choices based on their personal, cultural, or religious beliefs. Therefore, FDA is not making the requested change in the standard of identity for canned tuna.

FDA acknowledges that "and/or" labeling is used for fats and oils to provide a measure of flexibility in the selection and use of these ingredients in foods. In such cases, however, FDA notes that there is potential for cost savings which can be passed on to consumers when manufacturers have the option of selecting oils suitable for a particular food operation, based on cost and availability. This is particularly significant because food oils are used in large volumes in food production; protein hydrolysates generally are not. Moreover, no information on the magnitude of potential costs savings was presented in the comment. In addition, the use of "and/or" labeling with fats and oils is augmented by information concerning the fat, fatty acid, and cholesterol contents of the foods in nutrition labeling, thus providing further information to enable consumers to avoid foods that contain levels of cholesterol, total fat, or saturated fat that are inconsistent with their nutrition goals.

65. Comments requesting that the agency reconsider its position on the use of "and/or" labeling for sweeteners argued that, while present price relationships between sugar and corn sweeteners may be relatively constant, there is no guarantee that either sugar processing costs or the impact of the U.S. sugar program on prices will remain static. The comments further stated that advances in processing technologies may cause changes in traditional price relationships, and that manufacturers will need the flexibility of "and/or" labeling to remain competitive.

The agency acknowledges that price fluctuations between sugar and corn sweeteners may eventually occur. If and when FDA is provided evidence that significant price fluctuations occur among different sweeteners, or the flexibility of "and/or" labeling otherwise becomes necessary, the agency will consider initiating rulemaking to permit this labeling exemption.

66. Comments from the soft drink industry requested that the agency reconsider the citizen petition of the National Soft Drink Association (NSDA) (January 20, 1984—Docket No. 84P-0029) and provide for use of "and/or" labeling for sweeteners in soft drinks. The agency has reconsidered the citizen petition of the NSDA and is proposing, as discussed elsewhere in this issue of the **Federal Register**, to allow "and/or" labeling for sweeteners in soft drinks.

X. Other Labeling Issues

A. Ingredient List Format

In the June 21, 1991, proposal, the agency discussed several ways that the readability of the ingredient list might be enhanced. However, the agency was not aware of any evidence that the current ingredient labeling format was not adequate to meet the labeling requirements provided in section 403(f) of the act. Without such evidence, the agency had no basis to propose new format requirements for ingredient labeling. Hence, the agency requested that if there is a need to revise the ingredient list format, comments provide data to substantiate the need and to describe what changes would improve the label.

67. A number of comments opposed separation of ingredient declaration of major and minor ingredients and expressed concern that such a separation might lead consumers to pay less attention than is merited to those ingredients listed as minor, which may include chemicals that have a significant health effect. Some comments also expressed concern that such a requirement could result in a further division between the United

States and the European Economic Community labeling requirements and create a barrier to trade. Finally, one comment stated that proposed § 101.4(a)(2) allows the option of separate declaration for ingredients present at two percent or less when preceded by an appropriate quantifying statement. Thus, the comment saw no reason to require the separation of major and minor ingredients. On the other hand, a few comments supported separation of the ingredient statement.

The agency has considered the positions presented in all of the comments. As stated in the June 21, 1991, proposal, the agency believes that separation of the ingredient statement into major and minor ingredients, would improve readability. However, the comments supporting separation of the ingredient list did not present evidence that the current labeling format did not fully satisfy section 403(f) of the act. Thus, the agency is not requiring separation of major and minor ingredients in this final rule.

68. The comments addressing increased type size requirements on the ingredient label generally recommended that readability would be enhanced by the use of capital and lower case letters without right margin justification printed in distinct contrast to other printed or graphic matter on an appropriate background. One of the comments reported that labels with black lettering on blue background or black lettering on red background are difficult to read.

The agency allows manufacturers to print ingredient lists in capital and lower case letters. The agency has no requirements with respect to right margin justification and allows use of this format. Furthermore, the agency allows the manufacturer flexibility in choosing specific color schemes for labeling and packaging. However, the agency emphasizes that the color schemes and printing used in ingredient labeling must comply with the provisions of section 403(f) of the act, which require that the information be conspicuous and have sufficient contrast to its background as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. Furthermore, in § 101.2(c) with § 101.105(h), the agency requires that information appearing on the ingredient label shall appear prominently and conspicuously in easily legible boldface print or type in distinct contrast to other printed or graphic matter on the label. Thus, the agency has concluded that several of the recommendations presented in the comments are incorporated in current labeling requirements. The agency has further concluded that current labeling requirements with respect to format, except as discussed in the wax and resin section of this document, are adequate to meet the requirements of the act and, therefore, finds no basis to revise them at this time.

B. Restaurant Foods

In the June 21, 1991, proposal, the agency requested comments on the practicability and feasibility of requiring ingredient labeling of restaurant foods. In addition, the agency also requested suggestions for appropriate ingredient labeling formats for restaurant foods if such labeling were required.

69. Several comments from consumers and consumer interest groups supported full ingredient disclosure for restaurants that maintain standardized menus (e.g., chain or fast food restaurants). In support of their position, these comments argued that because standardized menu items are all prepared in the same manner, they are conducive to ingredient labeling. One comment recommended, however, that ingredient labeling for chain restaurants be done on a trial basis before instituting regulations. Another comment from a chain pizza restaurant opposed ingredient labeling for restaurants. The comment asserted that it would be impossible for restaurants to use ingredient labeling because it would: (1) Hinder work on new formulations; (2) require a standardized menu; (3) limit menu items; and (4) escalate prices. In the alternative, the comment recommended that restaurants distribute a brochure providing ingredient information for any food item that might be used in their products. The brochures would be distributed at point of purchase or available upon request through a toll-free number. This comment urged the agency not to require ingredient labeling for chain restaurants.

The agency believes that it may be feasible for certain types of restaurants (e.g., chain or fast food restaurants with standardized food preparation and ingredient specifications) to provide ingredient information. However, the agency has not received enough information about the industry to determine the appropriateness and manner of requiring ingredient labeling by restaurants. While it is not adopting requirements at this time for ingredient labeling of restaurant foods, FDA encourages such declarations on a voluntary basis.

As discussed in the June 21, 1991, proposal, the agency cannot reasonably expect restaurants that frequently change their menu items to provide information on ingredients. The agency concurs with the comment that a brochure would be helpful to consumers in providing information on ingredients used in prepared foods when it is impractical for a restaurant to provide ingredient information for all menu items. The agency encourages restaurants to provide written information regarding ingredients used in prepared foods when practical.

C. Vendor Foods

70. Several comments from the vending industry requested that the agency exempt foods sold from automatic vending machines from ingredient declaration requirements. These comments did not, however, provide information to substantiate their request that the agency had not already considered in developing the June 21, 1991, proposal.

In the absence of information not already considered by the agency, and for the reasons discussed in the proposal, FDA reaffirms its previous decision not to exempt vendor foods from full ingredient labeling requirements.

D. Warning Statements

71. One of the issues addressed in the June 21, 1991, proposal was the practicality and desirability of requiring warning statements on foods to announce the presence of specific ingredients. At that time, the agency tentatively decided not to require the broad use of warning statements with respect to ingredients.

Comments on this issue generally supported FDA's position not to require warning statements in the absence of clear evidence of a health hazard. The comments warned that an overabundance of warning statements may desensitize the general public to safety concerns and subsequently cause warning statements to lose some of their value as a means of informing the consumer about potential health hazards.

The agency affirms its tentative position and does not intend to require warning statements except in specific instances where there is scientifically based evidence of a potential health hazard.

E. Simplified Names for Ingredients

72. The agency discussed, in the June 21, 1991, proposal, the various criteria that must be met before a new simplified name for an ingredient can supplant an established name in the ingredient list. Specifically, the new

name must be descriptive of the ingredient, must not provide misleading label information, and must be shown to be recognized by consumers.

The agency did not receive any comments addressing this issue. Therefore the agency does not plan to change any of the criteria discussed in the proposal.

F. Statements of Ingredients' Functions

73. In the June 21, 1991, proposal the agency said that it would consider any suggestions for declaration of the function of a particular ingredient or group of ingredients that are supported by appropriate evidence and that can be justified under one of the relevant statutory standards (i.e., sections 409(c) and 201(n) of the act). Since the comments did not provide evidence to support the declaration of the function of a particular ingredient or group of ingredients, the agency is not adopting any new requirements to list the function or purpose of food ingredients.

G. Irradiated Ingredients

74. One comment opposed declaration of irradiated foods by their common or usual names without specific declaration of irradiation and argued that consumers should be informed about the processing of the food. The comment did not present information not already considered by the agency in developing the June 21, 1991, proposal.

As stated in the proposal, the agency addressed the issue of declaration of irradiated ingredients in the **Federal Register** of December 30, 1988 (53 FR 53176). At that time, the agency concluded that irradiated ingredients should be declared by their common or usual name without additional information on processing. The agency finds no basis on which to revise its 1988 decision.

XI. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

XII. Environmental Impact

The agency previously considered the environmental effects of the action being taken in this final rule. As announced in the June 21, 1991, proposal the agency determined that under 21 CFR 25.24(a)(11), this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

XIII. Effective Date

Several comments from the food industry strongly urged FDA to reconsider the effective date for ingredient labeling regulations for standardized foods and certified color additives. The comments argued that a November 8, 1991, effective date would not allow the food industry enough time to develop the required labeling and would significantly increase costs, because inventory would have to be discarded. These comments strongly urged FDA to establish a uniform effective date, for all proposed changes in ingredient labeling, to comply with the effective date for section 403(q) of the act (mandatory nutrition labeling) and section 403(r) (claims), which were added by the 1990 amendments.

Section 10(c) of the 1990 amendments established an effective date of November 8, 1991, for ingredient labeling of standardized foods and color additives required to be certified. However, Congress changed that effective date on August 17, 1991, and established a new effective date of May 8, 1993. In the November 27, 1991, **Federal Register** (56 FR 60877), the agency published information on this change in the effective date for standardized foods and certified color additives. As stated in that document, labels attached to food after May 8, 1993, will be subject to amended section 403(i) of the act and to this final rule. However, labels printed after July 1, 1991, but before the effective date of this final rule and applied before May 8, 1993, must comply with the June 21, 1991, proposal. Thus, the effective date of the final provisions in this regulation for standardized foods and certified color additives is May 8, 1993. The other final provisions in this regulation become effective on May 8, 1994.

XIV. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects

21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

21 CFR Part 102

Beverages, Food grades and standards, Food labeling, Frozen foods, Fruit juices, Oils and fats, Onions, Potatoes, Seafood.

21 CFR Part 130

Food additives, Food grades and standards, Incorporation by reference.

21 CFR Part 135

Food grades and standards, Food labeling, Frozen foods, Ice cream.

21 CFR Part 136

Bakery products, Food grades and standards.

21 CFR Part 137

Cereals (food), Food grades and standards.

21 CFR Part 139

Food grades and standards.

21 CFR Part 145

Food grades and standards, Fruits.

21 CFR Part 146

Food grades and standards, Fruit juices.

21 CFR Part 150

Food grades and standards, Fruits.

21 CFR Part 152

Bakery products, Food grades and standards, Frozen foods, Fruits.

21 CFR Part 155

Food grades and standards, Vegetables.

21 CFR Part 156

Food grades and standards, Vegetable juices.

21 CFR Part 158

Food grades and standards, Frozen foods, Vegetables.

21 CFR Part 160

Eggs and egg products, Food grades and standards.

21 CFR Part 161

Food grades and standards, Frozen foods, Seafood.

21 CFR Part 163

Cacao products, Food grades and standards.

21 CFR Part 164

Food grades and standards, Nuts, Peanuts.

21 CFR Part 166

Food grades and standards, Food labeling, Margarine.

21 CFR Part 168

Food grades and standards, Sugar.

21 CFR Part 169

Food grades and standards, Oils and fats, Spices and flavorings.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, FDA is amending 21 CFR parts 101, 102, 130, 135, 136, 137, 139, 145, 146, 150, 152, 155, 156, 158, 160, 161, 163, 164, 166, 168, and 169 as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.4 is amended by revising paragraphs (a)(1), and (b)(2)(i), and by adding new paragraphs (b)(20) through (b)(22), (d), (e), and (f) to read as follows:

§ 101.4 Food; designation of ingredients.

(a)(1) Ingredients required to be declared on the label or labeling of a food, including foods that comply with standards of identity, except those ingredients exempted by § 101.100, shall be listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel in accordance with the provisions of § 101.2.

* * * * *

(b) * * *

(2) * * *

(i) By declaring the established common or usual name of the ingredient followed by a parenthetical listing of all ingredients contained therein in descending order of predominance except that, if the ingredient is a food subject to a definition and standard of identity established in subchapter B of this chapter that has specific labeling provisions for optional ingredients, optional ingredients may be declared within the parenthetical listing in accordance with those provisions.

* * * * *

(20) For purposes of ingredient labeling, the term "sugar" shall refer to sucrose, which is obtained from sugar cane or sugar beets in accordance with the provisions of § 184.1854 of this chapter.

(21) [Reserved]

(22) Wax and resin ingredients on fresh produce when such produce is held for retail sale, or when held for other than retail sale by packers or repackers shall be declared collectively by the phrase "coated with food-grade animal-based wax, to maintain freshness" or the phrase "coated with food-grade vegetable-, petroleum-, beeswax-, and/or shellac-based wax or resin, to maintain freshness" as appropriate. The terms "food-grade" and "to maintain freshness" are optional. The term "lac-resin" may be substituted for the term "shellac."

* * * * *

(d) When foods characterized on the label as "nondairy" contain a caseinate ingredient, the caseinate ingredient shall be followed by a parenthetical statement identifying its source. For example, if the manufacturer uses the term "nondairy" on a creamer that contains sodium caseinate, it shall include a parenthetical term such as "a milk derivative" after the listing of sodium caseinate in the ingredient list.

(e) If the percentage of an ingredient is included in the statement of ingredients, it shall be shown in parentheses following the name of the ingredient and expressed in terms of percent by weight. Percentage declarations shall be expressed to the nearest 1 percent, except that where ingredients are present at levels of 2 percent or less, they may be grouped together and expressed in accordance with the quantifying guidance set forth in paragraph (a)(2) of this section.

(f) Except as provided in § 101.100 ingredients that must be declared on labeling because there is no label for the food, including foods that comply with standards of identity, shall be listed prominently and conspicuously by common or usual name in the manner prescribed by paragraph (b) of this section.

§ 101.6 [Removed]

3. Section 101.6 *Label designation of ingredients for standardized foods* is removed from subpart A.

4. Section 101.22 is amended by adding new paragraphs (h)(7) and (k) to read as follows:

§ 101.22 Foods; labeling of spices, flavorings, colorings and chemical preservatives.

* * * * *

(h) * * *

(7) Because protein hydrolysates function in foods as both flavorings and flavor enhancers, no protein hydrolysate used in food for its effects on flavor may be declared simply as "flavor," "natural flavor," or "flavoring." The ingredient shall be declared by its specific common or usual name as provided in § 102.22 of this chapter.

* * * * *

(k) The label of a food to which any coloring has been added shall declare the coloring in the statement of ingredients in the manner specified in paragraphs (k)(1) and (k)(2) of this section, except that colorings added to butter, cheese, and ice cream, if declared, may be declared in the manner specified in paragraph (k)(3) of this section, and colorings added to foods subject to §§ 105.62 and 105.65 of this chapter shall be declared in accordance with the requirements of those sections.

(1) A color additive or the lake of a color additive subject to certification under 706(c) of the act shall be declared by the name of the color additive listed in the applicable regulation in part 74 or part 82 of this chapter, except that it is not necessary to include the "FD&C" prefix or the term "No." in the declaration, but the term "Lake" shall be included in the declaration of the lake of the certified color additive (e.g., Blue 1 Lake). Manufacturers may parenthetically declare an appropriate alternative name of the certified color additive following its common or usual name as specified in part 74 or part 82 of this chapter.

(2) Color additives not subject to certification may be declared as "Artificial Color," "Artificial Color Added," or "Color Added" (or by an equally informative term that makes

clear that a color additive has been used in the food). Alternatively, such color additives may be declared as "Colored with ——————" or "——————— color", the blank to be filled with the name of the color additive listed in the applicable regulation in part 73 of this chapter.

(3) When a coloring has been added to butter, cheese, or ice cream, it need not be declared in the ingredient list unless such declaration is required by a regulation in part 73 or part 74 of this chapter to ensure safe conditions of use for the color additive. Voluntary declaration of all colorings added to butter, cheese, and ice cream, however, is recommended.

§ 101.35 [Removed]

5. Section 101.35 *Notice to manufacturers and users of monosodium glutamate and other hydrolyzed vegetable protein products* is removed from subpart B.

6. Section 101.100 is amended by revising paragraph (a)(2) to read as follows:

§ 101.100 Food; exemptions from labeling.

(a) * * *

(2) A food having been received in bulk containers at a retail establishment, if displayed to the purchaser with either:

(i) The labeling of the bulk container plainly in view, provided ingredient information appears prominently and conspicuously in lettering of not less than one-fourth of an inch in height; or

(ii) A counter card, sign, or other appropriate device bearing prominently and conspicuously, but in no case with lettering of less than one-fourth of an inch in height, the information required to be stated on the label pursuant to section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act (the act).

* * * * *

PART 102—COMMON OR USUAL NAME FOR NONSTANDARDIZED FOODS

7. The authority citation for 21 CFR part 102 continues to read as follows:

Authority: Secs. 201, 403, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 343, 371).

8. New § 102.22 is added to subpart B to read as follows:

§ 102.22 Protein hydrolysates.

The common or usual name of a protein hydrolysate shall be specific to the ingredient and shall include the identity of the food source from which the protein was derived.

(a) "Hydrolyzed wheat gluten," "hydrolyzed soy protein," and "autolyzed yeast extract" are examples of acceptable names. "Hydrolyzed casein" is also an example of an acceptable name, whereas "hydrolyzed milk protein" is not an acceptable name for this ingredient because it is not specific to the ingredient (hydrolysates can be prepared from other milk proteins). The names "hydrolyzed vegetable protein" and "hydrolyzed protein" are not acceptable because they do not identify the food source of the protein.

(b) [Reserved]

PART 130—FOOD STANDARDS: GENERAL

9. The authority citation for 21 CFR part 130 continues to read as follows:

Authority: Secs. 201, 306, 401, 403, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 336, 341, 343, 371).

10. Section 130.3 is amended by adding new paragraph (e) to read as follows:

§ 130.3 Definitions and interpretations.

* * * * *

(e) Section 403(i) of the act requires the listing of all ingredients in standardized foods. All ingredients must be listed in accordance with the requirements of part 101 of this chapter, except that where a definition and standard of identity has specific labeling provisions for optional ingredients, optional ingredients may be declared in accordance with those provisions.

11. New § 130.9 is added to subpart A to read as follows:

§ 130.9 Sulfites in standardized food.

(a) Any standardized food that contains a sulfiting agent or combination of sulfiting agents that is functional and provided for in the applicable standard or that is present in the finished food at a detectable level is misbranded unless the presence of the sulfiting agent or agents is declared on the label of the food. A detectable amount of sulfiting agent is 10 parts per million or more of the sulfite in the finished food. The level of sulfite in the finished food will be determined using sections 20.123 through 20.125, "Sulfurous Acid (Total) in Food Modified Monier-Williams Method Final Action" in "Official Methods of Analysis of the Association of Official Analytical Chemists," 14th ed. (1984), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, and the refinements of the "Total Sulfurous Acid" procedure in the "Monier-Williams Procedure (with Modifications) for Sulfites in Foods," which is appendix A to part 101 of this chapter. A copy of sections 20.123 through 20.125 of the "Official Methods of Analysis of the Association of Official Analytical Chemists" is available from AOAC International, 1111 North 19th St., Suite 210, Arlington, VA 22209, or available for inspection at the Office of the Federal Register, 800 North Capitol St. NW., Suite 700, Washington, DC.

(b) Any standardized food that, as a result of actions that are consistent with current good manufacturing practice, contains an indirectly added sulfiting agent that has no functional effect in the food and that would, in the absence of § 101.100(a)(4) of this chapter, be considered to be an incidental additive for purposes of § 130.8, conforms to the applicable definition and standard of identity if the presence of the sulfiting agent is declared on the label of the food.

12. New § 130.11 is added to subpart A to read as follows:

§ 130.11 Label designations of ingredients for standardized foods.

Some definitions and standards of identity for foods set forth below require that designated optional ingredients such as spices, flavorings, colorings, emulsifiers, flavor enhancers, stabilizers, preservatives, and sweeteners be declared in a specified manner on the label wherever the name of the standardized food appears on the label so conspicuously as to be easily seen under customary conditions of purchase. Such requirements shall apply to a manufacturer, packer, or distributor of a standardized food only if the words or statements on the label of the standardized food significantly differentiate between two or more foods that comply with the same standard by describing the optional forms or varieties, the packing medium, or significant characterizing ingredients present in the food.

PART 135—FROZEN DESSERTS

13. The authority citation for 21 CFR part 135 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

14. Section 135.160 is amended by revising paragraph (a) to read as follows:

§ 135.160 Water ices.

(a) *Description.* Water ices are the foods each of which is prepared from the same ingredients and in the same manner prescribed in § 135.140 for sherbets, except that the mix need not

be pasteurized, and complies with all the provisions of § 135.140 (including the requirements for label statement of ingredients), except that no milk or milk-derived ingredient and no egg ingredient, other than egg white, is used.

* * * * *

PART 136—BAKERY PRODUCTS

15. The authority citation for 21 CFR part 136 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

16. Section 136.110 is amended by revising paragraph (f) to read as follows:

§ 136.110 Breads, rolls, and buns.

* * * * *

(f) *Label declaration.* Each of the ingredients used shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

PART 137—CEREAL FLOURS AND RELATED PRODUCTS

17. The authority citation for 21 CFR part 137 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

18. Section 137.105 is amended by revising paragraph (b)(1) to read as follows:

§ 137.105 Flour.

* * * * *

(b)(1) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

19. Section 137.155 is revised to read as follows:

§ 137.155 Bromated flour.

Bromated flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for flour by § 137.105, except that potassium bromate is added in a quantity not exceeding 50 parts to each million parts of the finished bromated flour, and is added only to flours whose baking qualities are improved by such addition.

20. Section 137.160 is revised to read as follows:

§ 137.160 Enriched bromated flour.

Enriched bromated flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for enriched flour by § 137.165, except that potassium bromate is added in a quantity not exceeding 50 parts to each million parts of the finished enriched bromated flour, and is added only to enriched flours whose baking qualities are improved by such addition.

21. Section 137.165 is amended by revising the introductory text to read as follows:

§ 137.165 Enriched flour.

Enriched flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for flour by § 137.105, except that:

* * * * *

22. Section 137.170 is amended by revising paragraph (a) to read as follows:

§ 137.170 Instantized flours.

(a) Instantized flours, instant blending flours, and quick-mixing flours, are the foods each of which conforms to the definition and standard of identity and is subject to the requirement for label statement of ingredients prescribed for the corresponding kind of flour by §§ 137.105, 137.155, 137.160, 137.165, 137.175, 137.180, and 137.185, except that each such flour has been made by one of the optional procedures set forth in paragraph (b) of this section, and is thereby made readily pourable. Such flours will all pass through a No. 20 mesh U.S. standard sieve (840-micron opening), and not more than 20 percent will pass through a 200 mesh U.S standard sieve (74-micron opening).

* * * * *

23. Section 137.175 is amended by revising the introductory text to read as follows:

§ 137.175 Phosphated flour.

Phosphated flour, phosphated white flour, and phosphated wheat flour, conform to the definition and standard of identity, and are subject to the requirements for label declaration of ingredients, prescribed for flour by § 137.105, except that:

* * * * *

24. Section 137.180 is amended by revising paragraph (b) to read as follows:

§ 137.180 Self-rising flour.

* * * * *

(b) Label declaration. Each of the ingredients used in the food, shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

25. Section 137.185 is amended by revising the introductory text to read as follows:

§ 137.185 Enriched self-rising flour.

Enriched self-rising flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for self-rising flour by § 137.180, except that:

* * * * *

26. Section 137.200 is amended by revising paragraph (b)(1) to read as follows:

§ 137.200 Whole wheat flour.

* * * * *

(b)(1) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

27. Section 137.205 is revised to read as follows:

§ 137.205 Bromated whole wheat flour.

Bromated whole wheat flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for whole wheat flour by § 137.200, except that potassium bromate is added in a quantity not exceeding 75 parts to each million parts of finished bromated whole wheat flour.

28. Section 137.225 is revised to read as follows:

§ 137.225 Whole durum flour.

Whole durum wheat flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for whole wheat flour by § 137.200, except that cleaned durum wheat, instead of cleaned wheat other than durum wheat and red durum wheat, is used in its preparation.

29. Section 137.235 is amended by adding new paragraph (c) to read as follows:

§ 137.235 Enriched corn grits.

* * * * *

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

30. Section 137.260 is amended by adding new paragraph (c) to read as follows:

§ 137.260 Enriched corn meals.

* * * * *

(c) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

31. Section 137.270 is amended by adding new paragraph (c) to read as follows:

§ 137.270 Self-rising white corn meal.

* * * * *

(c) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

32. Section 137.305 is amended by revising paragraph (b)(1) to read as follows:

§ 137.305 Enriched farina.

* * * * *

(b)(1) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

33. Section 137.350 is amended by adding new paragraph (g) to read as follows:

§ 137.350 Enriched rice.

* * * * *

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

PART 139—MACARONI AND NOODLE PRODUCTS

34. The authority citation for 21 CFR part 139 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

35. Section 139.110 is amended by adding new paragraph (g) to read as follows:

§ 139.110 Macaroni products.

* * * * *

(g) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

36. Section 139.115 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 139.115 Enriched macaroni products.

(a) Description. Enriched macaroni products are the class of food each of which conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients, prescribed for macaroni products by § 139.110(a), (f), and (g), except that:

* * * * *

37. Section 139.117 is amended by revising paragraph (e) to read as follows:

§ 139.117 Enriched macaroni products with fortified protein.

* * * * *

(e) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

38. Section 139.120 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 139.120 Milk macaroni products.

(a) Milk macaroni products are the class of food, each of which conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients prescribed for macaroni products by § 139.110(a), (f)(2), (f)(3), and (g), except that:

* * * * *

39. Section 139.121 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 139.121 Nonfat milk macaroni products.

(a) Each of the macaroni products made with nonfat milk for which a definition and standard of identity is prescribed by this section conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for macaroni products by § 139.110(a), (f)(2), (f)(3), (f)(4), and (g), except that:

* * * * *

40. Section 139.122 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 139.122 Enriched nonfat milk macaroni products.

(a) Each of the enriched macaroni products made with nonfat milk for which a definition and standard of identity is prescribed by this section conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for macaroni products by § 139.110(a), (f)(2), (f)(3), (f)(4), and (g), except that:

* * * * *

41. Section 139.125 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 139.125 Vegetable macaroni products.

(a) Vegetable macaroni products are the class of food each of which conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients prescribed for macaroni products by § 139.110(a), (f)(2), (f)(3), and (g), except that:

* * * * *

42. Section 139.135 is amended by revising paragraph (a) to read as follows:

§ 139.135 Enriched vegetable macaroni products.

(a) Each of the macaroni products for which a definition and standard of identity is prescribed by this section conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients prescribed for macaroni products by § 139.110(a), (f), and (g), and in addition is enriched to meet the requirements prescribed for enriched macaroni products by § 139.115 and contains a vegetable ingredient in compliance with the requirements prescribed for vegetable macaroni products by § 139.125.

* * * * *

43. Section 139.138 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 139.138 Whole wheat macaroni products.

(a) Whole wheat macaroni products are the class of food each of which conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients, prescribed for macaroni products by § 139.110(a), (f)(2), (f)(3), and (g), except that:

* * * * *

44. Section 139.140 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 139.140 Wheat and soy macaroni products.

(a) Wheat and soy macaroni products are the class of food each of which conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients, prescribed for macaroni products by § 139.110(a), (f)(2), (f)(3), and (g), except that:

* * * * *

45. Section 139.150 is amended by adding new paragraph (i) .o read as follows:

§ 139.150 Noodle products.

* * * * *

(i) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

46. Section 139.155 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 139.155 Enriched noodle products.

(a) Enriched noodle products are the class of food each of which conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for noodle products by § 139.150(a), (g), and (i), except that:

* * * * *

47. Section 139.160 is amended by revising paragraph (a) to read as follows:

§ 139.160 Vegetable noodle products.

(a) Vegetable noodle products are the class of food each of which conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for noodle products by § 139.150(a), (g), and (i), except that tomato (of any red variety), artichoke, beet, carrot, parsley, or spinach is added in such quantity that the solids thereof are not less than 3 percent by weight of the finished vegetable noodle product (the vegetable used may be fresh, canned, dried, or in the form of puree or paste).

* * * * *

48. Section 139.165 is amended by revising paragraph (a) to read as follows:

§ 139.165 Enriched vegetable noodle products.

(a) Each of the noodle products for which a definition and standard of identity is prescribed by this section conforms to the definition and standard of identity and is subject to the requirements for label declaration of ingredients prescribed for noodle products by § 139.150(a), (g), (h), and (i), and in addition is enriched to meet the requirements prescribed for enriched noodle products by § 139.155 and, except as hereinafter provided, contains a vegetable ingredient in compliance with the requirements prescribed for vegetable noodle products by § 139.160. Because they are apt to impart an egg-yolk color, carrots are not used in enriched vegetable noodle products.

* * * * *

49. Section 139.180 is amended by revising paragraph (a) to read as follows:

§ 139.180 Wheat and soy noodle products.

(a) Wheat and soy noodle products are the class of food each of which conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients prescribed for noodle products by § 139.150(a), (g), and (i), except that soy flour is added in a quantity not less than 12.5 percent of the combined weight of the wheat and soy ingredients used (the soy flour used is made from heat-processed, dehulled soybeans, with or without the removal of fat therefrom).

* * * * *

PART 145—CANNED FRUITS

50. The authority citation for 21 CFR part 145 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

51. Section 145.110 is amended by revising paragraph (a)(4) to read as follows:

§ 145.110 Canned applesauce.

(a) * * *

(4) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter. However, when ascorbic acid (vitamin C) is added as provided for in paragraph (a)(2)(viii)(*b*) of this section, after the application of heat to the apples, preservative labeling requirements do not apply.

* * * * *

52. Section 145.115 is amended by revising paragraph (a)(4)(iv) to read as follows:

§ 145.115 Canned apricots.

(a) * * *

(4) * * *

(iv) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

53. Section 145.116 is amended by revising paragraph (b)(2) to read as follows:

§ 145.116 Artificially sweetened canned apricots.

* * * * *

(b) * * *

(2) The artificially sweetened food is subject to the requirements for label statement of ingredients used, as prescribed for canned apricots by § 145.115(a). If the packing medium is thickened with pectin, the label shall bear the statement "thickened with pectin". When any organic salt or acid or any mixture of two or more of these is added, the label shall bear the common or usual name of each such ingredient.

54. Section 145.120 is amended by revising paragraph (a)(5)(iv) to read as follows:

§ 145.120 Canned berries.

(a) * * *

(5) * * *

(iv) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

55. Section 145.125 is amended by revising paragraph (a)(4)(iv) to read as follows:

§ 145.125 Canned cherries.

(a) * * *

(4) * * *

(iv) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

56. Section 145.126 is amended by revising paragraph (b)(2) to read as follows:

§ 145.126 Artificially sweetened canned cherries.

* * * * *

(b) * * *

(2) The artificially sweetened food is subject to the requirements for label statement of ingredients used, as prescribed for canned cherries by § 145.125(a). If the packing medium is thickened with pectin, the label shall bear the statement "thickened with pectin". When any organic salt or acid or any mixture of two or more of these is added, the label shall bear the common or usual name of each such ingredient.

57. Section 145.130 is amended by revising paragraph (d)(4) to read as follows:

§ 145.130 Canned figs.

* * * * *

(d) * * *

(4) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

58. Section 145.131 is amended by revising paragraph (b)(2) to read as follows:

§ 145.131 Artificially sweetened canned figs.

* * * * *

(b) * * *

(2) The artificially sweetened food is subject to the requirements for label statement of ingredients used, as prescribed for canned figs by § 145.130. If the packing medium is thickened with pectin, the label shall bear the statement "thickened with pectin". When any organic salt or acid or any mixture of two or more of these is added, the label shall bear the common or usual name of each such ingredient.

59. Section 145.134 is amended by adding new paragraph (f) to read as follows:

§ 145.134 Canned preserved figs.

* * * * *

(f) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

60. Section 145.135 is amended by revising paragraph (a)(4)(iv) to read as follows:

§ 145.135 Canned fruit cocktail.

(a) * * *

(4) * * *

(iv) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

61. Section 145.136 is amended by revising paragraph (b)(2) to read as follows:

§ 145.136 Artificially sweetened canned fruit cocktail.

* * * * *

(b) * * *

(2) The artificially sweetened food is subject to the requirements for label statement of ingredients used, as prescribed for canned fruit cocktail by § 145.135(a). If the packing medium is thickened with pectin, the label shall bear the statement "thickened with pectin". When any organic salt or acid or any mixture of two or more of these is added, the label shall bear the common or usual name of each such ingredient.

62. Section 145.140 is amended by revising paragraph (d)(4) to read as follows:

§ 145.140 Canned seedless grapes.

* * * * *

(d) * * *

(4) Label declaration Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

63. Section 145.145 is amended by revising paragraph (a)(4)(iii) to read as follows:

§ 145.145 Canned grapefruit.

(a) * * *

(4) * * *

(iii) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

64. Section 145.170 is amended by revising paragraph (a)(4)(iv) to read as follows:

§ 145.170 Canned peaches.

(a) * * *

(4) * * *

(iv) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

65. Section 145.171 is amended by revising paragraph (b)(2) to read as follows:

§ 145.171 Artificially sweetened canned peaches.

* * * * *

(b) * * *

(2) The artificially sweetened food is subject to the requirements for label statement of ingredients used, as prescribed for canned peaches by § 145.170(a). If the packing medium is thickened with pectin, the label shall bear the statement "thickened with pectin". When any organic salt or acid or any mixture of two or more of these is added, the label shall bear the common or usual name of each such ingredient.

66. Section 145.175 is amended by revising paragraph (a)(4)(iv) to read as follows:

§ 145.175 Canned pears.

(a) * * *

(4) * * *

(iv) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

67. Section 145.176 is amended by revising paragraph (b)(2) to read as follows:

§ 145.176 Artificially sweetened canned pears.

* * * *

(b) * * *

(2) The artificially sweetened food is subject to the requirements for label statement of ingredients used, as prescribed for canned pears by § 145.175(a). If the packing medium is thickened with pectin, the label shall bear the statement "thickened with pectin". When any organic salt or acid or any mixture of two or more of these is added, the label shall bear the common or usual name of each such ingredient.

68. Section 145.180 is amended by revising paragraph (a)(5)(iii) to read as follows:

§ 145.180 Canned pineapple.

(a) * * *

(5) * * *

(iii) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

69. Section 145.181 is amended by revising paragraph (b)(2) to read as follows:

§ 145.181 Artificially sweetened canned pineapple.

* * * * *

(b) * * *

(2) The artificially sweetened food is subject to the requirements for label statement of ingredients used, as prescribed for canned pineapple by § 145.180(a). If the packing medium is thickened with pectin, the label shall bear the statement "thickened with pectin".

70. Section 145.185 is amended by revising paragraph (a)(4)(iv) to read as follows:

§ 145.185 Canned plums.

(a) * * *

(4) * * *

(iv) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

71. Section 145.190 is amended by revising paragraph (c)(4) to read as follows:

§ 145.190 Canned prunes.

* * * * *

(c) * * *

(4) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the

applicable sections of parts 101 and 130 of this chapter.

PART 146—CANNED FRUIT JUICES

72. The authority citation for 21 CFR part 146 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

73. Section 146.113 is amended by adding new paragraph (h) to read as follows:

§ 146.113 Canned fruit nectars.

* * * * *

(h) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

74. Section 146.114 is amended by revising paragraph (a)(3)(ii) to read as follows:

§ 146.114 Lemon juice.

(a) * * *

(3) * * *

(ii) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

75. Section 146.120 is amended by revising paragraph (c) to read as follows:

§ 146.120 Frozen concentrate for lemonade.

* * * * *

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

76. Section 146.121 is amended by adding new paragraph (f) to read as follows:

§ 146.121 Frozen concentrate for artificially sweetened lemonade.

* * * * *

(f) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

77. Section 146.126 is amended by revising paragraph (c) to read as follows:

§ 146.126 Frozen concentrate for colored lemonade.

* * * * *

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

78. Section 146.132 is amended by revising paragraphs (a)(3)(iii) to read as follows:

§ 146.132 Grapefruit juice.

(a) * * *

(3) * * *

(iii) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

79. Section 146.140 is amended by adding new paragraph (g) to read as follows:

§ 146.140 Pasteurized orange juice.

* * * * *

(g) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

80. Section 146.141 is amended by adding new paragraph (f) to read as follows:

§ 146.141 Canned orange juice.

* * * * *

(f) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

81. Section 146.145 is amended by adding new paragraph (f) to read as follows:

§ 146.145 Orange juice from concentrate.

* * * * *

(f) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

82. Section 146.146 is amended by adding new paragraph (g) to read as follows:

§ 146.146 Frozen concentrated orange juice.

* * * * *

(g) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

83. Section 146.148 is amended by revising paragraph (a) to read as follows:

§ 146.148 Reduced acid frozen concentrated orange juice.

(a) Reduced acid frozen concentrated orange juice is the food that complies with the requirements for composition and label declaration of ingredients prescribed for frozen concentrated orange juice by § 146.146, except that it may not contain any added sweetening ingredient. A process involving the use of anionic ion-exchange resins permitted by § 173.25 of this chapter is used to reduce the acidity of the food so that the ratio of the Brix reading to the grams of acid, expressed as anhydrous citric acid, per 100 grams of juice is not less than 21 to 1 or more than 26 to 1.

* * * * *

84. Section 146.150 is amended by revising paragraph (a) to read as follows:

§ 146.150 Canned concentrated orange juice.

(a) Canned concentrated orange juice is the food that complies with the requirements of composition, definition of dilution ratio, and labeling of ingredients prescribed for frozen concentrated orange juice by § 146.146, except that it is not frozen and it is sealed in containers and so processed by heat, either before or after sealing, so as to prevent spoilage.

* * * * *

85. Section 146.152 is amended by revising paragraph (d) to read as follows:

§ 146.152 Orange juice with preservative.

* * * * *

(d) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter. In addition, the name of each preservative shall be proceeded by a statement of the percent by weight of the preservative used. If the food is packed in container sizes that are less than 19 liters (5 gallons), the label shall bear a statement indicating that the food is for further manufacturing use only.

* * * * *

86. Section 146.153 is amended by revising paragraph (a) to read as follows:

§ 146.153 Concentrated orange juice for manufacturing.

(a) Concentrated orange juice for manufacturing is the food that complies with the requirements of composition and label declaration of ingredients prescribed for frozen concentrated orange juice by § 146.146, except that it is either not frozen or is less concentrated, or both, and the oranges from which the juice is obtained may deviate from the standards for maturity in that they are below the minimum Brix and Brix-acid ratio for such oranges: *Provided*, however, that the concentration of orange juice soluble solids is not less than 20° Brix.

* * * * *

87. Section 146.154 is amended by revising paragraph (d) to read as follows:

§ 146.154 Concentrated orange juice with preservative.

* * * * *

(d) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter. In addition, the name of each preservative shall be preceded by a statement of the percent by weight of the preservative used. If the food is packed in container sizes that are less than 19 liters (5 gallons), the label shall bear a statement indicating that the food is for further manufacturing use only.

* * * * *

88. Section 146.185 is amended by revising paragraph (a)(3) to read as follows:

§ 146.185 Pineapple juice.

(a) * * *

(3) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

89. Section 146.187 is amended by adding new paragraph (d) to read as follows:

§ 146.187 Canned prune juice.

* * * * *

(d) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

PART 150—FRUIT BUTTERS, JELLIES, PRESERVES, AND RELATED PRODUCTS

90. The authority citation for 21 CFR part 150 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

91. Section 150.110 is amended by revising the introductory text of paragraph (e)(1) and by removing paragraph (e)(2)(ii) and reserving it, to read as follows:

§ 150.110 Fruit butter.

* * * * *

(e)(1) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

(2) * * *

(ii) [Reserved]

92. Section 150.140 is amended by revising the introductory text of paragraph (e)(2) to read as follows:

§ 150.140 Fruit jelly.

* * * * *

(e)(2) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

93. Section 150.141 is amended by adding new paragraph (h) to read as follows:

§ 150.141 Artificially sweetened fruit jelly.

* * * * *

(h) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

94. Section 150.160 is amended by revising the introductory text of paragraph (e)(2) to read as follows:

§ 150.160 Fruit preserves and jams.

* * * * *

(e) * * *

(2) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

95. Section 150.161 is amended by adding new paragraph (h) to read as follows:

§ 150.161 Artificially sweetened fruit preserves and jams.

* * * * *

(h) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

PART 152—FRUIT PIES

96. The authority citation for 21 CFR part 152 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

97. Section 152.126 is amended by revising paragraph (a)(4)(i) to read as follows:

§ 152.126 Frozen cherry pie.

(a) * * *

(4)(i) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

PART 155—CANNED VEGETABLES

98. The authority citation for 21 CFR part 155 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

99. Section 155.120 is amended by revising paragraph (a)(5) to read as follows:

§ 155.120 Canned green beans and canned wax beans.

(a) * * *

(5) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

100. Section 155.130 is amended by revising paragraph (a)(5) to read as follows:

§ 155.130 Canned corn.

(a) * * *

(5) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

101. Section 155.131 is amended by revising paragraph (a)(1) to read as follows:

§ 155.131 Canned field corn.

(a) *Identity.* (1) Canned field corn conforms to the definition and standard of identity, and is subject to the requirements for label declaration of ingredients, prescribed for canned corn by § 155.130(a), except that the corn ingredient consists of succulent field corn or a mixture of succulent field corn and succulent sweet corn.

* * * * *

102. Section 155.170 is amended by revising paragraph (a)(4) to read as follows:

§ 155.170 Canned peas.

(a) * * *

(4) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

103. Section 155.172 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 155.172 Canned dry peas.

(a) *Identity.* Canned dry peas conforms to the definition and standard of identity, and is subject to the requirements for label declaration of ingredients, prescribed for canned peas by § 155.170(a), except that:

* * * * *

104. Section 155.191 is amended by revising paragraph (a)(3)(iv) to read as follows:

§ 155.191 Tomato concentrates.

(a) * * *

(3) * * *

(iv) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

105. Section 155.194 is amended by revising paragraph (a)(3)(iii) to read as follows:

§ 155.194 Catsup.

(a) * * *

(3) * * *

(iii) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter; except that the name "tomato concentrate" may be used in lieu of the names "tomato puree," "tomato pulp," or "tomato paste" and when tomato concentrates are used, the labeling requirements of § 155.191(a)(3)(ii)(*a*) and (a)(3)(ii)(*b*) do not apply.

* * * * *

106. Section 155.200 is amended by revising paragraph (h) to read as follows:

§ 155.200 Certain other canned vegetables.

* * * * *

(h) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

107. Section 155.201 is amended by revising paragraph (a)(4)(ii) to read as follows:

§ 155.201 Canned mushrooms.

(a) * * *

(4) * * *

(ii) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

PART 156—VEGETABLE JUICES

108. The authority citation for 21 CFR part 156 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371).

109. Section 156.145 is amended by revising paragraph (a)(2)(ii) to read as follows:

§ 156.145 Tomato juice.

(a) * * *

(2) * * *

(ii) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

PART 158—FROZEN VEGETABLES

110. The authority citation for 21 CFR part 158 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371).

111. Section 158.170 is amended by revising paragraph (a)(4) to read as follows:

§ 158.170 Frozen peas.

(a) * * *

(4) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

PART 160—EGGS AND EGG PRODUCTS

112. The authority citation for 21 CFR part 160 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

113. Section 160.105 is amended by adding new paragraph (e) to read as follows:

§ 160.105 Dried eggs.

* * * * *

(e) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

114. Section 160.110 is amended by adding new paragraph (d) to read as follows:

§ 160.110 Frozen eggs.

* * * * *

(d) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

115. Section 160.115 is amended by redesignating the existing text as paragraph (a) and by adding new paragraph (b) to read as follows:

§ 160.115 Liquid eggs.

* * * * *

(b) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

116. Section 160.140 is amended by adding new paragraph (c) to read as follows:

§ 160.140 Egg whites.

* * * * *

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

117. Section 160.145 is amended by adding new paragraph (f) to read as follows:

§ 160.145 Dried egg whites.

* * * * *

(f) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

118. Section 160.150 is amended by adding new paragraph (c) to read as follows:

§ 160.150 Frozen egg whites.

* * * * *

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

119. Section 160.180 is amended by redesignating the existing text as paragraph (a) and by adding new paragraph (b) to read as follows:

§ 160.180 Egg yolks.

* * * * *

(b) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

120. Section 160.185 is amended by adding new paragraph (e) to read as follows:

§ 160.185 Dried egg yolks.

* * * * *

(e) Label declaration. Each of the ingredients used in the food shall be

declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

121. Section 160.190 is amended by redesignating the existing text as paragraph (a) and by adding new paragraph (b) to read as follows:

§ 160.190 Frozen egg yolks.

* * * * *

(b) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

PART 161—FISH AND SHELLFISH

122. The authority citation for 21 CFR part 161 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

123. Section 161.145 is amended by adding new paragraph (a)(4) to read as follows:

§ 161.145 Canned oysters.

(a) * * *

(4) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

124. Section 161.170 is amended by revising paragraph (a)(5)(iii) to read as follows:

§ 161.170 Canned Pacific salmon.

(a) * * *

(5) * * *

(iii) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

125. Section 161.173 is amended by revising paragraph (a)(5)(ix) to read as follows:

§ 161.173 Canned wet pack shrimp in transparent or nontransparent containers.

(a) * * *

(5) * * *

(ix) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

126. Section 161.175 is amended by adding new paragraph (i) to read as follows:

§ 161.175 Frozen raw breaded shrimp.

* * * * *

(i) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

127. Section 161.190 is amended by revising paragraphs (a)(6)(ii) through (a)(6)(viii), by removing paragraph (a)(6)(ix), and by revising paragraph (a)(8)(vi) to read as follows:

§ 161.190 Canned tuna.

(a) * * *

(6) * * *

(ii) Monosodium glutamate.

(iii) Hydrolyzed protein declared in accordance with the applicable provisions of § 101.22.

(iv) Spices or spice oils or spice extracts.

(v) Vegetable broth in an amount not in excess of 5 percent of the volume capacity of the container, such broth to consist of a minimum of 0.5 percent by weight of vegetable extractives and to be prepared from two or more of the following vegetables: Beans, cabbage, carrots, celery, garlic, onions, parsley, peas, potatoes, green bell peppers, red bell peppers, spinach, and tomatoes.

(vi) Garlic.

(vii) Lemon flavoring to be prepared from lemon oil and citric acid together with safe and suitable carriers for the lemon oil which are present at nonfunctional and insignificant levels in the finished canned food. When lemon flavoring is added, a safe and suitable solubilizing and dispersing ingredient may be added in a quantity not exceeding 0.005 percent by weight of the finished food. A substance used in accordance with this paragraph is deemed to be suitable if it is used in an amount no greater than necessary to achieve the intended flavor effect, and is deemed to be safe if it is not a food additive as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act (the act), or if it is a food additive as so defined, it is used in conformity with regulations established pursuant to section 409 of the act.

(viii) Edible vegetable oil or partially hydrogenated vegetable oil, excluding olive oil, used alone or in combination in an amount not to exceed 5 percent of the volume capacity of the container, with or without any suitable form of emulsifying and suspending ingredients that has been affirmed as GRAS or approved as a food additive to aid in dispersion of the oil, as seasoning in canned tuna packed in water.

* * * * *

(8) * * *

(vi) Where the canned tuna contains one or more of the ingredients provided for in paragraph (a)(6) of this section, the label shall bear the statement "Seasoned with _____", the blank being filled in with the name or names of the ingredient or ingredients used, except that if the ingredient designated in paragraph (a)(6)(v) of this section is used, the blank shall be filled in with the term "vegetable broth", and if the ingredients designated in paragraph (a)(6)(viii) of this section are used, the blank may be filled in with the term "oil", and if the ingredient designated in paragraph (a)(6)(iv) of this section is used alone, the label may alternatively bear either the statement "spiced" or the statement "with added spice"; and if salt is the only seasoning ingredient used, the label may alternatively bear any of the statements "salted", "with added salt", or "salt added". If the flavoring ingredients designated in paragraph (a)(6)(vii) of this section are used, the words "lemon flavored" or "with lemon flavoring" shall appear as part of the name on the label; for example, "lemon flavored chunk light tuna". Citric acid and any optional solubilizing and dispersing agent used as specified in paragraph (a)(6)(vii) of this section in connection with lemon flavoring ingredients or emulsifying and suspending ingredients used as specified in paragraph (a)(6)(viii) of this section shall be designated on the label by their common or usual name.

* * * * *

PART 163—CACAO PRODUCTS

128. The authority citation for 21 CFR part 163 continues to read as follows:

Authority: Secs. 201, 301, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 341, 343, 348, 371, 376).

129. Section 163.110 is amended by adding new paragraph (c) to read as follows:

§ 163.110 Cacao nibs.

* * * * *

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by applicable sections of parts 101 and 130 of this chapter.

130. Section 163.111 is amended by adding new paragraph (c) to read as follows:

§ 163.111 Chocolate liquor.

* * * * *

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by applicable sections of parts 101 and 130 of this chapter.

131. Section 163.112 is amended by adding new paragraph (c) to read as follows:

§ 163.112 Breakfast cocoa.

* * * * *

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by applicable sections of parts 101 and 130 of this chapter.

132. Section 163.113 is revised to read as follows:

§ 163.113 Cocoa.

Cocoa, medium fat cocoa conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for breakfast cocoa by § 163.112, except that it contains less than 22 percent but not less than 10 percent of cacao fat as determined by the method referred to in § 163.112(a).

133. Section 163.114 is revised to read as follows:

§ 163.114 Lowfat cocoa.

Lowfat cocoa conforms to the definition and standard of identity, and is subject to the requirements for label declaration of ingredients for breakfast cocoa in § 163.112, except that the cacao fat content is less than 10 percent by weight, as determined by the method prescribed in § 163.112(a).

134. Section 163.117 is amended by revising paragraph (a) to read as follows:

§ 163.117 Cocoa with dioctyl sodium sulfosuccinate for manufacturing.

(a) Description. Cocoa with dioctyl sodium sulfosuccinate for manufacturing is the food additive complying with the provisions in § 172.520 of this chapter. It conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, for breakfast cocoa in § 163.112, or for cocoa in § 163.113, or for lowfat cocoa in § 163.114, except that the food additive contains dioctyl sodium sulfosuccinate (complying with the requirements of § 172.810 of this chapter, including the limit of not more than 0.4 percent by weight of the finished food additive).

* * * * *

135. Section 163.123 is amended by adding new paragraph (i) to read as follows:

§ 163.123 Sweet chocolate.

* * * * *

(i) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by applicable sections of parts 101 and 130 of this chapter.

136. Section 163.130 is amended by adding new paragraph (f) to read as follows:

§ 163.130 Milk chocolate.

* * * * *

(f) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by applicable sections of parts 101 and 130 of this chapter.

137. Section 163.135 is amended by adding new paragraph (c) to read as follows:

§ 163.135 Buttermilk chocolate.

* * * * *

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by applicable sections of parts 101 and 130 of this chapter.

138. Section 163.140 is amended by adding new paragraph (c) to read as follows:

§ 163.140 Skim milk chocolate.

* * * * *

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by applicable sections of parts 101 and 130 of this chapter.

139. Section 163.145 is amended by adding new paragraph (c) to read as follows:

§ 163.145 Mixed dairy product chocolates.

* * * * *

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by applicable sections of parts 101 and 130 of this chapter.

140. Section 163.150 is amended by adding new paragraph (d) to read as follows:

§ 163.150 Sweet cocoa and vegetable fat (other than cacao fat) coating.

* * * * *

(d) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by applicable sections of parts 101 and 130 of this chapter.

141. Section 163.153 is amended by adding new paragraph (c) to read as follows:

§ 163.153 Sweet chocolate and vegetable fat (other than cacao fat) coating.

* * * * *

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by applicable sections of parts 101 and 130 of this chapter.

142. Section 163.155 is amended by adding new paragraph (c) to read as follows:

§ 163.155 Milk chocolate and vegetable fat (other than cacao fat) coating.

* * * * *

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by applicable sections of parts 101 and 130 of this chapter.

PART 164—TREE NUT AND PEANUT PRODUCTS

143. The authority citation for 21 CFR part 164 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

144. Section 164.110 is amended by revising the introductory text of paragraph (e), by removing paragraphs (e)(3) and (e)(4), and by revising paragraph (f) to read as follows:

§ 164.110 Mixed nuts.

* * * * *

(e) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

(f) The words and statements specified in paragraph (e) of this section showing the ingredients present shall be listed on the principal display panel or panels or any appropriate information panel without obscuring design, vignettes, or crowding. The declaration shall appear in conspicuous and easily legible letters of boldface print or type the size of which shall be not less than one-half of that required by part 101 of this chapter for the statement of net quantity of contents appearing on the label, but in no case less than one-sixteenth of an inch in height. The entire ingredient statement shall appear on at least one panel of the label. If the label bears any pictorial representation of the mixture of nuts, it shall depict the relative proportions of the nut ingredients of the food. If the label bears a pictorial representation of only one of each nut ingredient present, the nuts shall be depicted in the order of decreasing predominance by weight. A factual statement that the food does not contain a particular nut ingredient or ingredients may be shown on the label if the statement is not misleading and does not result in an insufficiency of label space for the proper declaration of information required by or under

authority of the act to appear on the label.

145. Section 164.150 is amended by revising paragraph (e) to read as follows:

§ 164.150 Peanut butter.

* * * * *

(e) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

PART 166—MARGARINE

146. The authority citation for 21 CFR part 166 continues to read as follows:

Authority: Secs. 201, 401, 403, 407, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 347, 348, 371, 376).

147. Section 166.110 is amended by revising paragraph (d) to read as follows:

§ 166.110 Margarine.

* * * * *

(d) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter. For the purposes of this section the use of the term "milk" unqualified means milk from cows. If any milk other than cow's milk is used in whole or in part, the animal source shall be identified in conjunction with the word milk in the ingredient statement. Colored margarine shall be subject to the provisions of section 407 of the Federal Food, Drug, and Cosmetic Act as amended.

PART 168—SWEETENERS AND TABLE SIRUPS

148. The authority citation for 21 CFR part 168 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

149. Section 168.110 is amended by revising paragraph (b) to read as follows:

§ 168.110 Dextrose anhydrous.

* * * * *

(b) The name of the food is "Dextrose anhydrous" or "Anhydrous dextrose" or alternatively, "———— sugar anhydrous" or "Anhydrous sugar", with the blank to be filled with the name of the food source, for example, "Corn sugar anhydrous".

150. Section 168.111 is amended by revising paragraph (c) to read as follows:

§ 168.111 Dextrose monohydrate.

* * * * *

(c) The name of the food is "Dextrose monohydrate" or "Dextrose" or alternatively, "———— sugar monohydrate" or "———— sugar", with the blank to be filled with the name of the food source, for example, "Corn sugar monohydrate" or "Corn sugar".

* * * * *

151. Section 168.130 is amended by revising paragraph (d) to read as follows:

§ 168.130 Cane sirup.

* * * * *

(d) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

152. Section 168.160 is amended by revising paragraph (d) to read as follows:

§ 168.160 Sorghum sirup.

* * * * *

(d) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

153. Section 168.180 is amended by revising paragraph (d)(1) to read as follows:

§ 168.180 Table sirup.

* * * * *

(d)(1) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

PART 169—FOOD DRESSINGS AND FLAVORINGS

154. The authority citation for 21 CFR part 169 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

155. Section 169.115 is amended by revising paragraph (e) to read as follows:

§ 169.115 French dressing.

* * * * *

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

156. Section 169.140 is amended by revising paragraph (f) to read as follows:

§ 169.140 Mayonnaise.

* * * * *

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

157. Section 169.150 is amended by revising paragraph (g) to read as follows:

§ 169.150 Salad dressing.

* * * * *

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

158. Section 169.175 is amended by adding new paragraph (c) to read as follows:

§ 169.175 Vanilla extract.

* * * * *

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

159. Section 169.176 is amended by revising paragraph (a) to read as follows:

§ 169.176 Concentrated vanilla extract.

(a) Concentrated vanilla extract conforms to the definition and standard of identity and is subject to any requirement for label statement of ingredients prescribed for vanilla extract by § 169.175, except that it is concentrated to remove part of the solvent, and each gallon contains two or more units of vanilla constituent as defined in § 169.3(c). The content of ethyl alcohol is not less than 35 percent by volume.

* * * * *

160. Section 169.177 is amended by revising paragraph (a) to read as follows:

§ 169.177 Vanilla flavoring.

(a) Vanilla flavoring conforms to the definition and standard of identity and is subject to any requirement for label statement of ingredients prescribed for vanilla extract by § 169.175, except that its content of ethyl alcohol is less than 35 percent by volume.

* * * * *

161. Section 169.178 is amended by revising paragraph (a) to read as follows:

§ 169.178 Concentrated vanilla flavoring.

(a) Concentrated vanilla flavoring conforms to the definition and standard of identity and is subject to any requirement for label statement of ingredients prescribed for vanilla flavoring by § 169.177, except that it is concentrated to remove part of the solvent, and each gallon contains two or more units of vanilla constituent as defined in § 169.3(c).

* * * * *

162. Section 169.179 is amended by adding new paragraph (d) to read as follows:

§ 169.179 Vanilla powder.

* * * * *

(d) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

163. Section 169.180 is amended by revising paragraph (a) to read as follows:

§ 169.180 Vanilla-vanillin extract.

(a) Vanilla-vanillin extract conforms to the definition and standard of identity and is subject to any requirement for label statement of ingredients prescribed for vanilla extract by § 169.175, except that for each unit of vanilla constituent, as defined in § 169.3(c), contained therein, the article also contains not more than 1 ounce of added vanillin.

* * * * *

164. Section 169.181 is amended by revising paragraph (a) to read as follows:

§ 169.181 Vanilla-vanillin flavoring.

(a) Vanilla-vanillin flavoring conforms to the definition and standard of identity and is subject to any requirement for label statement of ingredients prescribed for vanilla-vanillin extract by § 169.180, except that its content of ethyl alcohol is less than 35 percent by volume.

* * * * *

165. Section 169.182 is amended by revising paragraph (a) to read as follows:

§ 169.182 Vanilla-vanillin powder.

(a) Vanilla-vanillin powder conforms to the definition and standard of identity and is subject to any requirement for label statement of ingredients prescribed for vanilla powder by § 169.179, except that for each unit of vanilla constituent as defined in § 169.3(c) contained therein, the article also contains not more than 1 ounce of added vanillin.

* * * * *

Dated: October 22, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 92-31522 Filed 12-28-92; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 131, 133, 135, and 168

[Docket No. 90N-361D]

RIN 0905-AD08

Food Labeling; Declaration of Ingredients for Dairy Products and Maple Sirup

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA), in accordance with the Nutrition Labeling and Education Act of 1990 (Pub. L. 101-535) (the 1990 amendments) is amending the U.S. standards of identity for dairy products (parts 131, 133, and 135 (21 CFR parts 131, 133, and 135)) and maple sirup (21 CFR 168.140) to require the listing of the common or usual names of all ingredients in these standardized foods.

Section 701(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(e)), as amended by the 1990 amendments, requires formal rulemaking for the amendment or repeal of standards of identity for dairy products and maple sirup. The 1990 amendments removed food standards rulemaking for all other foods from the coverage of section 701(e) of the act. Because of the procedural differences between amending the standards for dairy products and maple sirup and amending other food standards, the agency is publishing two separate final rules amending food standards. This final rule on dairy products and maple sirup is issued under formal rulemaking procedures. A companion document for other foods is published elsewhere in this issue of the **Federal Register**.

DATES: Effective May 8, 1993, except as to any provisions that may be stayed by the filing of proper objections; compliance may begin January 6, 1993, written objections and requests for a hearing by February 5, 1993.

ADDRESSES: Written objections may be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Michelle A. Smith, Center for Food Safety and Applied Nutrition (HFS-158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5106.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 21, 1991 (56 FR 28592), FDA published a proposed rule concerning the declaration of ingredients (hereinafter referred to as the June 21, 1991, proposal) and solicited public comment on ingredient labeling issues. The June 21, 1991, proposal addressed several current requirements that bear on ingredient labeling. Most significantly, section 403(i) of the act (21 U.S.C. 343(i)) requires, with certain specific exceptions, that ingredients be listed by their common or usual names on food labels. Before the 1990 amendments, the act provided FDA with authority under section 403(g) of the act to require the declaration of optional ingredients in standardized foods, but mandatory ingredients were exempt from such a requirement under section 403(i) of the act. In the absence of statutory authority, FDA could not require the complete listing of all ingredients in standardized foods. However, the 1990 amendments removed the portion of section 403(i) of the act that excluded mandatory ingredients used in standardized foods from the requirement for label declaration.

In the June 21, 1991, proposal, the agency proposed revisions of § 101.4(a)(1) and (b)(2)(i) (21 CFR 101.4(a)(1) and (b)(2)(i)) and proposed to adopt new § 130.3(e) (21 CFR 130.3(e)) to implement the new ingredient listing requirements for standardized foods prescribed by amended section 403(i) of the act. Proposed § 130.3(e) provides that all mandatory and optional ingredients of standardized foods must appear on food labels in accordance with the requirements of part 101 (21 CFR part 101), except where a definition and standard of identity contains a specific provision with respect to the declaration of optional ingredients. In addition, the agency proposed to amend specific standards of identity either by changing the existing language for label declaration of ingredients or by adding a new paragraph, to require that all ingredients be declared on the label in accordance with the applicable sections of parts 101 and 130 (21 CFR part 130).

The agency notes that several standards of identity define foods by cross-referencing other standardized foods. For example, § 133.114 *Cheddar cheese for manufacturing* describes a food that, with certain exceptions, "conforms to the definition and standard of identity prescribed for cheddar cheese by § 133.113." Similar language is contained in §§ 133.109, 133.119, 133.137, 133.145, 133.157, 133.161, and 133.196. FDA advises that conformance with a cross-referenced definition and standard of identity includes compliance with the labeling provisions in the referenced standard. Thus, except where existing standards contained language contrary to the ingredient labeling requirements prescribed by amended section 403(i) of the act, it was not necessary for the June 21, 1991, proposal to change the wording of standards of identity that define foods by cross-reference. These standards are being amended by modifying the standards they cross-reference.

The 1990 amendments removed food standards rulemakings, except for actions for the amendment or repeal of food standards for dairy products or maple sirup, from the coverage of section 701(e) of the act. Section 701(e) of the act establishes formal rulemaking procedures that must be followed for the issuance, amendment, or repeal of regulations under certain sections of the act. Under formal rulemaking procedures, there is an opportunity to object to any final rule and to request a public hearing upon such objection. Such an opportunity is not provided as part of the notice and comment rulemaking procedures followed by the agency under section 701(a) of the act.

Because of the procedural differences between amending the standards for dairy products and maple sirup and amending other food standards, the agency is publishing two separate final rules. This final rule, issued under formal rulemaking procedures, amends the requirements for label declaration of ingredients in the standards of identity for dairy products (parts 131, 133, and 135) and for maple sirup (§ 168.140). A companion document amending declaration of ingredient regulations in part 101, establishing ingredient labeling requirements in part 102 (21 CFR part 102) and part 130 for nonstandardized and standardized foods, respectively, and amending the labeling requirements for standardized foods under the provisions of section 701(a) of the act appears elsewhere in this issue of the **Federal Register**. In addition, elsewhere in this issue of the **Federal Register**, FDA is publishing a proposal on other ingredient labeling issues that arose from the June 21, 1991, proposal.

The 1990 amendments gave the Secretary the authority to extend the applicability of certain of its provisions. However, the provision of the amendments that established a requirement that all ingredients in standardized foods be listed on the label is not among those provisions for which

an extension is permitted. Thus, this new labeling requirement is effective May 8, 1993.

II. Comments and Agency Response

In response to the June 21, 1991, proposal, the agency received over 700 letters containing one or more comments from a wide range of sources, including consumers, consumer organizations, professional associations, government agencies, industry, and industry trade associations. None of the comments specifically addressed ingredient labeling of maple sirup or dairy products. In addition, many comments were not relevant to these foods. However, a few of the comments, and of the agency's conclusions on the issues raised by the comments, bear generally on dairy product and maple sirup standards. A summary of comments and the agency's responses follow. The comments are discussed in more detail in the companion document on declaration of ingredients published elsewhere in this issue of the **Federal Register**.

A. Declaration of Mandatory Ingredients in Standardized Foods

The majority of comments from consumers and the food industry generally supported the declaration of mandatory as well as optional ingredients in foods in the ingredient list. In support of their position, consumers asserted that they had a right, and in many cases a need, to know the identity of all of the ingredients in the food they consume. Moreover, some comments expressed the belief that the average consumer has no idea of what mandatory ingredients go into a standardized food and, therefore, is unable to make informed decisions.

The agency agrees with these comments. FDA is amending its ingredient labeling regulations to require that all mandatory and optional ingredients of standardized foods appear on food labels in accordance with the requirements of part 101, except where a definition and standard of identity contains a specific provision with respect to the declaration of optional ingredients. In such instances, certain ingredients may be declared in accordance with that provision. Accordingly, FDA is codifying this requirement, as proposed, in new § 130.3(e). (New § 130.3(e) is being issued as part of the general final rule on declaration of ingredients, published elsewhere in this issue of the **Federal Register**.) The exceptions for certain ingredients in specified standards of identity permit continued use of alternatives to the labeling requirements of part 101 where compliance with those requirements would be impracticable.

In the June 21, 1991, proposal, the agency proposed revisions of § 101.4(a)(1) and (b)(2)(i) to reflect the new ingredient listing requirements in amended section 403(i) of the act. The proposed revisions clarify that: (1) All standardized foods must comply with § 101.4, rather than only those foods specifically required to do so by the standards; and (2) a standardized food is subject to the same treatment as any other food, except that, where the food is subject to a standard that makes specific provisions for the labeling of optional ingredients, the optional ingredients may be declared in accordance with those provisions. The agency did not receive any comments objecting to these changes. Therefore, FDA is finalizing these revisions as proposed. (New § 101.4(a)(1) and (b)(2)(i) are being issued as part of the general final rule on declaration of ingredients, published elsewhere in this issue of the **Federal Register**.)

The agency is also amending the dairy product and maple sirup standards of identity, as proposed, to require that all ingredients be declared on the label in accordance with the applicable sections of parts 101 and 130. Many of the standards already provide for declaration of all optional ingredients used in accordance with the applicable sections of part 101, and the wording in these standards has been amended to require the declaration of all ingredients. Where there is no existing provision for ingredient labeling, FDA has added a paragraph to the standard to include the new labeling provisions.

As proposed, FDA is retaining a number of existing optional ingredient listing provisions in the dairy standards that permit collective terms to be used rather than specific ingredient names where similar provisions are not present in part 101. Thus, the agency is retaining the provisions for listing the term "enzymes" rather than the specific name of the enzyme and the terms "milkfat and nonfat milk" or "nonfat milk and milkfat" for dairy ingredients in standards such as § § 133.106 *Blue cheese*, 133.133 *Cream cheese*, and 133.164 *Nuworld cheese*.

B. Labeling Exemptions

As discussed in the June 21, 1991, proposal (56 FR 28592 at 28593), part 101 provides for a number of labeling exemptions. The agency does not believe that these exemptions need to be duplicated in individual standards. For instance, several of the dairy standards in part 133 contain exemptions that provide for the declaration of the use of bacterial cultures on the label by the word "cultured" followed by the name of the substrate, e.g., "cultured cream" or "made from cultured skim milk." Other cheese standards provide for the use of terms such as "cream" for plastic cream and dried cream, "milk" for concentrated milk and dried milk, "skim milk" for concentrated skim milk and nonfat dry milk, and "whey" for cheese whey, concentrated cheese whey, and dried cheese whey. Section 101.4(b) currently provides for these labeling exemptions, and FDA concludes that the language does not need to be repeated in each standard of identity. To do so would only add needlessly repetitive language to the standards. In proposing to update the language of the standards in part 133 to require the listing of the common or usual name of all ingredients, these provisions were deleted from several of the proposed standards. There were no objections to this change. Accordingly, FDA is deleting these provisions as proposed.

III. Economic Impact

In accordance with the Regulatory Flexibility Act (Pub. L. 96–354) (5 U.S.C. 601), FDA has reviewed the final rule to amend the standards of identity for dairy products and maple sirup to determine its impact on small entities, including small businesses. The amendments will require label declaration of ingredients used in these foods in accordance with the ingredient labeling requirements of parts 101 and 130. FDA has determined that because the effect of the amendments is to require declaration of mandatory ingredients primarily (as most optional ingredients are already required to be declared on labels), and because most manufacturers already declare all ingredients on labels of these products, this action will not result in a significant impact on a substantial number of small entities. FDA has not received any new information or comments that would alter this determination. Therefore, in accordance with section 605(b) of the Regulatory Flexibility Act, FDA certifies that no significant impact on a substantial number of small entities will derive from this action.

In accordance with Executive Order 12291, FDA has carefully analyzed the economic effects of this final rule, and the agency has determined that the rule, if promulgated, will not be a major rule as defined by that order.

IV. Objections

Any person who will be adversely affected by this regulation may at any time on or before February 5, 1993, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FDA will publish notice of the objections that the agency has received or lack thereof in the **Federal Register**.

List of Subjects

21 CFR Part 131

Cream, Food grades and standards, Milk, Yogurt.

21 CFR Part 133

Cheese, Food grades and standards, Food labeling.

21 CFR Part 135

Food grades and standards, Food labeling, Frozen foods, Ice cream.

21 CFR Part 168

Food grades and standards, Sugar.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 131, 133, 135, and 168 are amended as follows:

PART 131—MILK AND CREAM

1. The authority citation for 21 CFR part 131 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

2. Section 131.110 is amended by revising paragraph (f) to read as follows:

§ 131.110 Milk.

* * * * *

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

3. Section 131.111 is amended by revising paragraph (h) to read as follows:

§ 131.111 Acidified milk.

* * * * *

(h) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

4. Section 131.112 is amended by revising paragraph (g) to read as follows:

§131.112 Cultured milk.

* * * * *

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

5. Section 131.115 is amended by revising paragraph (f) to read as follows:

§ 131.115 Concentrated milk.

* * * * *

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

6. Section 131.120 is amended by revising paragraph (e) to read as follows:

§ 131.120 Sweetened condensed milk.

* * * * *

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

7. Section 131.122 is amended by revising paragraph (e) to read as follows:

§ 131.122 Sweetened condensed skimmed milk.

* * * * *

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

8. Section 131.123 is amended by revising paragraph (f) to read as follows:

§ 131.123 Lowfat dry milk.

* * * * *

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

9. Section 131.125 is amended by revising paragraph (e) to read as follows:

§ 131.125 Nonfat dry milk.

* * * * *

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

10. Section 131.127 is amended by revising paragraph (f) to read as follows:

§ 131.127 Nonfat dry milk fortified with vitamins A and D.

* * * * *

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

11. Section 131.130 is amended by revising paragraph (f) to read as follows:

§ 131.130 Evaporated milk.

* * * * *

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

12. Section 131.132 is amended by revising paragraph (f) to read as follows:

§ 131.132 Evaporated skimmed milk.

* * * * *

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

13. Section 131.135 is amended by revising paragraph (f) to read as follows:

§ 131.135 Lowfat milk.

* * * * *

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

14. Section 131.136 is amended by revising paragraph (h) to read as follows:

§ 131.136 Acidified lowfat milk.

* * * * *

(h) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

15. Section 131.138 is amended by revising paragraph (g) to read as follows:

§ 131.138 Cultured lowfat milk.

* * * * *

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

16. Section 131.143 is amended by revising paragraph (f) to read as follows:

§ 131.143 Skim milk.

* * * * *

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

17. Section 131.144 is amended by revising paragraph (h) to read as follows:

§ 131.144 Acidified skim milk.

* * * * *

(h) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

18. Section 131.146 is amended by revising paragraph (g) to read as follows:

§ 131.146 Cultured skim milk.

* * * * *

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

19. Section 131.147 is amended by revising paragraph (f) to read as follows:

§ 131.147 Dry whole milk.

* * * * *

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

20. Section 131.149 is amended by revising paragraph (e) to read as follows:

§ 131.149 Dry cream.

* * * * *

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

21. Section 131.150 is amended by revising paragraph (e) to read as follows:

§ 131.150 Heavy cream.

* * * * *

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

22. Section 131.155 is amended by revising paragraph (e) to read as follows:

§ 131.155 Light cream.

* * * * *

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

23. Section 131.157 is amended by revising paragraph (e) to read as follows:

§ 131.157 Light whipping cream.

* * * * *

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

24. Section 131.160 is amended by revising paragraph (e) to read as follows:

§ 131.160 Sour cream.

* * * * *

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

25. Section 131.162 is amended by revising paragraph (e) to read as follows:

§ 131.162 Acidified sour cream.

* * * * *

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

26. Section 131.170 is amended by revising paragraph (h) to read as follows:

§ 131.170 Eggnog.

* * * * *

(h) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

27. Section 131.180 is amended by revising paragraph (e) to read as follows:

§ 131.180 Half-and-half.

* * * * *

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

28. Section 131.185 is amended by revising paragraph (e) to read as follows:

§ 131.185 Sour half-and-half.

* * * * *

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

29. Section 131.187 is amended by revising paragraph (e) to read as follows:

§ 131.187 Acidified sour half-and-half.

* * * * *

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

30. Section 131.200 is amended by revising paragraph (g) to read as follows:

§ 131.200 Yogurt.

* * * * *

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

31. Section 131.203 is amended by revising paragraph (g) to read as follows:

§ 131.203 Lowfat yogurt.

* * * * *

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

32. Section 131.206 is amended by revising paragraph (g) to read as follows:

§ 131.206 Nonfat yogurt.

* * * * *

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

PART 133—CHEESES AND RELATED CHEESE PRODUCTS

33. The authority citation for 21 CFR part 133 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

34. Section 133.102 is amended by revising paragraph (e) to read as follows:

§ 133.102 Asiago fresh and asiago soft cheese.

* * * * *

(e) Label declaration: Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that enzymes of animal, plant, or microbial origin may be declared as "enzymes".

35. Section 133.103 is revised to read as follows:

§ 133.103 Asiago medium cheese.

Asiago medium cheese conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients prescribed by § 133.102 for asiago fresh cheese, except that it contains not more than 35 percent moisture, its solids contain not less than 45 percent of milkfat, and it is cured for not less than 6 months.

36. Section 133.104 is revised to read as follows:

§ 133.104 Asiago old cheese.

Asiago old cheese conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients prescribed by § 133.102 for asiago fresh cheese, except that it contains not more than 32 percent moisture, its solids contain not less than 42 percent of milk fat, and it is cured for not less than 1 year.

37. Section 133.106 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.106 Blue cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

38. Section 133.108 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.108 Brick cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that.

* * * * *

39. Section 133.111 is amended by revising paragraph (f) to read as follows:

§ 133.111 Caciocavallo siciliano cheese.

* * * * *

(f) Label declaration: Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that enzymes of animal, plant, or microbial origin may be declared as "enzymes".

40. Section 133.113 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.113 Cheddar cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

41. Section 133.118 is amended by adding new paragraph (f) to read as follows:

§ 133.118 Colby cheese.

* * * * *

(f) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that enzymes of animal, plant, or microbial origin may be declared as "enzymes".

42. Section 133.121 is amended by revising the introductory text to read as follows:

§ 133.121 Low sodium colby cheese.

Low sodium colby cheese is the food prepared from the same ingredients and in the same manner prescribed in § 133.118 for colby cheese and complies with all the provisions of § 133.118, including the requirements for label statement of ingredients, except that:

* * * * *

43. Section 133.123 is amended by revising the introductory text of paragraph (f) to read as follows:

§ 133.123 Cold-pack and club cheese.

* * * * *

(f) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that cheddar cheese, washed curd cheese, colby cheese, granular cheese, or any mixture of two or more of these, may be designated as "American cheese".

* * * * *

44. Section 133.124 is amended by revising paragraph (h) to read as follows:

§ 133.124 Cold-pack cheese food.

* * * * *

(h) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that cheddar cheese, washed curd cheese, colby cheese, granular cheese, or any mixture of two or more of these, may be designated as "American cheese".

45. Section 133.125 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 133.125 Cold-pack cheese food with fruits, vegetables, or meats.

(a) Cold-pack cheese food with fruits, vegetables, or meats or mixtures of these is the food which conforms to the definition and standard of identity, and is subject to the requirements for label declaration of ingredients, prescribed for cold pack cheese food by § 133.124, except that:

* * * * *

46. Section 133.127 is amended by revising paragraph (d) to read as follows:

§ 133.127 Cook cheese, koch kaese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130, except that enzymes of animal, plant, or microbial origin may be declared as "enzymes".

47. Section 133.128 is amended by revising paragraph (e) to read as follows:

§ 133.128 Cottage cheese.

* * * * *

(e) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that milk-clotting enzymes may be declared by the word "enzymes"

48. Section 133.129 is amended by revising paragraph (e) to read as follows:

§ 133.129 Dry curd cottage cheese.

* * * * *

(e) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that milk-clotting enzymes may be declared by the word "enzymes"

49. Section 133.131 is amended by revising the introductory text to read as follows:

§ 133.131 Lowfat cottage cheese.

Lowfat cottage cheese is the food prepared from the same ingredients and in the same manner prescribed in § 133.128 for cottage cheese and complies with all the provisions of § 133.128 (including requirements for the label statement of ingredients), except that:

* * * * *

50. Section 133.133 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.133 Cream cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be

declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

51 Section 133.134 is amended by revising the introductory text paragraph (d) to read as follows:

§ 133.134 Cream cheese with other foods.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

52. Section 133.136 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.136 Washed curd and soaked curd cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

53. Section 133.138 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.138 Edam cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

54. Section 133.140 is amended by revising paragraph (c) to read as follows:

§ 133.140 Gammelost cheese.

* * * * *

(c) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

55. Section 133.141 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.141 Gorgonzola cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

56. Section 133.144 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.144 Granular and stirred curd cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

57. Section 133.146 is amended by revising the introductory text of paragraph (e) to read as follows:

§ 133.146 Grated cheeses.

* * * * *

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

58. Section 133.147 is amended by revising paragraph (e) to read as follows:

§ 133.147 Grated American cheese food.

* * * * *

(e) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that cheddar cheese, washed curd cheese, colby cheese, granular cheese, or any mixture of two or more of these may be designated "American cheese".

59. Section 133.148 is amended by revising the introductory text of paragraph (f) to read as follows:

§ 133.148 Hard grating cheeses.

* * * * *

(f) Label declaration: Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

60. Section 133.149 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.149 Gruyere cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

61. Section 133.150 is amended by revising the introductory text of paragraph (f) to read as follows:

§ 133.150 Hard cheeses.

* * * * *

(f) Label declaration: Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

62. Section 133.152 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.152 Limburger cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

63. Section 133.153 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.153 Monterey cheese and monterey jack cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

64. Section 133.154 is revised to read as follows:

§ 133.154 High-moisture jack cheese.

High-moisture jack cheese conforms to the definition and standard of identity and is subject to the requirement for label statement of ingredients prescribed for monterey cheese by § 133.153, except that its moisture content is more than 44 percent but less than 50 percent.

65. Section 133.155 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.155 Mozzarella cheese and scamorza cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

66. Section 133.156 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.156 Low-moisture mozzarella and scamorza cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

67. Section 133.158 is revised to read as follows:

§ 133.158 Low-moisture part-skim mozzarella and scamorza cheese.

Low-moisture part-skim mozzarella cheese and low-moisture part-skim scamorza cheese conform to the definition and standard of identity and comply with the requirements for label declaration of ingredients prescribed for low-moisture mozzarella cheese and low-moisture scamorza cheese by § 133.156, except that their milkfat content, calculated on the solids basis, is less than 45 percent but not less than 30 percent.

68. Section 133.160 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.160 Muenster and munster cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

69. Section 133.162 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.162 Neufchatel cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

70. Section 133.164 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.164 Nuworld cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

71. Section 133.165 is amended by revising paragraph (e) to read as follows:

§ 133.165 Parmesan and reggiano cheese.

* * * * *

(e) Label declaration: Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that enzymes of animal, plant, or microbial origin may be declared as "enzymes".

72. Section 133.167 is amended by revising the introductory text to read as follows:

§ 133.167 Pasteurized blended cheese.

Pasteurized blended cheese conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for pasteurized process cheese by § 133.169, except that:

* * * * *

73. Section 133.168 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 133.168 Pasteurized blended cheese with fruits, vegetables, or meats.

(a) Pasteurized blended cheese with fruits, vegetables, or meats, or mixtures of these is the food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for pasteurized blended cheese by § 133.167, except that:

* * * * *

74. Section 133.169 is amended by revising paragraph (g) to read as follows:

§ 133.169 Pasteurized process cheese.

* * * * *

(g) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that cheddar cheese, washed curd cheese, colby cheese, granular cheese, or any mixture of two or more of these may be designated as "American cheese".

75. Section 133.170 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 133.170 Pasteurized process cheese with fruits, vegetables, or meats.

(a) Unless a definition and standard of identity specifically applicable is established by another section of this part, a pasteurized process cheese with fruits, vegetables, or meats, or mixtures of these is a food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for pasteurized process cheese by § 133.169, except that:

* * * * *

76. Section 133.171 is amended by removing paragraph (f) and revising the introductory text to read as follows:

§ 133.171 Pasteurized process pimento cheese.

Pasteurized process pimento cheese is the food which conforms to the definition and standard of identity for pasteurized process cheese with fruits, vegetables, or meats, and is subject to the requirement for label statement of ingredients, except that:

* * * * *

77. Section 133.173 is amended by revising paragraph (h) to read as follows:

§ 133.173 Pasteurized process cheese food.

* * * * *

(h) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that cheddar cheese, washed curd cheese, colby cheese, granular cheese, or any mixture of two or more of these may be designated as "American cheese".

78. Section 133.174 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 133.174 Pasteurized process cheese food with fruits, vegetables, or meats.

(a) Pasteurized process cheese food with fruits, vegetables, or meats, or mixtures of these is the food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for pasteurized process cheese food by § 133.173, except that:

* * * * *

79. Section 133.175 is revised to read as follows:

§ 133.175 Pasteurized cheese spread.

Pasteurized cheese spread is the food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for pasteurized process cheese spread by § 133.179, except that no emulsifying agent as prescribed by § 133.179(e) is used.

80. Section 133.176 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 133.176 Pasteurized cheese spread with fruits, vegetables, or meats.

(a) Pasteurized cheese spread with fruits, vegetables, or meats, or mixtures of these is a food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for pasteurized cheese spread by § 133.175, except that:

* * * * *

81. Section 133.178 is amended by revising paragraph (d) to read as follows:

§ 133.178 Pasteurized neufchatel cheese spread with other foods.

* * * * *

(d) Each of the ingredients used in the food shall be declared on the label as

required by the applicable sections of parts 101 and 130 of this chapter.

82. Section 133.179 is amended by revising paragraph (i) to read as follows:

§ 133.179 Pasteurized process cheese spread.

* * * * *

(i) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that cheddar cheese, washed curd cheese, colby cheese, granular cheese, or any mixture of two or more of these may be designated as "American cheese".

83. Section 133.180 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 133.180 Pasteurized process cheese spread with fruits, vegetables, or meats.

(a) Pasteurized process cheese spread with fruits, vegetables, or meats, or mixtures of these is a food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for pasteurized process cheese spread by § 133.179, except that:

* * * * *

84. Section 133.181 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.181 Provolone cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

85. Section 133.182 is amended by adding paragraph (f) to read as follows:

§ 133.182 Soft ripened cheeses.

* * * * *

(f) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

86. Section 133.183 is amended by revising the introductory text of paragraph (f) to read as follows:

§ 133.183 Romano cheese.

* * * * *

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

87. Section 133.184 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.184 Roquefort cheese, sheep's milk blue-mold, and blue-mold cheese from sheep's milk.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

88. Section 133.185 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.185 Samsoe cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

89. Section 133.186 is amended by revising paragraph (d) to read as follows:

§ 133.186 Sap sago cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

90. Section 133.187 is amended by adding new paragraph (g) to read as follows:

§ 133.187 Semisoft cheeses.

* * * * *

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

91. Section 133.188 is amended by adding new paragraph (g) to read as follows:

§ 133.188 Semisoft part-skim cheeses.

* * * * *

(g) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

92. Section 133.189 is amended by adding new paragraph (e) to read as follows:

§ 133.189 Skim milk cheese for manufacturing.

* * * * *

(e) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

93. Section 133.190 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.190 Spiced cheeses.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

94. Section 133.191 is revised to read as follows:

§ 133.191 Part-skim spiced cheeses.

Part-skim spiced cheeses conform to the definition and standard of identity, and are subject to the requirements for label statement of ingredients prescribed for spiced cheeses by § 133.190, except that their solids contain less than 50 percent, but not less than 20 percent, of milkfat.

95. Section 133.193 is amended by revising paragraph (a) to read as follows:

§ 133.193 Spiced, flavored standardized cheeses.

(a) Except as otherwise provided for herein and in applicable sections in this part, a spiced or flavored standardized cheese conforms to the applicable definitions, standard of identity and requirements for label statement of ingredients prescribed for that specific natural cheese variety promulgated pursuant to section 401 of the Federal Food, Drug, and Cosmetic Act. In addition a spiced and/or flavored standardized cheese shall contain one or more safe and suitable spices and/or flavorings, in such proportions as are reasonably required to accomplish their intended effect: Provided, That, no combination of ingredients shall be used to simulate the flavor of cheese of any age or variety.

* * * * *

96. Section 133.195 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.195 Swiss and emmentaler cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

PART 135—FROZEN DESSERTS

97. The authority citation for 21 CFR part 135 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

98. Section 135.110 is amended by revising paragraph (f) to read as follows:

§ 135.110 Ice cream and frozen custard.

* * * * *

(f) *Label declaration.* Each of the ingredients used shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that the sources of milkfat or milk solids not fat may be declared in descending order of predominance either by the use of all the terms "milkfat and nonfat milk" when one or any combination of two or more of the ingredients listed in § 101.4(b)(3), (b)(4), (b)(8), and (b)(9) of this chapter are used or, alternatively, as permitted in § 101.4 of this chapter. Under section 403(k) of the Federal Food, Drug, and Cosmetic Act, artificial color need not be declared in ice cream, except as required by § 101.22(c) or (k) of this chapter. Voluntary declaration of all colors used in ice cream and frozen custard is recommended.

99. Section 135.115 is amended by revising paragraph (d) to read as follows:

§ 135.115 Goat's milk ice cream.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

100. Section 135.120 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 135.120 Ice milk.

(a) *Description.* Ice milk is the food prepared from the same ingredients and in the same manner prescribed in § 135.110 for ice cream and complies with all the provisions of § 135.110 (including the requirements for label statement of ingredients), except that:

* * * * *

101. Section 135.130 is amended by revising paragraph (e) to read as follows:

§ 135.130 Mellorine.

* * * * *

(e) *Label declaration.* Each of the ingredients used shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that sources of milkfat or milk solids not fat may be declared in descending order of predominance either by the use of the terms "milkfat and nonfat milk" when one or any combination of two or more of the ingredients listed in § 101.4(b)(3), (b)(4), (b)(8), and (b)(9) of this chapter are used, or alternatively as permitted in § 101.4 of this chapter.

102. Section 135.140 is amended by revising paragraph (i) to read as follows:

§ 135.140 Sherbet.

* * * * *

(i) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

PART 168—SWEETENERS AND TABLE SIRUPS

103. The authority citation for 21 CFR part 168 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

104. Section 168.140 is amended by revising paragraph (d) to read as follows:

§ 168.140 Maple sirup.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

Dated: October 26, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 92-31523 Filed 12-28-92; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 101 and 102

[Docket No. 80N-0140]

RIN 0095-AC48

Food Labeling; Declaration of Ingredients; Common or Usual Name For Nonstandardized Foods; Diluted Juice Beverages

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food labeling regulations to establish requirements for the declaration of the percentage of juice in foods that purport to be beverages containing fruit or vegetable juice. The agency is also revising the existing common or usual name regulation for diluted fruit or vegetable juice beverages. FDA is also revoking the common or usual name regulations for noncarbonated beverage products that contain no fruit or vegetable juice and for diluted orange juice beverages. This final rule responds to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) and is part of FDA's ongoing rulemaking on juices and juice beverages.

EFFECTIVE DATE: May 8, 1993, except that amendments to part 102 become effective May 8, 1994.

FOR FURTHER INFORMATION CONTACT: Elizabeth J. Campbell, Center for Food Safety and Applied Nutrition (HFS-155), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5229.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 2, 1991 (56 FR 30452), FDA proposed requirements for the declaration of the percentage of juice in foods that purport to be beverages containing fruit or vegetable juice (hereinafter referred to as the July 2, 1991, proposal). There had been a longstanding controversy over percentage juice declaration in diluted fruit and vegetable juice beverages. The 1990 amendments (Pub. L. 101-535) settled the question of whether, and where, a declaration of the percentage of juice in a fruit or vegetable juice beverage must be included on the product's label. Section 7 of the 1990 amendments amends section 403(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(i)) to require, that "if the food purports to be a beverage containing vegetable or fruit juice, it bear a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food." In the preamble to the July 2, 1991, proposal, FDA discussed questions remaining about the exact meaning and the implementation of this provision (56 FR 30452 at 30453). The agency proposed to add new § 101.30 to establish requirements for the percentage declaration, and to delete the similar provision from the existing common or usual name regulation for diluted fruit or vegetable juice beverages in § 102.33 (21 CFR 102.33)). The agency also proposed to make revisions to the requirements in § 102.33 pertaining to the product name. FDA also proposed to revoke the common or usual name regulations for noncarbonated beverage products containing no fruit or vegetable juice in § 102.30 (21 CFR 102.30) and for diluted orange juice beverages in § 102.32 (21 CFR 102.32). Because these products would be covered under proposed § 101.30 and the revised § 102.33, the agency tentatively found that separate regulations for these products are no longer needed. In addition, the agency withdrew its July 16, 1987, proposal to revoke the existing regulations on common or usual names for diluted fruit or vegetable juice beverages (52 FR 26690).

The agency received over 200 responses to the July 2, 1991, proposal from a wide range of sources, including consumers, consumer organizations, professional associations, State and local government agencies, manufacturers, and trade associations. Each of the responses contained one or more comments. Several comments addressed issues outside the scope of the July 2, 1991, proposal and will not be discussed here. A number of comments suggested modification of various provisions of the July 2, 1991, proposal. A summary of the relevant issues raised in the comments and the agency's responses follow.

II. Percentage Juice Labeling

A. Applicability (Covered Products)

Section 403(i) of the act requires that the label of any food that purports to be a beverage containing fruit or vegetable juice bear a percent juice declaration on the information panel. In the July 2, 1991, proposal, FDA described this requirement for percentage juice declaration as applying to full-strength juices and to various other standardized and nonstandardized fruit and vegetable beverages. The scope of the proposed regulation included waters, carbonated and noncarbonated beverages containing juice, juice nectars, diluted juices, wine coolers containing juice, and any beverage that contains no juice but whose labeling, color, or flavor represents, suggests, or implies that fruit or vegetable juice may be present.

1. One comment stated that the agency should not determine for consumers when a beverage purports or does not purport to contain juice. The comment stated that consumers will come to recognize the presence or absence of juice in a beverage by the presence or absence of a percent juice declaration.

The agency points out that the statute requires percentage declaration of fruit or vegetable juice on the label of a food if it "purports" to be a beverage containing vegetable or fruit juice. The agency is therefore obliged to base its requirements on whether or not the product purports to contain juice. FDA is applying its longstanding policy on whether a food purports to contain an ingredient, i.e., a food purports to contain an ingredient if it conveys, implies, or professes outwardly that it contains that ingredient; or the food has the appearance of being, intending, or claiming to contain that ingredient. The term "purports" is used in its ordinary sense, and includes what the food is accepted as by the average consumer under ordinary conditions of purchase as well as what it appears or is represented to be by labeling or other means. (*United States* v. *306 Cases Containing Sandford Tomato Catsup with Preservative*, 55 F. Supp. 725, 727 (E.D.N.Y. 1944); *United States* v. *30 Cases, More or Less, labeled in part: "Leader Brand Strawberry Fruit Spread,"* 93 F. Supp. 764 (S.D. Iowa 1950). Accordingly, a beverage purports to contain juice if it states or implies on the label that it contains juice or has the appearance of being juice or containing juice. New § 101.30(a) applies this policy for beverages.

2. Several comments said that FDA should be able to use extra-label sources of information, such as advertisements and store promotions as well as the beverage label, in determining whether percent juice declaration requirements apply. Several comments stated that percent juice declaration requirements should apply to carbonated soft drinks if a manufacturer uses advertising to represent that the firm's beverage contains juice. On the other hand, one comment opposed the use of extra-label sources of information to determine whether a product purports to contain

juice because there is no precedent for it.

The agency agrees that advertisements in the form of store promotions or other extra-label information stating or implying that the particular beverage contains juice result in the advertised beverage purporting to contain juice, and therefore percentage juice declaration is required. While FDA is not attempting to regulate advertising or claims made in advertising, contrary to the second comment, statements made in advertising have long affected the labeling of food products. FDA has given similar significance to advertising in the regulations on nutrition labeling (§ 101.9 (21 CFR 101.9)) and on the characterizing flavor labeling requirements (§ 101.22 (21 CFR 101.22)). In both of these instances, an advertising claim for a nutrition or flavor characteristic of a food invokes the requirement for nutrition labeling or flavor characterization labeling on the basis that the consumer who wants the food because of its particular nutrient content or flavor is entitled to examine a label that reveals facts material in light of the representations made, including those made in advertising, at the time of purchase. Similarly, FDA concludes that once a juice content claim is made for a beverage, the consumer who wants the product because of claims about its juice content is entitled to examine a label that provides juice content information at the time of purchase. Therefore, the agency is providing in new § 101.30(a) that advertising is a means by which a beverage purports to contain juice.

3. One comment expressed the belief that the requirement in the 1990 amendments for percent declaration of juice content does not apply to full-strength juice (including 100 percent juice prepared from concentrate). It stated that the 1990 amendments mandated this information for beverages that contain fruit or vegetable juices and not those that are 100 percent fruit or vegetable juice.

The agency disagrees with this interpretation of the statute. The statute states, "* * * if the food purports to be a beverage containing vegetable or fruit juice * * *." A single-strength juice product may contain a single juice as its only ingredient. A beverage that is a single-strength juice made from concentrate and water contains 100 percent juice. Likewise, a beverage that is a blend of more than one single-strength juice may contain 100 percent juice. The agency believes that using the interpretation in the comment would result in inconsistent requirements, e.g., the second and third types of products described above would bear percentage juice declarations, while the beverage consisting of one single-strength juice as its only ingredient would not.

The legislative history for this provision is not helpful in determining congressional intent. It states only: "Section 7(2) would require statements as to the percentage of fruit or vegetable juice contained in products sold as such juice." (136 Congressional Record—H5842 (July 30, 1990)). Thus, FDA finds no basis to conclude that Congress intended such an inconsistent outcome and therefore concludes that the interpretation of the statute in the comment is incorrect. Accordingly, the agency finds that beverages that contain only a single-strength juice are subject to the percentage juice declaration requirements.

4. A number of comments requested that juice flavored waters and seltzers be exempted from the requirement for declaration of percent of juice. They stated that the juice ingredient in these beverages is present in minor amounts (usually less than 2 percent) for flavoring, and that the beverages are not considered by consumers to be sources of juice. They stated further that naming the juice used as a flavor in the ingredient list should not be considered as purporting to be a beverage that contains juice. Several of the comments stated that a product should not have to declare percent of juice if the label states that it is flavored with the fruit juice, e.g., "———— flavored drink" or "A-B drink with a touch of lemon." The comments explained that the term "flavored" used with the common or usual name of the beverage informs the consumer that the juice is present in minor amounts for flavoring or taste, and that the beverage does not contain a significant amount of fruit or vegetable juice.

The agency agrees with the comments that a beverage flavored with a small amount of juice may not "purport to be a beverage containing juice" as that phrase is meant in the 1990 amendments. FDA believes that declaration of juice content provides information essential to the consumer in determining the nature of the product and reveals facts material in light of any representation made that the beverage contains juice. The agency considers that where a beverage contains a small amount of juice (usually less than 2 percent) for flavoring purposes, the label makes clear that the juice is present for flavoring, the word "juice" is not used on the label except in the ingredient list, the beverage is not represented as containing a significant amount of juice. In such a case, information on the amount of juice present would not be essential to describe the nature of the product. The agency concludes that such a product does not purport to contain juice within the meaning of the statute, and that therefore declaration of percent of juice is not required.

However, the label statement describing the flavor role of the small amount of juice must include the term "flavor" or "flavored" or otherwise indicate that the amount of juice is small and not use the word "juice." When a beverage contains a fruit or vegetable juice but does not use a form of the word "flavor" or otherwise indicate that the amount of juice is small, e.g., "lemon iced tea" or "lemon drink," the combination of the name of the fruit in the name of the product and declaration of the juice in the ingredient list implies that the beverage not only derives its flavor from the juice, but that it contains the juice. Thus, the product would purport to contain juice. In addition, use of the word "juice" in the flavor designation or elsewhere on the label, except in the ingredient list, would convey a similar impression. The statute requires the declaration of the percent of the juice in such circumstances.

In addition, the overall impression of the label, packaging, and physical characteristics of the beverage taken together may give the consumer the impression that the beverage contains juice and not just minor amounts of juice for flavor. For example, vignettes, such as one depicting juice flowing or oozing from a fruit or vegetable, or the physical characteristics of juice, such as the presence of pulp, would give the impression that the beverage contains juice. As described in new § 101.30(a), beverages bearing such representations purport to contain juice and are therefore required to bear the percent juice declaration.

Accordingly, the agency is including in the final regulation as new § 101.30(c) (proposed § 101.30(c) and (d) are deleted in response to comment 10 of this document) an exemption from percentage juice declaration for juice flavored beverages such as waters or seltzers provided that the beverage is labeled with a juice flavor description using the term "flavor," "flavored," or "flavoring" or otherwise makes clear that the juice is present in a small amount. To be exempt, the product's advertising, label, and labeling must not bear: (1) The term "juice" on the label other than in the ingredient statement, e.g., "seltzer water flavored with raspberry" or "seltzer water with a touch of raspberry;" (2) a vignette, e.g., depicting juice exuding from a fruit or vegetable; or (3) specific resemblance to

a juice, e.g., via distinctive juice characteristic such as pulp.

5. In the preamble to the July 2, 1991, proposal, FDA tentatively concluded that wine coolers and similar beverages containing less than 7 percent alcohol by volume that purport to contain unfermented fruit or vegetable juice are covered by proposed § 101.30 and are required to bear a percentage juice declaration (56 FR 30452 at 30454). While several comments supported this position, others objected, stating that wine coolers do not purport to contain juice but are juice flavored wine. The comments stated that many brands of wine coolers and some sangrias currently sold in the United States contain natural and artificial juice flavors rather than juice or pulp and are labeled in compliance with § 101.22, indicating that they contain flavors rather than juice. One of the comments stated that brands representing approximately 93 percent of all wine coolers sold in the United States are manufactured with fruit flavors rather than fruit juice. Several comments stated that wine coolers, including sangrias, should be treated in the same fashion as juice flavored soft drinks because consumers purchase wine coolers as alternatives to other alcoholic beverages, the same as soda drinkers who drink cherry cola when they want a change from regular cola.

The agency points out that wine coolers that do not contain unfermented juice are not covered by this regulation unless they purport to contain juice by means of advertising, labeling statements, vignettes, or physical characteristics. Thus, if a wine cooler does not contain any juice, has labeling that makes clear that it contains flavors rather than juice, and does not bear a vignette that implies fruit juice content, it is not subject to new § 101.30. In addition, FDA advises that noncarbonated beverages that purport to contain juice but do not, in fact, contain any juice were required by § 102.30 to state that they contain no juice. FDA concludes that this new regulation does not appreciably change the requirements for juice content declaration for the wine coolers referred to in these comments. Accordingly, no change in the regulation or its applicability is warranted by these comments.

6. Several comments stated that requiring percentage juice declaration on wine coolers is unfair because the same requirement does not apply to most other alcoholic beverages including spirits-based and malt-based coolers, which compete directly against wine coolers.

The agency advises that the labels of alcoholic beverages (those that contain 7 percent or more alcohol by volume and malt beverages) are regulated in accordance with the Federal Alcohol Administration Act (27 U.S.C. 205) administered by the Bureau of Alcohol, Tobacco and Firearms and are controlled differently from wine coolers. The labeling of wine coolers, like other beverages that contain less than 7 percent alcohol by volume, are regulated under the act. To the extent that these statutes differ, the products are regulated differently in other labeling aspects as well as in declaration of percentage juice content. It is not up to FDA, but to Congress, to decide that the same requirements must apply to wine coolers, other alcoholic beverages, and malt based beverages.

7. Some comments agreed with the agency proposal that traditional carbonated fruit-flavored soft drinks (sodas) have a substantial history of marketing as products with fruit flavor and are recognized as containing only fruit flavor and not necessarily fruit juice. These comments recommended that carbonated fruit flavored soft drinks be exempted from percentage juice declaration. However, several other comments said that the percent juice declaration regulation should apply if a soft drink manufacturer uses labeling to represent that a carbonated beverage does contain juice, such as vignettes depicting juice dripping from a fruit.

These comments are consistent with the preamble to the July 2, 1991, proposal, in which FDA stated that the label and labeling of soft drinks (sodas) generally do not give the impression through words or explicit vignettes that these beverages contain juice (56 FR 30452 at 30454). FDA therefore concludes that if a soft drink (soda) does not represent or suggest in the name, labeling statement, or ingredient statement that it contains fruit or vegetable juice, there is no basis to find that it purports to contain juice. Accordingly, for clarity the agency is adding a statement to that effect to the regulation in § 101.30(a). However, FDA also concludes that, as discussed in the preamble to the July 2, 1991, proposal, a soft drink (soda) that contains ingredients, such as pulp, that give the impression that it contains juice or that bears an explicit vignette that gives the impression of juice content, purports to contain juice (56 FR 30452 at 30454). Such a product would be required under § 101.30(d) to declare juice content. In addition, those soft drinks that do contain juice usually make that fact known. These products purport to contain juice and are subject to the percentage juice declaration requirement.

8. In the July 2, 1991, proposal, FDA also addressed requests for exemption from percentage declaration for bulk juice concentrates for institutional use. The agency stated that it was not proposing to exempt these bulk concentrates because of a lack of information substantiating the need or value of such an exemption. Some comments requested exemption from percent juice declaration for bulk juice concentrates for institutional use because they claimed this information is provided to consumers in other ways by the institution, and the institution specifies the juice content of the product in contracts and purchasing agreements.

Because these comments provided no additional information to support their assertions, the agency still does not have information that demonstrates a need for an exemption from percentage juice declaration for bulk juice concentrates for institutional use. Therefore, FDA is not including such an exemption in this final rule.

However, those requesting an exemption from percentage juice declaration for bulk juice concentrates for institutional use may petition for such an exemption under § 10.30 (21 CFR 10.30), providing the agency with information such as actual contracts or purchasing agreements specifying juice content and verifiable instances and examples of the percentage juice content presentation provided to consumers served the juice derived from the bulk juice concentrates by specific institutions, as well as data demonstrating the extent of use of these products by institutions.

9. Some comments requested exemption from percent juice declaration for bulk concentrates intended for further processing because consumers would not see the labeling, and manufacturers require bulk concentrate that meets their specifications from their suppliers.

The agency advises that bulk concentrates for further processing are covered by the exemptions provided in § 101.100(d) (21 CFR 101.100(d)). That regulation specifies criteria for exemption from labeling requirements including those of section 403(i) of the act. Therefore, there is no need to grant a new exemption.

B. What Percentage Must be Declared

Section 403(i) of the act, as modified by section 7(2) of the 1990 amendments, requires that if a food purports to be a beverage containing fruit or vegetable juice, it must bear a statement of "* * *

the total percent of such fruit or vegetable juice contained in the food * * *." In the July 2, 1991, proposal, FDA tentatively concluded that this statement could be read two ways, one to require declaration of percent of total juice and the other to require declaration of percent of each juice represented to be in the beverage. The agency found that under either reading a material fact would not be disclosed. Reading section 403(i) of the act together with section 201(n) of the act (21 U.S.C. 321(n)) and section 403(a) of the act, FDA proposed to require declaration of both the percent of total juice and the percent of each juice represented to be in a multiple-juice beverage.

10. Many comments opposed the requirement for declaration of percent of individual juices in multiple-juice beverages. They cited the following reasons for their opposition: (1) The statutory language of the 1990 amendments does not require declaration of percent of individual juice in multiple-juice beverages; (2) proprietary formula information would be revealed by a 1-percent increment declaration of individual juices; (3) variable (least cost) juice blend formulation driven by fluctuations in cost or availability of individual juices would be eliminated with the proposed 1-percent increment label declaration requirement as labels would have to be changed to reflect formulation changes; (4) the requirement is unenforceable with current analytical methodology; (5) there are no data or information that demonstrate consumer interest in or benefit from the requirement; and (6) label clutter on the information panel would be increased.

In contrast, other comments supported the proposed requirement for individual juice percentage declaration, stating: (1) The 1990 amendments clearly require a total percent juice declaration, and it does not follow that Congress did not intend for the consumer to be fully apprised of the identity and amount of the juices that make up the declared total amount of juice; (2) some juice beverages have misleading labels in that high cost/value or intense flavor juices are given greatest label prominence but are present in minor amounts; (3) some manufacturers misrepresent the juice content of their beverage through the use of added pulp, clouding agents, and thickening agents which mislead consumers into believing that these beverages have more juice than is actually present; (4) more precise, direct information on relative amounts of specific juices in multiple-juice beverages is needed by consumers to make in-store purchasing decisions; (5) among multiple-juice beverages with the same total juice percentage, a juice's order of predominance in the ingredient statement does not directly translate to its percentage in the beverage; and (6) enforcement actions by Federal, State, and local consumer protection agencies will be needed less often because the percent of individual juice declaration will remove possible ambiguity as to whether a product label may be misleading to the consumer.

The agency has reconsidered its interpretation of the amendment to section 403(i) of the act in light of the arguments presented in the comments. The agency notes the contrast in language in section 403(i)(2) of the act, which, on the one hand, requires the declaration of the common or usual name of "each such ingredient" when a product is fabricated from two or more ingredients but only the declaration of the total juice percentage of "such" fruit or vegetable juice contained in the food, not "each" fruit or vegetable juice contained in the food. Thus, had the intent of Congress been to require percent individual juice declaration, it clearly knew how to do so. Based on the face of the law, it is reasonable to expect that Congress would have used the word "each" in place of, or preceding, the word "such" in the phrase "such fruit or vegetable juice," as it did in the phrase "each such ingredient." Without relevant legislative history on the provision, FDA now finds that the better reading of section 7 of the 1990 amendments is that it requires declaration of percent of total juice but not declaration of percent of individual juices in a multiple-juice beverage.

Nor is it clear that the percent of each individual juice represented on the label is a material fact under section 201(n) of the act for all multiple-juice beverages. In the July 2, 1991, proposal, FDA stated that if the label of a beverage declared the presence of one or more juices by representation (i.e., word or vignette) and declared the total percentage of juice in the product, but did not declare the percentage of each individual represented juice, the label would be misleading (56 FR 30452 at 30456). The agency tentatively found that such a label would create an impression that overstates the amount of the represented juices in the beverage if not all the juice in the beverage is supplied by the represented juices.

While beverage labels clearly are misleading if they misrepresent the contribution of one or more individual juices to the total amount of juice, the agency acknowledges that not all multiple-juice beverage labels that bear representations of individual juices misrepresent the contribution of the individual juices to the total. For example, a vignette that depicts all the fruits or vegetables in the product may not misrepresent an individual juice contribution. In addition, declaration as a part of the product name of all juices present (in descending order by volume of single-strength juice) would generally not be misleading.

Accordingly, FDA is not including in the final regulation the requirements in proposed § 101.30(c) and (d) for the declaration of the percent of juice for all juices in multiple-juice beverages that are declared in the label or labeling, by word, vignette, or other means, other than inclusion in the statement of ingredients, to be present in the beverage. The agency is also deleting proposed § 101.30(e), which provided for optional declaration of percent of individual juices not represented on the label. Instead, the agency has included in the final regulation on the common or usual name of such beverages, provisions for adequately descriptive names that will inform the consumer of the nature of the product. As discussed in detail in Section III. of this document, for beverages where one or more but not all the juices are named and the named juice is not the predominant juice, the agency is providing two alternatives for describing the contribution of the named juice. The label must either state that the beverage is flavored by the named juice (e.g., "raspberry flavored juice drink") or declare the content of the named juice in a 5 percent range (e.g., "raspberry juice drink 2 to 7 percent raspberry juice"). The agency believes that this approach will adequately deal with the kinds of misleading labeling discussed in the comments from consumer groups.

Because FDA is deleting the requirement for declaration of percent of individual juice content in multiple-juice beverages, a number of comments are no longer relevant. Such comments include those regarding which juices should be included in the percent of individual juice declaration and the impracticability of declaring individual juices in 1-percent increments. The agency is not addressing these comments because the concerns they express are moot. In addition, allegations that this regulation would result in a compensable taking of private property are no longer relevant. These allegations were based on the contention that a requirement for declaration of percent of individual juices would be a mandatory disclosure of proprietary information and would thereby constitute a taking. Because the

requirement in question has been deleted, there is no need for FDA to address the issue.

11. No comments objected to the requirement that the declaration of percent of total juice be in 1-percent increments. However, several comments pointed out that the regulation should provide for beverages that contain less than 1 percent juice. They stated that to have a "0 percent juice" declaration on a product with juice declared in the ingredient list would be confusing to the consumer. One comment suggested that FDA provide for a statement such as "less than 1 percent juice" instead of requiring "0 percent juice" for those products that contain juice at a volume of less than 1 percent.

The agency agrees that a declaration of juice content of less than 1 percent may be appropriate if it accurately describes the amount of juice in the product. Therefore, FDA is revising the provisions in new § 101.30(b) for percentage juice declaration to allow for this declaration.

C. How Declarations Should Be Made—Placement and Prominence

Section 403(i)(2) of the act requires "a statement with appropriate prominence on the information panel" of the percentage of juice. The agency proposed requirements that it believed would provide appropriate prominence for the percentage juice declaration and still allow room for other required information. The agency proposed in § 101.30(g) that if the beverage is sold in a package that has an information panel, the percentage juice declaration is to be prominently placed near the top of the information panel, with no other printed label material appearing above it. Additionally, the agency proposed to require that the declaration be in easily legible boldface print or type in distinct contrast to other printed or graphic matter, in a height not less than the largest type found on the information panel except that used for the product name, and in lines generally parallel to the base on which the package rests.

The agency also proposed in § 101.30(h) that the percentage juice declaration may also be placed on the principal display panel if the declaration is consistent with that presented on the information panel. Further, the agency proposed in § 101.30(i) that if the beverage package does not include an information panel, the percentage juice declaration must be placed on the principal display panel: (1) In type size not less than that required for the declaration of net quantity of contents statement, (2) located near the name of the food, and (3) in lines generally parallel to the base on which the package rests. (Paragraph designations of new § 101.30 have been changed to paragraphs (e), (f), and (g), respectively, as a result of changes discussed in response to comment 10 of this document.)

12. Some comments suggested that the total juice content should be required to be placed at the top of the principal display panel with the common or usual name. They stated that otherwise the declaration of total juice would not have appropriate conspicuousness or prominence, because many consumers do not routinely, or cannot easily, read fine print, i.e., one-sixteenth of an inch minimum height, on the information panel.

The agency advises that the act requires that the percent juice declaration be on the information panel. The comments did not provide a legal basis on which the agency could require an additional declaration on the principal display panel. However, as provided in new § 101.30(f), the agency is permitting percent total juice on the principal display panel as an optional declaration.

13. Several comments stated that in addition to the percent juice declaration on the information panel, percent juice declaration should be allowed on the principal display panel.

As stated in response to the previous comment, the agency does not object to the additional declaration of percent juice content on the principal display panel, provided that it is consistent with the declaration on the information panel. This additional declaration is provided for in new § 101.30(f).

14. Although no comments objected to the requirement that a total percent juice declaration appear on the principal display panel in the absence of an information panel, some comments objected to the requirement that placement of the percent juice declaration on the principal display panel be near the name of the food. These comments asserted that there is no compelling reason for such placement, and that there should be more flexibility in the location of the declaration.

The agency disagrees with the comments. Consumer use of the percent juice content declaration will be facilitated if it is in a consistent, prominent location on the food label. The comments did not recommend alternative placement criteria.

Currently, some juice beverage labels bear percent juice statements such as "100 percent juice" or "100 percent juice blend" on the principal display panel near the name of the juice product. Because of the longstanding industry tradition of marketing food products bearing percentage claims near the name of the food on the principal display panel, and because of agency regulations providing for such percentage declarations in association with the common or usual names of nonstandardized foods (§ 102.5(b) (21 CFR 102.5(b))), consumers have become accustomed to seeing such percent juice information, when it appears on the principal display panel, near the name of the food. Therefore, the agency concludes that the proposed requirement for placement of the percent juice declaration on the principal display panel near the name of the food, if there is no information panel, provides appropriate prominence as required by the statute. This requirement is set forth below as new § 101.30(g).

15. Several comments objected to the proposed requirement that the percent juice declaration be near the top of the information panel with no printed information appearing above it. These comments wanted more flexibility to use available label space efficiently and to minimize label clutter that they said would result from declaration of percent juice statements near the top of the information panel. The comments stated that the 1990 amendments did not mandate that the percentage juice declaration be the most prominent or conspicuous item on the information panel. Finally, the comments said that the July 2, 1991, proposal gives the declaration more prominence than health and safety statements such as those required for saccharin section 403(o) and (p) of the act (codified at 21 CFR 100.130(d)(2), 101.11, 105.66(b) and 180.37) or phenylalanine (21 CFR 172.804(e)(2)), and other statements concerning storage, preparation, recycling, and deposit information. The comments requested that they have, at a minimum, the option of placing such information as the brand name, product name, product logos, and the universal product code (UPC) above the percentage juice declaration.

The suggestion in the comments that required information on the information panel is not more important than optional information, and should have equal but not greater prominence, is contrary to existing regulatory requirements that have not been changed by the 1990 amendments. The agency is not requiring that the percent juice declaration be the most prominent and conspicuous item on the information panel by virtue of its placement near the top of the

information panel. FDA considered that the same regulations that currently apply to labeling information appearing on the information panel (§ 101.2 (21 CFR 101.2)) will also apply to the total percent juice declaration and did not wish to unduly disrupt the customary sequence of required information on the information panel, i.e., nutrition information, ingredient statement, and name and place of business of the distributor (§ 101.2(b)). Further, because the percentage juice declaration is now required information, the agency believes it must be at least as prominent as other required information to have the "appropriate prominence" required by the statute (21 CFR 101.2(c) and 101.15).

Consistent with these considerations, the agency finds that placing optional information such as storage instructions and recipes, which need not appear on the information panel at all, above the total percentage declaration, and consequently above all other required information on the information panel, will not give the percentage declaration "appropriate prominence." The comments did not provide any examples or information to substantiate a need for additional flexibility, and the agency is not convinced by the comments' assertions that the prominence and placement of the required total percent juice declaration is unreasonably restrictive.

However, having considered all the comments on this issue, the agency concludes that since the product name or brand name or logo often appear at the top of the information panel, they may continue to appear above the percentage juice declaration on the information panel. However, any additional printed material, other than product name or brand name or logo that appears above the percentage juice declaration will render the percent juice declaration so inconspicuous that the "appropriate prominence" required by the 1990 amendments will not be provided. Consistent with past agency practice, foods whose labeling omits or fails to prominently or conspicuously convey required information, and instead utilizes available label space to give prominence and conspicuousness to nonmandatory information, will be subject to legal action.

Finally, FDA considers the UPC to be a sufficiently distinctive label feature that it does not affect the prominence and conspicuousness of other information on the label. The agency has therefore not seen a need to regulate its location on the label in relation to required information. Consequently, the final regulation does not prohibit the UPC from appearing above the percentage declaration on the information panel.

Accordingly, the agency is revising the regulation in new§ 101.30(e)(1) to include the words "except the brand name, product name, logo, or universal product code" after the word "statement."

16. Several comments objected to the requirement that the percent total juice declaration be not less than the largest type on the information panel except that used for the product name because it gave the percent declaration undue prominence. These comments asserted that the type size requirements should not be any greater than for other required information, i.e., a minimum one-sixteenth of an inch in height unless exempted pursuant to § 101.2(f). Additionally, the comments asserted that type size requirements should relate only to type size of the required information on the information panel and not to the brand name, product name, UPC, or any other nonmandatory information on the information panel. One comment suggested a minimum 3/32 of an inch type size instead of the proposed one-sixteenth of an inch on large containers such as half-gallon cartons, so that the print size would be more proportional to other printed material on the carton.

In the July 2, 1991, proposal, the agency attempted to strike a balance between "appropriate prominence" for the percent juice declaration and that of other required information and of nonmandatory information on the information panel. The agency believes that the total percentage juice declaration should be at least as prominent as any other information on the same panel, whether required or not. However, because the agency also recognized that manufacturers may desire to place the product name prominently on the information panel, it proposed to exclude the name from consideration relative to the type size for the total percent juice declaration. Consistent with the decision above to permit brand name, product name, logo, or UPC to be located above the percent juice declaration, the exclusion from type size comparison should also apply to the brand name and the logo. The agency also did not intend to include the UPC among the label information on which type size for the percent juice declaration is based. As stated above, it considers that the UPC is sufficiently distinctive in appearance that it does not interfere with the prominence or conspicuousness of other label information.

In meeting the mandate of the 1990 amendments for appropriate prominence of the percentage juice declaration, FDA did not wish to deviate unnecessarily from existing type size requirements or to establish new type size requirements such as the requested 3/32 of an inch type size for large containers. The comment requesting larger minimum type size for large containers did not provide information to substantiate a need for larger type or to demonstrate that the 3/32-inch type size would be appropriate to meet such a need. Therefore, FDA is retaining the one-sixteenth of an inch minimum type size provision in the final rule.

To summarize, the type size requirement of not less than the largest type on the information panel with the exception of product or brand name, the logo, and the UPC ensures a certain proportionality of type size for required and nonmandatory statements. This proportionality of type size both provides for "appropriate prominence" of the percentage juice declaration and helps to curb instances of inappropriate prominence of nonmandatory information over required information on the information panel.

Therefore, the agency is requiring in new § 101.30(e)(2) that the declaration of percentage juice be prominently placed on the information panel, appearing in easily legible boldface type, in distinct contrast to other printed or graphic matter, in a height not less than the largest type on the information panel except for that used for the brand name, product name, logo, or UPC.

17. Some comments objected to the requirement in proposed § 101.30(g)(2) that the percentage juice declaration on the information panel be in lines generally parallel to the base upon which the package rests. They stated that the requirement limits the flexibility of beverage manufacturers in placement of the required declaration and other required information on the information panel. Several other comments suggested that the percent juice declaration be in lines generally parallel to other required information, whether or not this information is also parallel to the base on which the package rests.

The agency advises that placing required information on the principal display panel in lines other than generally parallel to the base upon which the package rests requires the consumer to unnecessarily manipulate the package to read the required information, making it less likely to be read. Consistent with this fact,

statements of identity and net quantity of contents are required to appear on the principal display panel in lines generally parallel to the base upon which a package rests (§ § 101.3(d) and 101.105(f) (21 CFR 101.3(d) and 101.105(f)), respectively).

However, the agency agrees with the comments that requiring that the percent juice declaration be on the information panel in lines generally parallel to the base is not justified because other mandatory information on the information panel is not required to be in lines generally parallel to the base of the package. The regulations in § 101.2 do not include specific orientation requirements for mandatory declarations such as the ingredient statement, nutrition labeling, or name and place of business of the manufacturer, packer, or distributor.

Accordingly, FDA concludes that because it does not have substantial justification for this additional orientational requirement and in light of objections from comments, the proposed requirement should be withdrawn. Therefore, FDA has deleted the phrase "and in lines generally parallel to the base on which the package rests" from proposed § 101.30(g)(2) (redesignated as new § 101.30(e)(2) in this final rule).

The agency, however, is persuaded by the suggestion in the comments that the percent juice declaration should be in lines generally parallel to other required information, whether or not this information is also parallel to the base on which the package rests. Because existing § 101.2(e) provides that all information appearing on the information panel pursuant to this section must appear in one place without intervening material, it is reasonable that the percent juice declaration should be in lines generally parallel with this information, so that the consumer will not have to manipulate the package to read all the required information. This orientational requirement will ensure that appropriate prominence of the percent juice declaration is maintained. Therefore, the agency has inserted the phrase "in lines generally parallel to other required information" after the word "panel" in new § 101.30(e).

D. Associated Label Statements

In the July 2, 1991, proposal, FDA discussed declarations that use a percentage (usually 100) to describe a term other than juice, such as "100 percent pure" or "100 percent natural" (56 FR 30452 at 30457). The agency stated that these declarations have a great potential to mislead the consumer into believing that the product is 100 percent juice. FDA advised that such statements should not be used. In addition, the agency requested comments as to whether FDA should adopt regulations specifically providing that declarations such as "100 percent pure" or "100 percent natural" or "100 percent" to describe a term other than juice are misleading, particularly when used on the principal display panel of diluted juice beverages.

18. Several comments stated that the terms "pure" and "natural" are ambiguous and tend to mislead consumers about the nature of a product. These comments stated that at times, the terms "pure" and "natural" mislead a consumer into believing that the product consists entirely of juice. A number of comments stated that using the term "100 percent" with the terms "pure" and "natural" exaggerates and exacerbates the already ambiguous and misleading nature of the terms "pure" and "natural" on diluted juice beverages. These comments said that consumers are consistently confused and misled by such statements into believing that the beverages are all juice with no additional ingredients or are full-strength (100 percent) juice. These comments stated that the use of these phrases should be restricted by FDA because most juice beverages are not 100 percent juice, or they are processed, i.e., reconstituted with water and ingredients other than juice such as sweeteners, preservatives, flavors, colors, pulp, and thickening and clouding agents to restore the juice to its original expressed juice state, to compensate for seasonal or regional variations, or to create a unique juice based beverage.

Opposing comments stated that the terms "pure" and "natural" can be used in some contexts in which they would not be misleading. These comments argued that consumers read the terms "pure" and "natural" to mean that the product is made of natural ingredients such as fruit juices, water, natural sweeteners, and flavors. They recommended that labels bearing the terms "pure" and "natural" be evaluated on a case-by-case basis.

Several comments were of the opinion that use of a percentage to describe an undefined attribute on products required to bear a percent juice declaration could potentially be misleading to consumers. They stated that therefore, any use of "100 percent" on the label in conjunction with an undefined term should be prohibited unless the product is a full-strength (100 percent) juice product. However, these comments stated that this policy should not restrict use of a percentage declaration that is clearly defined as not being related to juice content, i.e., "contains 100 percent of U.S. Recommended Daily Allowance (U.S. RDA) for Vitamin C."

The agency advises that while there is no specific prohibition against the use of the terms "pure" and "natural," it has discouraged the use of these terms because they are ambiguous and may be misleading. For example, "orange juice," "pure orange juice," and "100 percent pure orange juice" are identical foods, but "pure" as applied to the food implies that other identical products are "impure" or "not pure" if they do not bear the same term on their label. The term "natural" is similarly ambiguous when applied to any food except flavors and flavorings.

The agency concludes that this rulemaking is not the appropriate vehicle to consider whether terms such as "pure" and "natural" should be permitted on juice product labels. The comments presented opinions on the word "pure," but they did not provide sufficient information on which to base a regulation. The term "natural" is included in another agency rulemaking. In the **Federal Register** of November 27, 1991 (56 FR 60421 at 60466), FDA published a proposal entitled "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms" that included, among other things, a discussion of various aspects of defining the term "natural." A final rule based on that proposal is published elsewhere in this issue of the **Federal Register**. In that rulemaking, however, the agency decided not to define the term "natural."

However, FDA also concludes that the use of a percentage, particularly 100 percent, in conjunction with terms other than "juice," such as "pure" and "natural," on a beverage that is not full-strength juice can be misleading, particularly where the 100 percent figure appears near the name of the product but not in close proximity to a prominent declaration of the percentage of juice. On the other hand, FDA agrees with those comments that stated that statements clearly unrelated to juice content, e.g., "provides 100 percent of U.S. RDA of vitamin C," are not misleading.

Therefore, to clarify these matters, under sections 403(a) and 701(a) of the act (21 U.S.C. 371(a)), the agency is including in the final regulation a prohibition on the use of "100 percent" or any other percentage unrelated to juice content that could be misunderstood to represent the percent of juice in the beverage. This provision in the final regulation, designated new

§ 101.30(l), states: "A beverage required to bear a percentage juice declaration on its label shall not bear any other percentage declaration that describes the juice content of the beverage in its label or in its labeling (e.g., "100 percent natural" or "100 percent pure"). However, the label or labeling may bear percentage statements clearly unrelated to juice content (e.g., "provides 100 percent of U.S. RDA of vitamin C").

E. Calculation of Percentage Juice

1. Juice From Concentrate

The agency proposed that in enforcing the act and in ensuring that percentage juice declarations are truthful and not misleading, it would calculate the percentage juice from concentrate in a juice or juice beverage using the minimum Brix levels that were listed in proposed § 101.30(j)(1). (Because of revisions to the final regulation proposed § 101.30(j) is redesignated as new § 101.30(h)). In the July 2, 1991, proposal, the agency strongly recommended that manufacturers use this method in calculating the percentage juice from concentrate. The agency also advised that if the July 2, 1991, proposal were adopted, while manufacturers may use any appropriate alternate method, they should ensure that this alternate method produces similar results.

In the preamble to the July 2, 1991, proposal, FDA listed proposed minimum Brix values for a number of fruit and vegetable juice products and minimum anhydrous citric acid contents for two fruit juices, based primarily on data from the National Juice Products Association (NJPA) in December of 1989 and May of 1990 (56 FR 30452 at 30466).

FDA received comments on 13 of the 51 proposed minimum Brix values for 100 percent juice and comments regarding minimum Brix values for two other juice products not listed in the proposed regulation. Most comments claimed that one or more of the 13 values were too high and offered information or data to support their claims. Several comments simply objected to the proposed Brix values as being too high without suggesting more appropriate values. Brix data in the comments were provided in several forms: Individual values, ranges of values, monthly or yearly averages, and mean values with designated standard deviations. A presentation of the data submitted, and the agency's review and conclusions, follow.

a. Evaluation of Brix data in comments.

FDA acknowledges that much of the Brix data in agency files is old and may be out of date. The Brix data used in establishing the fruit or fruit juice content in the standards of identity for fruit butter and fruit jelly (§§ 150.110 and 150.140 (21 CFR 150.110 and 150.140)) were obtained from authentic fruit samples collected before 1940. Although the data were used for many years without question for fruit butters and fruit jelly, when these data were incorporated in the standard of identity for canned nectars, FDA received an objection that questioned the applicability of the single-strength juice values to canned nectars and suggested that they be reevaluated in light of current commercial practice in the manufacture of nectars. Thus, the standard for canned nectars (§ 146.113 (21 CFR 146.113)) was stayed in 1968 (33 FR 10713, July 27, 1968).

Differences in juice composition that result from factors such as horticultural practices, processing operations, and geographical origin, as well as the use of new varieties of certain species, may account for differences in Brix values obtained on juice products prior to 1940 and values obtained for fruit juices currently produced under current good manufacturing practice. In reviewing the data submitted in comments, FDA has consulted published references on juice composition, e.g., U.S. Department of Agriculture (USDA) Food Composition Tables (Handbook 8–9: Fruits and Fruit Products and Handbook 8–11: Vegetables and Vegetable Products) (Refs. 5 and 6). FDA has also reviewed Brix data in files that were used in support of existing standards of identity and data contained in published articles on juice research and composition. In instances where there are established values in standards of identity that appear to be too high compared to newer information, and the data submitted in support of lower values seem reasonable in light of this newer information, FDA has adopted a lower value in new § 101.30(h)(1). Where FDA has adopted a lower Brix value for 100 percent juice than is currently listed for the fruit juice in an existing standard of identity, FDA intends to consider revision of the standard of identity at a later date to make it consistent with the Brix value that the agency is adopting in this regulation.

b. Use of Brix data.

19. Several comments supported FDA's proposal to calculate the labeled percentage of juice from concentrate in a reconstituted juice or in a diluted juice beverage based on the minimum Brix standards. One comment expressed the opinion that the Brix concept represents the most workable method for accurately and consistently calculating the percentage of juice. A comment from the Government of Canada also expressed support for specifying minimum Brix values for use in calculating the percentage of juice included in diluted juice beverages and reconstituted juices. However, the comment stated that it does not support the proposed Brix values because they would effectively exclude Canadian products from the U.S. market. Other comments in the letter from the Government of Canada on specific juices are discussed below. One comment opposed the proposed method of calculating the percentage of juice based on minimum Brix values, established by regulation, instead of requiring the percentage of juice to be calculated in terms of the actual soluble solids content of the original juice. The comment maintained that use of the table of fixed Brix values in proposed § 101.30(j)(1) (redesignated as new § 101.30(h)(1)), which, the comment contended, contains values well below the Brix of sound ripe fruit, gives food processors a license to overstate the quantity of juice in their products.

FDA recognizes that when a minimum Brix value based on the mean or a range of values for a particular fruit or vegetable juice is established by regulation, there will always be some juices that will have Brix values above the minimum, and some juices that will be below the minimum because of natural variations in the source fruits and vegetables. The agency also acknowledges that, in some instances, producers of lower Brix juices will have to use more juice to meet the minimum soluble solids requirements for reconstituted full-strength juice. However, use of standardized Brix levels in preparing and labeling blended juice products and diluted juice products from concentrates will ensure that consumers obtain products with a reliably determined minimum juice soluble solids content. As a result consumers will be able to make meaningful value comparisons between brands of such products based on the labeled juice content. Use of actual Brix levels of the original juice used to manufacture the concentrates could lead to variations in the levels of soluble solids on labels of products that bear the same percentage juice declaration. Therefore, FDA is not modifying its proposed use of standardized minimum Brix levels to determine the percent juice in juice products made from

concentrate, as requested by the comment.

c. Approaches other than use of Brix.

20. One comment proposed an alternative to Brix calculation for percentage juice in the case of orange juice and other citrus juices that have been modified by the removal of the naturally occurring sugars that are then replaced partially or wholly by intense sweetening agents. The proposed method would use citric acid content or the ascorbic acid content consistent with FDA's proposal for lemon juice and lime juice.

The comment provided guide values of 8.0 grams per liter citric acid and 200 milligrams per liter ascorbic acid for orange juice as an alternative for the determination of percentage juice for orange juice with sugars removed and referenced methods for determination of the citric acid and ascorbic acid content ("RSK–Values, The Complete Manual, Guide Values and Ranges of Specific Numbers, Including the Revised Methods of Analysis," Verband der deutschen Fruchtsaftindustrie e.V., Bonn, 1987). However, the comment did not include any data to correlate and verify these values and methods as they apply to an "artificially sweetened, sugars-reduced orange juice."

The agency is not incorporating the suggested alternative method for determining the percentage of "juice" contributed by modified juices in which the native sugars have been removed and have been replaced wholly or partially by intense sweetening agents. As discussed in section II. F. of this document, these products are not considered to be juice. Under new § 101.30(h)(1), FDA is establishing minimum Brix values for fruit and vegetable juices based on the soluble solids content (i.e., primarily sugars content of the juice), with the exception of lemon juice and lime juice that are defined by citric acid content, for use in percent juice labeling. Therefore, such modified juices cannot be included in the percent juice calculation or depicted as juice in the vignette on a beverage. The description of the modification (e.g., "sugar-reduced orange juice") as part of the common or usual name of the product makes clear that the change in the product is such that it no longer purports to be juice. The product may substitute for juice, but it is not juice. Although the suggested alternative methodology may be useful for validating claims about modified juice products, the agency is not aware of acceptable methodology to confirm the content of any modified juice products, e.g., "reduced sugars" or "sugars removed" juice products.

d. Meaning of Brix standards.

21. One comment stated that from the proposed single-strength Brix standards, it is not clear whether the standards are intended to represent mean values, or whether they are minimum values. In some instances, e.g., in normalizing compositional data of juice concentrates, the comment stated, it may be appropriate to use mean values. In other instances, minimum values may be more appropriate, e.g., regulations for 100 percent fruit juice made from concentrate.

The agency advises that the Brix values set out in new § 101.30(h)(1) are minimum values that are based on average values for the respective juice products. As stated in the preamble to the July 2, 1991, proposal, the purpose of establishing these Brix values for 100 percent juice is to provide a "minimum" acceptable level for determining whether a juice should be considered to be full-strength (56 FR 30452 at 30459).

e. How Brix values are set.

22. One comment stated that it is desirable to take a statistical approach in revising or establishing the Brix values. The comment stated that in some instances, it may be appropriate to use "mean" values, e.g., normalizing compositional data of juice concentrates; and in other instances, minimum values may be more appropriate, e.g., in establishing minimum Brix requirements to define 100 percent fruit juice from concentrate. The comment added that where minimum Brix values are appropriate, the minimum value could be one standard deviation below the mean if 66 percent confidence limits were applied, or two standard deviations if 95 percent confidence limits were thought to be more appropriate. For some juices, e.g., orange juice and apple juice, the comment maintained that there should be adequate data bases available for such statistical applications. For many commodities, the data will need to be developed. The comment also maintained that there needs to be agreement on the sample protocol for developing such data bases.

FDA agrees that a statistical approach should be used to establish the minimum Brix values when adequate data bases are available. However, because of the limited amount of data available to FDA for most juice products for which minimum values were proposed, a statistical approach could not be used. Where comments supplied Brix data in statistical terms, means and standard deviations, FDA used these data in evaluating the proposed Brix values and in some instances has incorporated these values in new § 101.30(h)(1). In other instances, FDA has adopted the Brix values established in the standards of identity for fruit products because they represent consensus values that are acceptable to both consumers and food processors.

Although the comment stated that there should be adequate data bases for orange juice and apple juice for statistical calculation to determine the minimum Brix value, no data bases for these juices were provided in the comment.

FDA agrees that a statistical analysis could be used to establish a Brix value for the single-strength juices. However, in the case of orange juice, the proposed Brix value of 11.8° for orange juice from concentrate is consistent with the Brix value established in the standard of identity for orange juice from concentrate (§ 146.145 (21 CFR 146.145)). In the absence of new data or information that demonstrates that the established Brix value is no longer representative of the soluble solids content of orange juice used to make frozen concentrated orange juice in this country, the agency has no reasonable basis to revise the Brix value for orange juice in new § 101.30(h)(1). A discussion on information received in comments on apple juice follows.

Because the Brix values represent minimum values, food processors are free to pack to higher soluble solids contents to meet consumers expectations when making juice products from concentrate. FDA points out, however, that should food processors use higher levels of soluble solids than is required by new § 101.30(h)(1) in reconstituting a juice to single-strength (100 percent juice) to meet consumer expectations for a sweeter juice, for example, FDA still considers the product to be 100 percent juice and not a higher percentage, such as 110 percent juice, when the additional soluble solids are the result of added juice.

23. Several of the comments cited the German RSK Brix values in support of the modifications that they suggested in the minimum Brix values listed in the July 2, 1991, proposal. One comment requested that these values be considered in establishing U.S. standards so as to achieve worldwide uniformity.

FDA agrees with the comment that the use of the German RSK Brix values may serve as useful guidelines in establishing Brix values in this country. The RSK values (termed Richwerte und Schwankungsbreiten bestimmter Kennzahlen or RSK–WERTE) are used by the German fruit juice industry as

reference points or guidelines for specified constituents in fruit juices. They assist food processors in determining whether fruit juices have been produced lawfully without adulteration. Factors influencing juice composition, such as growing region, variety, and production year, are considered in their establishment. Soluble solids content (Brix value) is one of the quality parameters defined by the RSK–WERTE guidelines. Other parameters include density, titratable acidity, sugars, acids, and amino acids. Mean values, standard values, ranges, and commentary are provided for each parameter.

A standard RSK value is usually a "minimum" or a "maximum" value, with data seldom falling above or below this value. In other words, the standard Brix value would be the minimum value in the range of values and not the mean or average Brix value. The mean RSK Brix value is not the arithmetic mean value but the value around which most of the values of industrially manufactured juice products congregate. RSK Brix values cited by the agency in this document are from "Adulteration of Fruit Juice Beverages," edited by S. Nagy, et al. (Ref. 7).

24. Several comments stated that the Brix calculation is only valid for juices to which sweeteners have not been added, and that other methods should be used to test for adulteration.

The agency agrees that the Brix calculation is only valid for juices to which sweeteners have not been added. Further, the Brix calculation to determine the percent juice content can only be used before sweeteners are added to the juice beverage in instances where the beverage is not 100 percent juice. The agency does not use Brix measurements by themselves to test for adulteration. Brix measurements can be used in conjunction with the results of other analytical methodologies and inspectional observations to support charges of product adulteration.

25. Other comments stated that the percent juice declaration should be calculated on weight/weight basis utilizing reference Brix levels because that is the manner in which the concentrates are sold.

The agency disagrees with these comments. The purpose of the regulation was not to prescribe how concentrates should be sold but to ensure that when reconstituted juice or juice from concentrate is used to produce a single-strength juice or a multiple-juice beverage, there is a standardized criterion for determining the percentage juice in the finished product. The standardized criterion allows consumers to make price and value comparisons across the range of juice beverages. Because the juice beverages are sold on a single-strength volume basis to the consumer, and percentage juice declaration is based on this standardized criterion, it would be inappropriate to utilize a weight/weight basis.

26. One comment requested that manufacturers be allowed to reconstitute concentrated juice back to the Brix in original expressed juice if the Brix of the expressed juice is known, and records are kept for the purpose of percent juice calculation and declaration. For example, expressed apple juice with a Brix value of 9.0° could be reconstituted and declared as 100 percent apple juice even though the Brix value provided by proposed § 101.30(j)(1) for 100 percent apple juice from concentrate is 12.5°.

The agency made an exception to the use of Brix values in calculating percentage juice for expressed juices because these juices have a naturally occurring range of Brix beyond the control of the manufacturer. Similarly, in consideration of existing industry conditions, the agency's decision to use Brix value for calculation of percent juice from concentrate was derived from the industry practice of commingling juice concentrates whose original Brix is unknown.

The agency differentiated between percent juice calculation for expressed juices and juice concentrates on the basis of industry practice and out of fairness to the expressed juice segment of the industry, which is subject to the vagaries of nature. While the agency does not object to reconstituting of concentrated expressed juice to the Brix level of the original juice if that Brix value level is known, the agency finds that once a juice has been concentrated, for the purpose of percent juice calculation and subsequent percent juice declaration, the Brix value as prescribed in the regulation must be used. Use of the same minimum Brix value level in labeling juice content for a specific juice from concentrate will enhance consumer comparisons between competing brands of that juice.

Therefore, the agency is denying the comment's request to reconstitute juice to its original Brix as expressed juice and declare it as 100 percent juice from concentrate although it does not have the minimum Brix value as prescribed in the regulation. This policy is consistent with Brix value requirements established in standards of identity for juice products made from concentrate.

f. Provisions to revise Brix values.

27. Many comments urged FDA to establish a mechanism to amend the table of Brix values because it may be necessary to include juices in the table that are not included now, and revised brix values may be needed in response to changes in technology, new crop varieties, and other matters.

The agency agrees that periodic amendments to the Brix value table will be necessary. However, the agency believes that adequate provisions exist in the regulation for citizen petitions, (§ 10.30). Therefore, the agency is not proposing any additional mechanisms to amend the Brix value table as adequate provisions already exist.

g. Individual juices.

28. Many comments submitted information to revise 1 or more of 13 proposed Brix values for various juices, such as apple, apricot, carrot, celery, cherry, grape, guava, lemon, orange, passion fruit, peach, pear, and raspberry (red). One comment submitted data to establish a Brix value for pomegranate juice.

i. Apple juice.

In the preamble to the July 2, 1991, proposal, FDA specifically requested comment on the proposed Brix value for apple juice, 12.5°, which the agency selected using values in the lower portion of the range of Brix values available to the agency (56 FR 30452 at 30459). NJPA had suggested that FDA adopt a Brix value of 11.0° for apple juice, based on USDA standards for grades (7 CFR 52.301 through 52.301) for U.S. Grade A apple juice.

Several comments contended that the proposed Brix value of 12.5° for apple juice is too high and urged FDA to adopt a Brix value of 11.0° as originally submitted by NJPA in comments to the agency in December 1989 and May 1990. In a comment on the July 2, 1991, proposal, NJPA stated that its suggested Brix value of 11.0° for apple juice reflects a consensus not only of NJPA's member companies but also of members of the National Food Processors Association (NFPA), with which NJPA coordinated the adoption of its December 1989 voluntary percent juice labeling policy. NJPA also pointed out that much of the concentrated apple juice used by its members is imported from foreign countries, and that any Brix value established should take into consideration the Brix value of juice produced in these countries. It noted that over 35 percent of all imported apple juice products during 1990 came from Argentina, and that the majority of the remainder came from European Community (EC) countries. According to the comment, there is no enforceable minimum Brix value requirement for

single-strength apple juice in Argentina but, in Germany and EC countries, the minimum Brix value for single-strength apple juice is 11.18°. The comment also noted that the Codex Alimentarius Commission has recommended a Brix value of 10.0° for reconstituted apple juice.

NJPA stated that Brix data from a major U.S. processor for juice expressed from apples grown in the State of Washington reflects an average Brix value of 11.58°, with a monthly range of 10.38° to 12.62° Brix (n=51) for two processing seasons (1989 to 1990 and 1990 to 1991). It claimed that similar data obtained from Michigan for the period November 1986 through November 1990 showed that monthly average Brix values ranged from 9.6° to 13.09°. The mean of the monthly Brix averages in Michigan for the 4-year period was 11.47°, with a standard deviation of 0.875°. The comment pointed out that the average Brix would have met FDA's proposed Brix value of 12.5° in only 6 months of the 4-year period, while the suggested Brix value of 11.0 would have been met in 26 months during the 4-year period. According to the comment, average monthly Brix values obtained from New York, for the period January 1987 through July 1991, ranged from a low of 9.5° to a high of 11.8°. The comment noted that, generally, juice from apples grown in the northwestern region of the United States has a higher average Brix and a lower acid content than juice produced from apples grown in the midwestern and eastern regions.

A comment from one firm noted that production records from their Austrian supplier showed that the Brix value of Austrian apple juice ranges from about 10° to 12° over the apple juice processing season. Another of the firm's suppliers provided information on apple juice from Germany, showing that in September the Brix value range of apple juice is from 9.8° to 11.0°, in October 10.5° to 11.5°, and in November 11.5° to 12.3°. It noted that most of the apple juice from Germany is processed during September and October. The comment recommended that FDA establish a minimum Brix value of 11.0° for apple juice. To establish a higher value, the comment added, would be to establish an artificially high Brix level that would impose an unfair trade barrier.

A comment suggested a minimum Brix value of 10.5° for apple juice. The comment noted that minimum Brix level for U.S. Grade B apple juice is set at 10.5° in the USDA standards for grades for apple juice (7 CFR 52.308). The comment maintained that the proposed Brix value of 12.5° would effectively exclude Canadian products from the U.S. market.

Other comments supported a Brix value of 11.5° for apple juice. One comment recommended a minimum Brix of 11.5° for apple juice reconstituted from apple concentrate, based on available data including records collected at 21 apple processing facilities, operated by 13 companies. According to the comment, the average Brix level reported by 17 of 21 plants fell in the range of 11.1° to 11.8°, with 11 of the plants reporting data in the 11.3° to 11.7° Brix range. Thus, the comment concluded, a Brix value of 11.5° is more representative of the Brix level of expressed apple juice than is the Brix value of 12.5° proposed by FDA.

Several comments contended that increasing the Brix value of apple juice to 12.5° would result in a Brix higher than normal for the expressed juices commonly used and would force food processors to produce a product that is incompatible with consumer expectations. They maintained that apple juice at a Brix of 12.5° is too sweet, especially in the Northeastern region where the taste preference for apple juice is a tart product (lower Brix/acid ratio). One comment stated that the proposed higher Brix value level of 12.5° would result in a 9 percent increase in soluble solids content over that of the currently marketed apple juice which contains from 11.0 to 11.5 soluble solids. It estimated that the increase would cost consumers of reconstituted juice products approximately $25 million annually. It further contended that the cost of some single-strength apple juice that contains added apple juice concentrate to achieve a preferred flavor profile would be increased as well if a Brix value of 12.5° is adopted. Another comment stated that changing the Brix from 11° to 12.5° would increase the ingredient cost by 14 percent and would further serve to put the product out of reach of many mothers who have been using apple juice for their babies.

After reviewing the data on the soluble solids content of apple juice submitted in the comments on the July 2, 1991, proposal, FDA has reconsidered its position regarding the proposed Brix value of 12.5° for 100 percent apple juice from concentrate. Data provided by industry in comments showed that mean Brix values for individual lots of apple juice range from 8.9° to 13.4°, with summary mean values (averaged monthly and yearly mean values) ranging from 11.0° to 11.58. NJPA pointed out that the minimum RSK Brix of apple juice is 11.18° and recommended that FDA adopt a minimum value of 11.0°. The agency notes, however, that the RSK mean Brix value for apple juice is 12.08°. With respect to the comment that requested that FDA adopt the minimum Brix of 10.5° for U.S. Grade B apple juice, FDA believes that this value is too low and does not reflect average Brix values of apples produced and processed in this country, as evidenced in the comments cited above.

In response to the comment requesting adoption of the USDA U.S. Grade A Brix value of 11.0° for apple juice, FDA points out that the USDA lowered the Brix value of U.S. Grade A apple juice from 11.5° to 11.0° in response to a request from the Processed Apple Institute (47 FR 5875, February 6, 1982). At that time, USDA stated that the change was being made to include differences in growing conditions in various parts of the country, increased use of more varieties of apples in the manufacture of canned apple juice, consumer preference for a less sweet product, and differences in processing techniques. However, comments summarized in the USDA rule noted that northwest apples have a Brix average of 12.5° or higher, to which USDA responded that the Brix requirements provided for in their standards for grades are minimum standards for each grade. It also stated that lowering the Brix by one-half of a degree will accommodate apple processors using varieties that have lower soluble solids compared with other varieties processed in other parts of the country.

FDA points out that the USDA standard (7 CFR 52.308), referenced by the comments, applies to canned single-strength apple juice, in which no more than one-fourth of the juice may have been concentrated. In the case of the USDA standard in 7 CFR 52.6221 et seq., for frozen concentrated apple juice, the minimum Brix value for a concentrate that is to be diluted 1 plus 1 is 22.9°. Such a product on dilution would have a Brix value of approximately 11.45°.

FDA acknowledges that there are differences in Brix values of apples depending on geographical growing regions, and that consumers may have developed certain preferences based on these regional differences. However, FDA believes that it should set the minimum Brix for apple juice at a level that is toward the middle of the range of Brix values for apple juice in order not to penalize producers of freshly expressed apple juice, which may have a higher solids content, to the benefit of those producers who sell reconstituted

or diluted apple juice products. It would also be fairer to consumers because they would be assured of getting reconstituted juices that more closely resembled the juice from which it was made. Consumers who prefer a less sweet juice can dilute the juice further by adding water. However, consumers who find that a reconstituted juice tastes weak because of a lower apple juice soluble solids content cannot rectify this condition by adding more apple juice solids.

Although most of the apple juice may be sold at Brix levels ranging from 11.0° to 11.5°, according to industry-based standards established by USDA, the agency believes that in establishing a minimum value for reconstituted apple juice or diluted apple juice, the minimum should reflect the average Brix value of expressed apple juice. Thus, consideration must be given to the higher Brix apple juice produced in the northwestern areas of the United States as well as to the lower Brix value juices produced in the midwestern and eastern areas. As noted in the July 2, 1991, proposal, a study by Mattick and Moyer (Ref. 2) of the Brix of 93 authentic apple samples collected from many different areas of the country and representing many apple varieties demonstrated average Brix values of 12.60°, 12.80°, 12.83°, and 12.74° (56 FR 30452 at 30459). The German RSK value noted in the comment provides for a range of Brix values from 11.18° to 14.01° with a mean Brix value of 12.08°. In view of these higher values, FDA believes that the minimum Brix value of 11.0° suggested by several comments from industry is too low, and that a minimum Brix value of 11.5° for apple juice is more appropriate because it takes into account the apples with the higher Brix values. Further, it is consistent with the Brix of reconstituted apple juice made in compliance with the USDA standard for grades for frozen concentrated apple juice. It also represents a value on the low side of the mean Brix value established for German apple juice, as well.

Accordingly, FDA has revised the minimum Brix value for apple juice by reducing it from 12.5° to 11.5°.

ii. Apricot juice.

FDA proposed a minimum Brix value of 14.0°, based on the data submitted by NJPA. According to NJPA, this value was derived from the USDA File code 147–A–2 (March 1988), Inspection of 50 percent Juice Drinks and Juice Drink Products under the Child Nutrition Labeling Program (Food and Nutrition Service).

One comment from a fruit and vegetable processing and marketing cooperative stated that their analyses of apricot juice over the period 1986 to 1990 showed an average Brix of 11.7° with a standard deviation of 0.8°. This average value was derived from a total of 502 measurements. The comment stated that it believed that the data were adequate because they include five different growing seasons, several varieties, and various weather conditions and cultural practices.

FDA notes that a National Canners Association report on the Brix values of authentic samples of apricots, as reported by Nelson and Tressler (Ref. 10), lists the Brix values of whole Blenheim apricots and Tilton apricots as ranging from 10.7° to 17.1°, with means of 14.1° for Blenheim apricots (n=6) and 12.6° for Tilton apricots (n=6). In this same reference, the Brix value of whole apricot pulp was 11.5°, and apricot nectar was 14.3° (n=6 in both cases). Thus, the Brix value of apricot juice appears to be dependent on the source of the extracted juice used in the analysis. Based on these data, FDA finds that the suggested Brix value of 11.7°, as provided in the comment, is reasonable. Use of the lower Brix value would permit use of an important variety, Tilton, which has a much lower Brix value than the proposed Brix value, 14.3°, from the canned nectars standard. In addition, the lower value would be representative of the Brix values currently encountered in industry as cited in the comment. Therefore, FDA is incorporating the Brix value of 11.7°, as suggested by the comment, in new § 101.30(h)(1) in place of the proposed Brix value of 14.3°. Because this amendment is based primarily on a single submission, FDA requests comments and data submitted in the form of a petition to amend this regulation if data are available that would support a different and more appropriate value.

iii. Carrot juice.

FDA proposed a minimum Brix value of 11.0° for carrot juice based on the NJPA Brix value submitted in December 1989. Subsequently, in May 1990, NJPA submitted a lower Brix value of 9.0° for carrot juice, based on data from NFPA. NJPA did not provide any justification as to why this value was more appropriate than the earlier submission. Thus, FDA published the Brix value of 11.0° because it was based on Government data rather than solely on industry practice. FDA specifically sought comments on the appropriateness of the proposed value and also requested justification for any suggested lower number.

Several comments were received on the Brix value of carrot juice that claimed that the proposed Brix level of 11.0° was too high. One comment provided 31 average Brix values (one average for each date of measurement) for the carrot juice produced during the period January 31, 1991, through June 12, 1991. The overall average Brix level from these data is 7.0° with a range of 5.4° to 8.0°.

Later, a trade association provided additional information concerning average Brix levels for carrot juice in a memorandum, dated January 22, 1992. This information consisted of the following: (1) An average Brix value of 8.6°, with a Brix value range from 7.0° to 9.3° and a standard deviation of 0.5°, based on 72 measurements, for the period of January 1, 1990, through December 12, 1990; and (2) an average Brix value of 8.1° with a Brix value range from 6.9° to 9.8° and a standard deviation of 0.5°, based on 39 measurements during the period of January 1, 1991, through July 31, 1991. No specific value was suggested for a minimum Brix for carrot juice in this comment.

A comment from a manufacturer of concentrated carrot juice recommended a Brix value of 8.0° for the reconstituted carrot juice. The comment provided information on daily average Brix value levels of freshly expressed carrot juice (each day's volume was between 30 to 50 tons) showing that: (1) The daily Brix average values (n = 31) ranged from 5.4° to 8.0° with an overall average of 7.0° during the period of January 31, 1991, through June 12, 1991, and (2) the average daily values (n = 20) ranged from 6.9° to 8.3° with an average of 7.6° during the period of October 1, 1991, through January 21, 1992. The comment stated that the firm has processed in excess of 3,000 tons of carrots for juice and concluded that the values submitted are indicative of the true Brix value of single-strength carrot juice.

Only two comments provided data on the Brix of carrot juice. The average Brix values from both sources and the industry recommended Brix are considerably lower than the proposed Brix of 11.0°. The Brix averages of the four data sets received are 7.0°, 8.6°, 8.1°, and 7.6°, with an overall average Brix value of 7.8°. The proposed Brix value of 11.0° was based on data from USDA Handbook 8–11, which lists 11.12 percent of total solids in canned carrot juice, of which 9.9 percent is total carbohydrate (Ref. 6). Because the Brix measures soluble solids content, and not all of the total solids or total carbohydrate content of carrot juice is expected to be soluble (e.g., insoluble cellulose or fiber), the use of these values as the Brix value would result in

a figure that is higher than would result from measurement of the Brix by refractometer. Therefore, based on this information, FDA is adopting the value of 8.0° in new § 101.30(h)(1). The Brix value of 8.0°, set out in the regulation below, was recommended by the manufacturer of carrot juice and is very close to the calculated overall average Brix in the data supplied to the agency in the comments.

iv. Celery juice.

FDA proposed to establish a minimum Brix value of 4.5° for celery juice based on the NJPA Brix value submitted in December 1989. Subsequently, in 1990, NJPA submitted a lower Brix value of 3.6° for celery juice, based on data from NFPA. NJPA did not provide justification as to why this value was more appropriate than the earlier submission. As in the case with carrots, FDA published the higher Brix value of 4.5° because it was based on Government data rather than solely on industry practice.

Two comments received in response to the July 2, 1991, proposal claimed that the proposed Brix value level of 4.5° for celery juice, based on NJPA's December 1989 submission to the agency, was too high, but these comments did not provide any data in support of the claim. One of these comments, from a trade association, stated that members had expressed concern over the proposed minimum level of 4.5°, and that it is soliciting data on levels for celery juice. However, no data were received on the Brix of celery juice from the trade association during the comment period.

A comment from a food processor recommended a Brix value of 3.0° for reconstituted celery juice. The comment stated that daily average Brix levels of freshly expressed celery juice, during the period of April 9, 1991, through May 10, 1991, ranged from 2.95 to 3.4° (n=10), with an overall Brix value average of 3.1°; and for December 23, 1991, the 1-day average Brix value was 2.64°. The mean of the 11 average Brix values is 3.09°.

NJPA suggested Brix value of 4.5° for celery juice was based on information from USDA Handbook 8–11, which reflects the total solids content of celery, and thus may be too high. The data on the Brix of celery juice from the food processor and NJPA's May 1990 submission also suggest that proposed minimum Brix value of 4.5° is too high. USDA Handbook 8–11 lists the total carbohydrate content of celery as 3.63 g/100 g (per edible portion), of which 0.80 g is crude fiber (Ref. 6). Thus, the soluble carbohydrates (sugars) content would comprise approximately 2.83 percent by weight. FDA recognizes that the other constituents may affect the Brix determination by refractometer, and that the use of the soluble solids, determined by difference, from Handbook 8–11 can only serve as a rough approximation. However, in view of this calculation and the data supplied by the food processor, both values supplied by NJPA appear to be too high for celery juice. Because neither NFPA or NJPA provided a basis for the Brix value of 3.6° for celery juice, FDA concludes that for the purpose of labeling the content of celery juice from concentrate that a more appropriate Brix value is 3.1°, based on the mean of the data submitted by the food processor. Therefore, FDA is revising new § 101.30(h)(1), accordingly.

v. Cherry juices.

FDA proposed a single Brix value of 14.0° for juice from both sour cherry and sweet cherry varieties, based on the data submitted by NJPA.

A comment from a firm that processes juice beverages stated that it has encountered large variations in Brix between the varieties of sweet cherries and sour cherries, and that the single-strength Brix values should reflect these differences. The comment maintained that the proposed Brix value of 14.0° is a compromise that does not reflect the actual situation for either cherry classification. In support of this contention, the comment included summary data from its U.S. supplier for dark sweet cherries and for red sour cherries obtained from the Pacific northwest.

Data from the supplier for the dark sweet cherries, collected during the years 1982 to 1990, showed a mean Brix value of 20.0°, a median of 19.9°, with a standard deviation of 3.0° (n=120) and a Brix value range from 14.0° to 30.0°. Using these data, the comment suggested that the minimum Brix value for dark sweet cherries be set at one standard deviation below the mean Brix value or 17.0°.

With respect to the red sour cherries, the comment supplied data for the years 1983 to 1990 that showed a mean Brix value of 15.8, a median of 14.0°, with a standard deviation of 3.4° (n=23) and a range from 11.2° to 22.9°. Using these data, the comment suggested that the minimum Brix value for sour cherries be set at one standard deviation below the mean Brix value or 12.4°. The comment also supplied data for five other mean Brix values or ranges for red sour cherries. These Brix values were for products obtained from Germany, Austria, and the United States, and ranged from a low Brix value of 10.0° to a high Brix value of 13.0°. This comment also pointed out that the German RSK Brix values (Ref. 7) for sour cherry juice are as follows: 14.71° mean Brix value, 12.36° minimum Brix value, and a Brix value range of 12.36° to 19.30°.

The comment also noted that food processors generally do not find that sweet cherry and sour cherry varieties are interchangeable in their beverage products.

FDA concurs with the comment that it should establish specific Brix values for sweet cherry and for sour cherry varieties because of the differences between the two types of cherries. Sweet cherries are higher in sugar and lower in acid than sour cherries. Accordingly, FDA has amended new § 101.30(h)(1) to reflect the differences, based in part of the data supplied by the comment.

In making this determination, FDA compared the suggested Brix value of 12.4° for sour cherries to data collected by FDA in 1962 (Ref. 11) for red sour pitted cherries that show a mean Brix value of 14.3° (n=15, std. dev. = 0.96° and range = 12.7° to 16.0°). FDA believes that the suggested Brix value of 12.4° may be too low in view of the FDA data, the median value of 14.0° cited by the comments and the RSK mean value, 14.71°. In keeping with establishing Brix values close to the mean Brix value, but in the lower portion of the Brix range, FDA believes that a more appropriate Brix value for sour cherries is 14.0°, as proposed. This value is slightly lower than the RSK mean value, the mean from the FDA data, and the mean value submitted by the comment. It is also consistent with the median value for sour cherries submitted in the comment. Therefore, FDA is retaining the proposed Brix value of 14.0° for sour cherries in new § 101.30(h)(1).

In the case of sweet cherries, FDA compared the suggested Brix value for dark sweet cherries of 17.0° (mean=20°, median=19.9°, std. dev.=3°) to data collected by FDA in 1962 on authentic sweet cherries (Ref. 11) that show a Brix range of 18.0° to 21.9° for sweet cherries (n=3). Because the mean values from the comment and the FDA data, as well as the median value supplied by the comment, cluster around 20.0°, the agency believes that the Brix value of 20° is more representative of the Brix value of sweet cherries than is the value of 17.0° suggested by the comment or the value of 14.0° for all types of cherries proposed by FDA. Therefore, FDA is modifying § 101.30(h)(1) to include a Brix value of 20.0° for sweet cherries.

FDA notes that the new Brix values are inconsistent with the single

requirement established for cherries in the standard of identity for fruit jelly, i.e., 14.3°, the reciprocal of the factor. 7. in § 150.140(b)(1) (21 CFR 150.140(b)(1)). The information that FDA has received suggests that there may be a need to revise the standard of identity for fruit jelly to reflect the separate values for the two classes of cherries, sour cherries and sweet cherries. In consideration of amending the standard of identity for fruit jelly, FDA requests information as whether substantial amounts of sweet cherries are being used in the manufacture of fruit jelly, and whether it should incorporate a specific value for sweet cherries in the standard.

vi. Coconut juice.

In the July 2, 1991, proposal, FDA stated that it has no data to support a specific Brix level for juice from coconut and requested comments on, and data for, an appropriate Brix level. The agency also noted that there are two portions of the coconut that can conceivably be used to produce a juice, i.e., the coconut water (liquid from coconut) and the coconut meat. FDA asked for information on the feasibility of using both portions of the coconut to produce juice and comments on whether there should be one or two Brix value levels for coconut.

According to one comment, there are no data to support a specific Brix value level for juice from coconut. The comment also noted that the method used for determining the Brix value of other juices may be inappropriate for use with coconut juice because of coconut juice's fat and oil content and their effects on refractometer readings. The comment stated that when data become available that might be useful to FDA in establishing a Brix or other value for determining what constitutes 100 percent coconut juice, it will submit such data.

In the absence of data on the soluble solids content of single-strength coconut juice, FDA is not establishing a minimum value for the food. Diluted or blended beverages made with coconut juice should be labeled with the percentage of coconut juice based on the content of the full-strength juice used. If made from coconut juice concentrate, the dilution should be based on the composition of the juice used in making the concentrate.

vii. Grape juice.

NJPA submitted a Brix value of 16° for grape juice in December 1989, based on information obtained from the Concord Grape Association. Subsequently, in May of 1990, NJPA suggested a lower Brix value of 13° based on the USDA File code 147–A–2 (March 1988). FDA proposed the higher Brix value of 16° for grape juice and solicited comments on the appropriate Brix level.

A comment from NJPA supported the proposed Brix value of 16.0° for grape juice. The comment stated that the higher Brix level for single-strength grape juice, recommended in its May 1990 comments, was based on comments it received from NFPA and the Concord Grape Association. NJPA stated that this level is the appropriate level.

A comment from a distributor and processor of juice products stated that in this country, no one in the industry is using a Brix level of 16.0° for grape juice, as set out in proposed § 101.30(j)(1), and urged that the final rule establish a minimum Brix level of 13.0° for single-strength grape juice. Citing two Federal regulations, the comment argued that FDA already recognizes 14.3° as the appropriate Brix value for grape juice in the standard of identity for fruit jelly in § 150.140, and that USDA uses a Brix value of 13° in the USDA standards for grades for frozen concentrated sweetened grape juice in 7 CFR 52.2460(b)(1) which, the comment maintained, is closer to reality.

FDA disagrees with this comment. The comment from the juice distributor cited the value for grape juice in USDA grade standard for frozen concentrated "sweetened" grape juice (7 CFR 52.2451 through 52.2464). FDA does not consider this Brix value to be applicable in defining the appropriate Brix for 100 percent grape juice. The USDA standard in 7 CFR 52.2452(a) states that not less than 50 percent of the total soluble solids of the finished concentrate shall be derived from Concord type grapes of the Labrusca species. In 7 CFR 52.2453, USDA requires a minimum Brix value of the finished concentrate including added sweetening ingredients to be 24.8° when the concentrate is made to be diluted 1 to 1 before consumption. The standard further states that in grading the prepared "grape juice beverage" from frozen concentrated sweetened grape juice, the Brix value of the beverage is not less than 13.0°. This "beverage" is the sweetened diluted grape juice product and thus is not relevant in determining the Brix of unsweetened, undiluted grape juice.

FDA notes, however, that the current USDA standards for grades for canned grape juice, in 7 CFR 52.1341–52.1351, list Brix values for two types of "unsweetened grape juice." Type I juice is from the Concord type grapes of the Labrusca species (slip skin varieties), and type II juice is from any type of grape other than the Concord type. The standard requires a minimum Brix value of 15.0° for both types of Grade A unsweetened grape juice and a minimum Brix value of 14.0° for both types of U.S. Grade B unsweetened grape juice. When the canned grape juice is sweetened, the minimum Brix value for each grade is increased by 2° to 17.0 and 16.0°, respectively (7 CFR 52.1350(a) and (b)).

The agency recognizes that much of the grape juice in the marketplace may have been sweetened or diluted because the strong and somewhat astringent flavor of freshly expressed grape juice may not appeal to some individuals. However, consumers have a right to know when the juice has been sweetened or diluted. Thus, FDA must establish a minimum Brix for the unsweetened full-strength grape juice to serve as the basis for the percent juice declaration on diluted juice beverages and reconstituted grape juice products.

FDA notes that the proposed Brix value of 16.0°, in accordance with the NJPA submission, was based on information from the Concord Grape Association. This value is also supported by information in the literature. Data reported by C.S. Pederson on grape juice support that the Brix value of the juice is around 16° for *Vitis labrusca* (Concord grapes) (Ref. 10). Average soluble solids levels for Concord grapes were 15.1, 16.4, and 16.7 for three regions in New York State in a 1949 publication by Robinson, et al., cited by Pederson (Ref. 10). The ranges for these three average Brix values were 12.9° to 17.8°, 13.1° to 19.5°, and 22.7° to 20.0°, respectively. Pederson also stated that nearly all grape juice prepared in the United States is from Concord grapes. The German RSK minimum Brix value for grape juice is 15.88°, based on a range of 15.88° to 19.30° and a mean of 17.03° (Ref. 7).

Based on these observations, FDA concludes that the minimum Brix value for grape juice should be at least 16.0°. Therefore, FDA is retaining the proposed Brix value of 16.0° for grape juice in new § 101.30(h)(1).

According to one comment, approximately 20 million gallons of 68 degree Brix grape juice concentrate (worth $130 million) is used annually in juice blends. The comment stated that because much of the juice is used at the 13° to 14° Brix level, an increase in the Brix level to 16.0° for purposes of juice percentage declaration, would have devastating economic effects. At an average cost of $6.50 per gallon, the comment claimed, this would represent a loss of $32.5 million which when passed on to consumers would become

much larger. The comment further stated that calorie conscious consumers will shy away from higher Brix juices in favor of others with lower Brix levels. Thus, a Brix value of 16.0° could also result in substantial losses in market volume that would be impossible to calculate.

FDA does not agree with the cost analysis in the comment. If the minimum Brix value is set at a higher level than food processors are currently using, food processors can still maintain the same diluted juice blend formulations. They simply will have to label the percentage of juice in the beverage appropriately.

viii. Grapefruit juice.

FDA proposed to adopt a minimum Brix value of 10.0° for grapefruit juice. This value was submitted by NJPA in December 1989 and is the same as that established in the standard of identity in § 146.132 (21 CFR 146.132) for grapefruit juice made from concentrated grapefruit juice exclusive of any added sweeteners.

A comment from a foreign government expressed support for a minimum Brix value of 9.0° for fresh or reconstituted grapefruit juice. The comment stated that this value would be consistent with the USDA standards for grades for unsweetened U.S. Grade A and U.S. Grade B grapefruit juice (7 CFR 52.1228, Table I).

FDA notes that the Brix value of 9.0° for fresh single-strength grapefruit juice is not applicable to "grapefruit juice from concentrate" (i.e., reconstituted grapefruit juice) in the United States or for use in calculating the percentage of juice contained in a juice blend in accordance with new § 101.30(h)(1). The standard of identity for grapefruit juice in § 146.132, as noted above, and the USDA standards for grades for grapefruit juice in 7 CFR 52.1228 (Table II, U.S. Grade A and U.S. Grade B), list a Brix value of 10.0° for unsweetened grapefruit juice from concentrate. The Brix value of freshly expressed grapefruit juice is not specifically designated in the standard of identity nor in the regulation (new § 101.30(h)(1)) set forth below. The Brix value for freshly expressed grapefruit juice is the Brix of the particular lot of grapefruit juice, before the addition of any water, sweetener, or any other additives, as determined by refractometer and corrected for acidity in accordance with § 146.132(a).

FDA is not revising the proposed Brix value of 10.0° for grapefruit juice because it was established by formal rulemaking (47 FR 43364, October 1, 1982). At the time that FDA adopted the standard, citrus processors and growers indicated that the preponderance of grapefruit juice produced in the United States contains, on average, 10.0 percent soluble solids or greater. Comments on the proposed standard of identity at that time also maintained that to establish a minimum soluble solids content of 9.0 percent would be to allow dilution of the finished product to a level substantially below that of the juice from the grapefruit fruit from which the concentrate is made. Therefore, FDA is adopting the 10.0° Brix value as proposed.

ix. Guava juice.

FDA proposed a minimum Brix value of 7.7° for guava juice, as suggested by NJPA. This value is consistent with the Brix value in the standards of identity for canned nectars (§ 146.113 and fruit jelly (21 CFR 146.140), the U.S. Customs Service requirements (19 CFR 151.91), and USDA File code 147-A-2 (March 1988).

One comment stated that using a statistical approach, it had calculated a standard Brix value of 6.6° for guava juice. The comment explained that its Brix data (mean of 7.1°, standard deviation of 0.5, a minimum of 6.0 and a maximum of 8.0°, median 7.1°, 20 data points, and mean minus 1 standard deviation to yield 6.6°) came from a single supplier of Hawaiian guava juice, who forwarded the weighted mean Brix values for each month's production. Using these data, the comment recommended a Brix value of 6.6° as the minimum level for a single-strength guava juice.

FDA has been unable to corroborate the suggested lower Brix value for guava juice in the published studies. FDA notes that one reference states that the Brix of guava averages around 9° (Ref. 12). Another reference lists soluble solids for the fruit from selected Hawaiian guava seedlings, which range from 8.0 to 11.5° Brix, and total soluble solids contents that range from 7.80 to 10.53 percent (n=10)(Ref. 10). In view of the published data on the Brix value of guava juice, FDA is adopting the proposed Brix value of 7.7°, which reflects FDA and U.S. Customs Service regulations, as well as USDA specifications. FDA recognizes that this value is higher than the mean and median in the comment's data, but the Brix published in the literature support a higher value than that suggested by the comment.

FDA is open to submission of information on the appropriateness of this value for 100 percent guava juice as a basis of a proposal to amend the standards of identity for fruit butter and fruit jelly. Any petition submitted to amend the fruit butter or fruit jelly standards (§ 150.110 (21 CFR 150.110)) and § 150.140) should be accompanied by data representative of the varieties of guava used in the manufacture of these products, as well as data on possible effects of factors such as maturity, growing conditions, and processing on the Brix of the fruit.

x. Orange juice.

FDA proposed a Brix value of 11.8° based on the requirement in the standard of identity for orange juice from concentrate in § 146.145. This value is also consistent with the Brix value submitted by NJPA.

A comment from a foreign government opposed the proposed Brix value of 11.8° for reconstituted orange juice and suggested a minimum Brix value of 9.7°. The comment stated that its suggested value would be consistent with the regulation in that country which establishes a minimum Brix value of 9.7° for orange juice (B.11.128 Food and Drugs Regulations, Canada).

FDA is not making the requested change. FDA notes that the Brix value of 11.8° set forth in new § 101.30(h)(1) for orange juice is the same as that established in the standard of identity for orange juice from concentrate in § 146.145. This value was established after a public hearing (28 FR 10900, October 11, 1963), by formal rulemaking, and represents a consensus of what interested parties believed to be appropriate at the time. A Brix value of 11.8° seemed reasonable and practical because it was equivalent to the approximate soluble solids content of reconstituted orange juice made in the home by consumers by diluting frozen concentrated orange juice. Frozen concentrated orange juice (§ 146.146 (21 CFR 146.146)) is generally made to 42° Brix and is diluted before consumption by adding 3 parts water, such that the resulting Brix value ranges from not less than 11.8° to 12.4°. FDA sees no reason for different values in the standard of identity for orange juice from concentrate and the regulation for defining "100 percent juice" for percent juice labeling purposes in new § 101.30(h)(1). Therefore, FDA is not revising the minimum Brix value of 11.8° for orange juice in new § 101.30(h)(1), as requested by the comment.

xi. Passion fruit juice.

NJPA suggested a Brix value of 12.0° for passion fruit juice based on the USDA File code 147-A-2 (March 1988). However, FDA proposed a minimum Brix value of 14.5° based on the Brix of passion fruit juice in the stayed canned nectar standard of identity (§ 146.113). FDA noted the variation in the two Federal specifications and expressed the

opinion that if there was justification for the lower suggested value, that it would be forthcoming in comments on the July 2, 1991, proposal.

A comment from NJPA stated that its original May 1990 suggestion of 12.0° as the minimum Brix value for passion fruit juice was based on a USDA data base, and that it has been unable to locate any other differing data except for the German RSK "guide" value for passion fruit juice of 13.5°. Noting that the FDA proposed Brix value of 14.5° was based on the canned nectar standard in § 146.113, which has been stayed for many years, the comment maintained that industry believes that the Brix levels contained in that standard are too high.

Another comment provided data obtained from its suppliers in 1990 on the soluble solids content of single-strength (unconcentrated) passion fruit juice from Ecuador (average Brix value of 14°) and Peru (Brix value range of 14° to 16°). The comment recommended that FDA adopt a minimum Brix level of 14.0° for the single-strength (100 percent) passion fruit juice.

FDA notes that the German RSK Brix value is based on a data range of 12.0° to 18.0° with a mean Brix of 14.0° and a standard value (minimum value) of 13.5°. Wallrauch, et al., (Ref. 7) stated that the data on passion fruit juice were based on extensive analyses of all industrially important varieties and provenances (South America, Africa, Australia, New Zealand, Fiji Islands, Sri Lanka, Taiwan, and Hawaii). It further stated with respect to the Brix of passion fruit juice, that only rarely and only for Brazilian juice has a Brix value for passion fruit juice been found to be as low as 11.5°. Wallrauch et al., also noted that a mean Brix value of 14° can be used in the dilution of concentrate to single-strength so as to maintain all of the organoleptic and analytical features of passion fruit juice.

FDA is adopting a Brix value of 14.0° for passion fruit juice based on the analytical data provided in the comments and supported by Wallrauch, et al. This value also is the same as the mean RSK Brix value reported by the German fruit industry (Ref. 7).

xii. Peach juice.

NJPA suggested a Brix value of 11.8° for peach juice which was published in the proposed § 101.30(j)(1). This Brix value is incorporated in the standards of identity for fruit butters (§ 150.110 (21 CFR 150.110)) and fruit jelly (§ 150.140) on September 5, 1940 (5 FR 3558) and in the standard of identity for canned nectars (§ 146.113) on May 7, 1968 (33 FR 6862) which was stayed because of objections on July 27, 1968 (33 FR 10713). It was based on the analysis of 33 authentic samples during the period 1924 to 1935 (Ref. 2). This Brix value is also used by the U.S. Customs (19 CFR 151.91) and by USDA in its specifications for its diluted juice products (USDA File code 147–A–2, March 1988).

One comment stated that its analyses of peaches over a 5-year period (1986–1990) showed an average Brix value of 10.5°, with a standard deviation of 0.9°. The average value was based on a total of 1,190 measurements. The comment recommended adoption of a Brix value of 10.5° in the final rule.

Based on its review of the data in the comment, FDA is adopting a Brix value of 10.5 as the minimum level for a single-strength peach juice because it is based on the data from over 1,000 samples obtained during a recent 5-year period. Thus, FDA has revised new § 101.30(h)(1) to reflect this minimum Brix value for peach juice.

FDA is open to additional information on the appropriateness of this value for 100 percent peach juice as a basis for a proposal to amend the standards of identity for fruit butter and fruit jelly. Any petition submitted to amend the fruit butter or fruit jelly standards (§§ 150.110 and 150.140) should be accompanied by data representative of the varieties of peaches used in the manufacture of these products, as well as data on possible effects of factors such as maturity, growing conditions, and processing on the Brix value of the fruit.

xiii. Pear juice.

NJPA suggested a Brix value of 11.0° for pear juice based on the USDA File code 147–A–2 (March 1988). FDA believed that this value may be too low and proposed a minimum Brix value of 15.4° based on the Brix value of pear juice in the stayed canned nectar standard of identity (§ 146.113). FDA noted the variation in the two Federal specifications and anticipated receipt of data in support of an appropriate Brix value for pear juice.

Seven comments stated that the proposed Brix value level of 15.4° for pear juice is unrealistically high. A comment from a university professor stated that it is common commercial practice to use a Brix value of 12.0° to represent single-strength pear juice. The comment stated that the RSK Brix values, which are widely applied as typical compositional indices for single-strength juice, list a Brix value range of 11.18° to 13.54° and mean of 12.13° for pear juice. According to the comment, pears are high in sugar content, even when harvested at the green and hard, but full-sized, stage of maturity. It noted that in one university study of changes in sugars and acids during the ripening of Bartlett pears, the data showed that green, hard pears contain 12.0 g of sugars per 100 g (12 percent) which increases to a maximum of 13.5 percent and then decreases to 12.4 percent at the fully ripe stage. The comment also stated that juice is easier to express from the green, hard fruit, and that processors often prefer to press at that stage of maturity. The comment reported a Brix range of 11.7° to 14.2° for pilot-plant processed pear juice (three varieties, unripe and ripened fruit, n=8). This comment did not recommend a specific Brix value.

One comment from a trade association stated that data from its members show that the proposed Brix value of 15.4° for pear juice is clearly excessive and recommended that the agency adopt a Brix value of 11.5° for pear juice from concentrate. According to the comment, the majority of pear concentrate is prepared from Bartlett pears. Other varieties may have a higher Brix, but they are normally marketed as fresh pears and have only limited use in the juice market. Therefore, the comment contended, other varieties should not be considered when establishing a minimum Brix level for pear juice from concentrate.

A comment from a juice products distributor provided data on unconcentrated pear juice that it collected from worldwide suppliers. The data included yearly average Brix values from Australia (1960), central and northern Argentina (1988 to 1991), and the northwestern United States (1988 to 1991). The overall weighted average Brix was 12.1° and the average Brix values ranged from a low of 10.5° to a high of 13.4°, with a standard deviation of 0.8°. Based on these data, the comment recommended that FDA adopt the Brix value of 12.2° as the minimum level of single-strength pear juice.

A comment from a fruit and vegetable processing and marketing cooperative stated that for the past 5 years, they have tested Brix levels in pear juice, and their results are much lower than FDA's proposed Brix value. The comment presented a summary of the data of Brix analyses for the years 1986 through 1990 (n = 2,446 measurements, mean Brix = 12.0°, and standard deviation = 0.8°). Based on these data, the comment recommended a Brix value of 12.0° as the minimum Brix level of single-strength pear juice.

One comment provided a summary of Brix data for more than 1,800 measurements on pear juice samples. The Brix averages for the last 3 years

were 11.7°, 11.6°, and 11.7°. The comment stated that many canners have been packing pears in pear juice for many years, and that the juice consistently runs between 11° and 12° Brix. No specific Brix level was suggested for the final rule.

A comment from a firm that imports apple and pear juice stated that data obtained from its research on pear juice suppliers in both the Northern and Southern Hemisphere showed that concentrate is produced from pears having a maximum Brix value not exceeding 12.3°, with a seasonal Brix value range of 11.3° to 12.3°. The comment recommended adoption of a Brix value of 11.0° for reconstituted single-strength pear juice.

One comment from a trade association expressed the opinion that a Brix value of 15.4° is too high and should be lowered. The comment cited a report showing that Brix values for unripe, fined Bartlett, Comice, and d'Anjou pear juice ranged from 11.7° to 14.1°, and that the majority of pear juice is produced from hard winter pears which generally average 11.0° Brix (Ref. 7). According to the comment, although some ripened Bartlett pears are juiced, they would have to be extremely ripe to approach even 15.0° Brix, and in that condition, they would be virtually impossible to press.

FDA agrees with the comments that a Brix of 15.4° for pear juice is too high. In proposing this value, which was based on the stayed canned nectar standard (§ 146.113), FDA acknowledged that the values had been challenged and specifically requested information on what values would be appropriate. NJPA's recommended Brix value of 11.0° was based on the USDA procedure for inspection of 50 percent juice drinks and juice drink products under the Child Nutrition Labeling Program (USDA file code 147§ A§ 2). According to USDA, this Brix value was recognized by industry as being appropriate in 1980. As far as this agency can determine, there is no identifiable data base that supports the USDA value.

Having reviewed the data in the comments, FDA concludes that the proposed Brix of 15.4° is not consistent with current commercial practice. The reported Brix values in the comments ranged from a low of 10.5° to a high of 14.1°. Industry recommendations for the minimum Brix value range from a low of 11.0° from a trade association to a high of 12.2° from a juice processor, with a mean recommended Brix value of 11.7°.

FDA acknowledges that the information provided consistently points to a lower Brix value for pear juice than the FDA proposed value of 15.4°. As stated above, however, one standard deviation below the mean is too low and is not in the best interest of the consumer. In this case, most of the data point to a mean Brix value around 12°. In fact, one comment recommended a minimum value of 12.2°, another 12°, and the university professor observed a Brix of 12.0° in his research. In addition, the German RSK "mean" Brix value is 12.13°. Use of a mean value of 12.0° would facilitate processing of pear juice which, according to the comments, is done most efficiently at the hard, green stage when the Brix of the juice is lower. Therefore, FDA is revising the minimum Brix for pear juice by lowering the level from 15.4° to 12.0°.

xiv. Pomegranate.

In the July 2, 1991, proposal, the agency solicited comments, as well as data, on any additional fruits and vegetables whose Brix values should be added to the final rule (56 FR 30452 at 30460). In response to this request, NJPA submitted data on the Brix value of pomegranate juice based on data from one of its members and suggested that a minimum Brix value of 16.0° be established as the Brix for 100 percent pomegranate juice. The suggestion was based on the firm's production records for the 1988, 1990, and 1991 processing seasons. Of the 257 samples taken during these seasons, the Brix values of samples ranged from 13.3° to 18.8°, with a weighted average of 15.9°. NJPA stated that the wide range in values is related to early season low Brix fruit versus late season high Brix fruit, varietal differences, and seasonal (climatic) variations.

FDA notes that the comment requested a minimum Brix value of 16.0° based on the firm's analyses over a 3-year period. FDA has an established Brix for pomegranate in the standard of identity for fruit jelly of 18.2°, expressed as the reciprocal by the designated factor of 5.5 for pomegranate (§ 150.140(b)(1)). This value was taken from data obtained before 1940 from authentic samples of pomegranates. According to USDA Handbook 8–9, pomegranates contain 17.17 percent total carbohydrate and 0.20 percent of fiber, or approximately 17.0 percent of sugars and other carbohydrate substances (Ref. 5). The agency recognizes that total carbohydrate content is only a rough approximation of the soluble solids content, and that other constituents of the juice may affect the refractometer readings.

Thus, FDA concludes that it is reasonable to adopt the comment's suggested lower value of 16.0° for pomegranate juice, which was based on actual analyses, instead of the higher value of 18.2° in the standard of identity for fruit jelly. In addition, the information from Handbook 8–9 suggests that a value lower than 18.2 would be more representative of the average Brix of pomegranate juice. Therefore, FDA is including the suggested minimum Brix of 16.0 for pomegranate juice in new § 101.30(h)(1) as set out below.

xv. Red raspberry juice.

In its 1989 submission of Brix data, NJPA suggested a Brix value of 9.0° for 100 percent red raspberry juice based on current industry practice. However, in evaluating the NJPA suggested value for red raspberry juice, FDA found that single-strength red raspberry juice can range between 5.6° and 10.7° (Ref. 3 at page 390). Other reports show Brix levels of 8.9°, 11.3°, and 10.8° (Ref. 3). Because these data (median value 10.7°) were not inconsistent with the Brix value set out in the standard of identity for fruit jelly (the reciprocal of the designated factor, 9.5, that equates to a Brix value of 10.5°) in § 150.140, FDA proposed a minimum Brix value for red raspberry juice from concentrate of 10.5°.

Four comments maintained that the proposed Brix value of 10.5° is too high for red raspberry juice. Two comments, one from a food processor and one from a trade association provided data on the Brix level for red raspberry juice obtained from three sources: (1) Lots of Pacific northwest red raspberries processed by the firm from 1985 to 1990 (mean Brix of 10.1°; standard deviation = 1.0°; n = 124); (2) 1988 European suppliers (mean Brix of 9.7°, standard deviation = 1.8, n = 16); and (3) 1990 European suppliers (mean Brix = 9.4°, standard deviation = 1.1°, n = 242). The comment from the food processor also included another compilation of seven average Brix values or Brix ranges provided by other juice suppliers from four countries (Austria—2 suppliers: mean Brix value of 8.5° and 6.3°; Belgium—mean Brix of 8.8°, with a range of 6.8 to 12.0°; Germany—Brix range of 7° to 8°; and United States—3 suppliers: Brix of 9° to 9.5°, 8.5°, and 8.5°). The comment also noted that the average RSK mean Brix value for raspberry juice is 8.7° with a range of 5.3° to 13.6°. Based on these data, both comments recommended a minimum Brix value of 8.4° for red raspberry juice.

Another comment, from a university professor, requested that the mean Brix values for red raspberry juice obtained from his research be considered in adopting a new standard. A statistical

summary of the Brix values resulting from the study are as follows: Mean of 9.95° (n = 41); std. dev. of 1.93°; and a range from 7.0° to 15.0°. The comment stated that if data for the underripe and overripe samples are excluded from the data base, the following summary values are obtained: mean of 9.50° Brix (n=26); standard deviation of 1.65°; and a range from 7.0° to 13.2°. Although the sampling protocol was not designed for the purpose of determining the "true" mean Brix value for single-strength red raspberry juice, the comment stated that these new data are relevant to the proposed regulations because the major commercial varieties from the Pacific Northwest and from Poland predominate in the sample set. Fall-bearing raspberries and several unusual varieties such as Golden are also included. The comment concluded that the proposed Brix level of 10.5° is too high and suggested that the 9.5° to 9.95° Brix values from the current research be considered in adopting the new standard.

One comment from a distributor of 100 percent fruit juice blends stated that the Brix value proposed by FDA for red raspberry fruit is incorrect and is not consistent with establishing a minimum acceptable value for a juice to be considered full-strength. The comment provided a brief summary of the Brix values collected from suppliers in northwestern United States (1990) and Europe (1991). It provided two average Brix values, 10.1° (range 9.0° to 12°) and 8.5° (no range provided) for the United States and an average Brix of 8.0° and a range of Brix values, 7.0° to 9.0° Brix for Europe, resulting in an overall average Brix value of 9.1° with standard deviation of 0.7°. The comment recommended 9.1° as the minimum Brix level of single-strength (100 percent juice) red raspberry.

FDA has reconsidered its proposed value of 10.5° Brix for red raspberries and agrees, based on the data submitted in the comments, that this value should be revised.

FDA also notes that soluble solids analyses conducted by the agency in 1964 and 1965 on five types of authentic red raspberries resulted in an average Brix of 8.91° (range 8.13° to 10.9° Brix; standard deviation 0.68°) (Ref. 14). In deciding to lower the proposed Brix value, FDA noted that most values cited in the comments tend to cluster between 8.5° and 9.7° Brix. Thus, FDA concludes that the suggested value of 8.4° is too low. The agency believes that a more appropriate minimum Brix value would be 9.2°, a Brix value in the lower portion of the range of suggested values provided in the comments. Accordingly, FDA has incorporated the value of 9.2° in new § 1.30(h)(1).

xvi. Other comments on specific values.

29. Several comments from the juice canning industry noted that FDA did not list any Brix values for beets, parsley, bell peppers, garlic, and onion. However, the comments did not propose any values or provide any information as to appropriate Brix values for these foods.

The July 2, 1991, proposal requested comments on, and data for, any additional fruits and vegetables whose Brix values should be added to the regulation. Because the comments provided no information or data, the agency is not placing these foods in the Brix value table. If a percentage juice determination is made for any fruit or vegetable juice not found in the Brix table in the regulation, the calculation for percentage juice declaration is to be made on the basis of the soluble solids content of the single-strength (unconcentrated) juice used to produce such a concentrated juice.

30. One comment proposed calculating the percentage juice at a Brix level equal to the average of the single-strength (unconcentrated) juice produced from that fruit in the United States.

Because the comment provided no data for the agency to review or evaluate, the agency cannot evaluate the comment's suggestion. Therefore, the percentage juice declaration will continue to be determined by using the Brix values in the table as revised in this final rule.

31. Several comments stated that acid correction of the Brix value in the calculation of percentage juice should be provided for certain juices, e.g., cranberry, lemon, lime, and raspberry as is currently provided in the standards of identity for grapefruit and pineapple juice (§§ 146.132 and 146.185 (21 CFR 146.185)). However, the comments stated that the methodology to do this correction at present is complex and not widely distributed. The comments suggested that Government and industry work together under the auspices of the Association of Official Analytical Chemists (AOAC) to determine the proper reliable methodology.

NJPA commented that the Brix values submitted by them in December 1989 and May 1990 were based on the assumption that the refractometric readings of Brix values were corrected for acidity to obtain the total soluble solids. They also stated that a footnote should be added to the table of values in new § 101.30(h)(1), stating that the Brix value, if determined by refractometer, is corrected for acidity by the method set forth in the grapefruit juice standard. Another comment that supported the NJPA suggested Brix values recommended that a correction for acid content be applied in the Brix value determination for all juices, and that this correction be based on the predominant acid type inherent to the individual juice (e.g., corrected on a citric acid, malic acid, or tartaric acid basis). NJPA suggested that the predominant acid type be identified as part of new § 101.30(h)(1) to provide a clear and consistent means for the determination of the Brix values. A comment from another trade association also stated that any method used to calculate the Brix value level of the juice should provide for an acidity correction factor in determining the actual Brix value level.

FDA notes that the correction factors in the grapefruit standard are specific to citric acid. Yeatman, et al., developed two correction factors based on percent of citric acid to be added to the sucrose values obtained by the refractometer to yield true soluble solids and true Brix for grapefruit juice (Ref. 8). The data used to develop the correction factors were based on data collected by Stevens and Baier (Ref. 9) for citric acid content in citrus juice products. There are other predominant acids in fruit juices, but data, similar to that for citric acid, would have to be collected for these other fruit acids before a correction factor could be established.

Consequently, the above suggestions are not workable because these correction factors are applicable only to citric acid.

FDA notes that NJPA's list of Brix values cited references that predate the 1976 date of the Yeatman publication on the citric acid correction factors. In addition, Brix values for the fruit butter and fruit jelly standards were proposed in September 1940, and the fruit nectars standard was stayed in 1968. Thus, FDA does not believe that all of the proposed Brix values would have been corrected for acidity. The suggestion of a joint Government and industry effort to determine reliable methodology will be considered. Until acid correction factors are established for other juices, FDA will use the Brix values as specified in new § 101.30(h)(1).

32. One comment mentioned that FDA had not addressed the need for temperature correction when determining the percent soluble solids by refractometer.

FDA disagrees with this comment. The cited method of analysis (56 FR 36452 at 30458), published by AOAC, for determining the percent soluble

solids by refractometer includes a temperature correction (AOAC Official Methods of Analysis, 15th ed., 1990, sections 976.20 and 983.17).

33. Some comments stated that a "100 percent juice" claim should mean that only juice is present, and that no preservatives or other ingredients have been added. On the other hand, one comment stated that the percentage juice calculation should be a function of total juice solids in the final product, and that any added ascorbic acid, natural flavors, and acidulents should be treated as ingredients that do not affect the 100 percent juice claim as long as there are sufficient juice solids present to substantiate the juice content declaration. Another comment asked whether the Brix measurement included salt added to vegetable juices. It requested clarification as to whether adding salt to a 100 percent juice would prohibit declaration of the juice as 100 percent.

The juice content declaration is based on the percent by volume of single-strength (100 percent) juice in the product. It is intended to provide information on whether a juice is diluted and if so, by how much. For example, a declaration of 10 percent juice means one part juice plus nine parts water, 50 percent juice means 1 part juice plus 1 part water, and 100 percent juice means 1 part juice and no water.

Further, the agency recognizes that certain ingredients, such as salt, are used to affect flavor, and that others may be added, for example, as nutrients or as preservatives. In most instances, these additives, excluding bulky ingredients such as carbohydrate sweeteners, are not added in volumes significant enough to result in a diminution of the juice's soluble solids content and therefore do not affect the percent juice calculation. The juice products in the beverage must contain sufficient juice soluble solids to meet the minimum Brix level for 100 percent juice where established by regulation, before the addition of any non-juice ingredients, where such requirements have been established. For example, under the standard of identity for grapefruit juice, when the juice product is made from concentrate, and liquid sweeteners are added, the Brix value of the juice must comply with the required Brix of 10° (and corrected for acidity) exclusive of any added sweetener.

The agency believes that limiting the 100 percent juice declaration to juice beverages that contain no additives, such as vitamin C would discourage some manufacturers from producing beverages that contain such useful added ingredients.

However, FDA agrees that it is necessary to clarify the issue of a 100 percent juice declaration on a product that includes non-juice ingredients because it may be interpreted by some to mean the beverage contains juice and no other ingredients. The agency has advised repeatedly for a number of years that an unqualified 100 percent juice declaration on the principal display panel is misleading when the juice also contains non-juice ingredients (Ref. 16). The agency believes that the industry is already in substantial compliance with this policy. Particularly for a beverage made from only one fruit or vegetable juice, the "100% juice" declaration introduces a precision to the description of the product that can result in the consumer concluding that the juice is the only ingredient. Because an ingredient statement is required only if a product contains two or more ingredients the consumer would not likely look for an ingredient statement under these circumstances. A 100 percent juice declaration appearing on the information panel is not likely to similarly mislead the consumer because it is in reasonable proximity to the ingredient statement, so that it will be read by the ordinary consumer in conjunction with that statement under normal conditions of purchase. Similarly, if there is no information panel, and the principal display panel bears an ingredient statement, a 100 percent juice declaration would not likely be misleading. In addition, the agency recognizes that some of these products declare the presence of the non-juice ingredients as part of the statement of identity (e.g., "prune juice with added vitamin C").

Accordingly, FDA is requiring in § 101.30(b)(3) that for those products that do not declare the presence of the non-juice ingredient in the statement of identity, when a "100% juice" declaration appears on a panel of a juice beverage that does not also bear the ingredient statement, and the product contains a non-juice ingredient, the 100 percent juice declaration shall be accompanied by the qualifying phrase "with added ————," the blank filled in with the generic term "ingredient" or a term such as "preservative" or "sweetener." For example, a beverage blend containing 100 percent juice with an added sweetener in any or all the juices would bear the phrase "100% juice with added sweetener" when the declaration appears on a panel that does not also bear the ingredient statement.

Therefore, the agency is not granting the comments' request but is permitting a qualified 100 percent juice declaration on the principal display panel of 100 percent juice beverages that contain non-juice ingredients that do not significantly affect product volume, such as preservatives, provided that these ingredients do not result in a diminution of the juice soluble solids content or otherwise adulterate the beverage.

The agency advises that in this discussion, it is not evaluating the appropriateness of any of these low volume ingredients for addition to specific juices. Determinations of whether a substance is suitable as an ingredient in a food are beyond the scope of this rulemaking. This discussion addresses only the effect on the declaration of 100 percent juice of the presence of suitable ingredients that do not have a significant effect on product volume. Further, FDA advises that the presence of such ingredients in these beverages may require specific label declaration.

2. Juice Not From Concentrate

FDA proposed in § 101.30(k), (redesignated as new § 101.30(i)) that juices expressed directly from a fruit or vegetable, i.e., not concentrated and reconstituted, be considered to be 100 percent juice and be declared as "100 percent juice." Likewise, the percentage of expressed juice, and not Brix level, is to be used in calculating the percentage of juice in diluted juice beverages made directly from expressed juice. Therefore, FDA proposed in § 101.30(l) (redesignated as new § 101.30(j)) to require that calculations of the percentage of juice in a juice beverage made directly from expressed juice (not from concentrate) be based on the percentage of the expressed juice in the product computed on a volume/volume basis.

34. One comment stated that expressed juice products should not be excluded from the Brix method of calculating percentage juice. The comment expressed concern that if manufacturers were not required to meet a specified Brix level, some might dilute high solids content expressed juice with water to a lower Brix level and sell the product as full-strength (100 percent) juice.

As FDA stated in the July 2, 1991, proposal, diluting expressed juice to a lower Brix level but still calling it 100 percent juice would constitute adulteration and misbranding. Such a product would be misbranded under section 403(a) of the act because its labeling would be false and misleading

in that it failed to reveal the material fact that the juice was diluted. It would also be adulterated under section 402(b) of the act (21 U.S.C. 342(b)) because it had been diluted with water.

The agency discussed in the July 2, 1991, proposal that it was necessary to exclude expressed juices from the requirement for a single Brix level because such a provision would result in high solid content juice being diluted to the standard Brix level (56 FR 30452 at 30460). FDA stated that such dilution was not acceptable, and that expressed juice had to be declared as 100 percent with the solids content of the juice as expressed. The agency believes that the adulteration and misbranding provisions cited above will deter manufacturers from diluting expressed juice with water. Thus, FDA concludes that the concerns expressed in the comment are unfounded. Accordingly, as proposed, § 101.30(i) and (j) exclude expressed juice from the provision that percent of juice is to be calculated using specified Brix levels.

35. Another comment expressed concern that allowing expressed juice to have a different Brix value than juice of the same fruit made from concentrate could lead to organoleptic as well as nutritional inconsistencies in the product.

The agency recognizes that organoleptic as well as nutritional inconsistencies may be created by requiring that manufacturers of juice products that consist solely of expressed juice base their calculation of the juice content of the product on the juice as expressed rather than on a Brix level. The agency has concluded that Brix values are the best standardized criteria for calculating percentage of juice from concentrate primarily because of the industry practice of commingling large quantities of concentrated fruit juice, often from foreign sources, with differing and possibly unknown soluble solids values.

However, because the actual percentage of the source expressed juice is known, the percentage of expressed juice, and not Brix level, must be used in calculating the percentage of juice in full-strength and in diluted juice products made directly from expressed juice. Additionally, because the Brix levels of expressed juice from the same fruit or vegetable grown in different regions may vary within a large range, e.g., the Brix value for expressed apple juice ranges from 9° to 14°, it would be economically unfair to penalize producers of expressed juice from fruit or vegetables grown in regions that have a lower Brix value by not allowing them to declare 100 percent fruit or vegetable juice, when in fact the juice was directly expressed from the fruit or vegetable as it occurred in nature.

Also, FDA finds that consumers will not be misled by the differences between juices made from concentrate and expressed juices. While consumers expect juice from concentrate to be processed into a uniform product, they understand that expressed juice may vary because of variation in the fruit. For example, a particular brand of frozen concentrated orange juice will taste a the same from purchase to purchase, but fresh squeezed, home prepared orange juice will vary in sweetness and taste, depending on the maturity and quality of the oranges used to prepare the juice.

Therefore, the agency is finalizing the provision that juices expressed directly from fruits or vegetables be considered 100 percent juice.

36. One comment stated that the proposed method of calculating the juice content based on the Brix value was not applicable to blends of full-strength juice and concentrated juice because the total amount of juice in the product may be greater than 100 percent. The comment suggested that the final rule be amended to state that the Brix values are to be used for labeling purposes only when the product is a single juice beverage that is derived from concentrate.

FDA acknowledges that the total soluble solids content exceeds the minimum level necessary to declare that the juice is full-strength (100 percent) when concentrates are blended with single-strength juices. FDA does not intend that these products be exempt from declaration of the percent of juice. The agency recognizes that strongly flavored juice concentrates may be blended with single-strength juices to provide flavor and color in blended juice products. As a result, the total level of juice soluble solids in the blend will be greater than the total of such juices if the concentrate were diluted to single-strength before its use in the blend. In such cases, unless the blended juice is to be further diluted by the consumer, FDA considers a declaration of more than 100 percent juice to be misleading. Thus, the juice should be labeled as 100 percent juice. The agency has no objection to manufacturers making a truthful statement on the label concerning the actual level of juice soluble solids contained in the blend provided that it is made in a manner that is not misleading to consumers.

37. Several comments requested that the fruit component of nectars not be required to be declared as percent of fruit juice. They stated that pulp and puree are the fruit ingredients in nectars, not fruit juice. Comments suggested alternate fruit content declarations, such as "apricot nectar—contains 45 percent apricot pulp" or "————————percent fruit + juice." The comments expressed concern that consumers might be confused by a declaration, for example, of 100 percent juice on a beverage in which only two of the ingredients are declared as juice while the other two ingredients are declared as fruit puree.

The agency acknowledges that there is generally more fruit or vegetable fiber or pulp present in nectars than in juice, which is otherwise processed, clarified, or filtered. However, the Brix values listed in the July 2, 1991, proposal were calculated to take into consideration that some of the starting materials may be puree or pulp, e.g., banana, papaya, or guava. Further, many comments expressed support for the agency's position that standardized criteria are needed to facilitate consistency in calculating percentage of juice. The Brix concept for percent juice calculation, while not without limitations, is a standardized criterion and provides a consistent and equitable frame of reference for manufacturers in determining percent juice in beverages derived from concentrates. The agency is unaware of a comparable standardized criterion for fruit content as opposed to fruit juice content. Therefore, FDA rejects the suggested alternative percent fruit content declaration or declarations such as "contains 45 percent apricot pulp" or "————— percent fruit + juice" in lieu of the prescribed percentage juice content declaration based on Brix for nectars. However, the agency does not object to voluntary disclosure of such fruit component information provided that it is factual. These comments did not provide alternative standardized criteria for consistently determining fruit content in nectars or purees by themselves and in combination with other fruit juice in beverages as opposed to fruit juice content based on Brix values.

F. Modified Juice

The agency proposed in § 101.30(m) (redesignated as new § 101.30(k)) that if major modifications (i.e., changes in the color, taste, or other organoleptic properties) are made to a juice to the extent that the original juice is not recognizable, or if its nutrient profile has been diminished, then the juice may not be included in the total juice percentage declaration. However, in the July 2, 1991, proposal, FDA pointed out that it is appropriate to include in the

total percentage juice declaration juices with minor modifications, such as acid-reduced orange juice, that are easily recognizable to consumers (56 FR 30452 at 30461).

38. One comment suggested that the industry work with FDA to develop information and data that will provide normal ranges for the constituents in juice, such as minerals, acids, and sugars. Such data would be used to determine at what point in the process modification of the juice is beyond the normal range of these constituents. According to the comment, a project has been initiated to develop these parameters for apple juice obtained from sources throughout the world. Additional juices are to be added to the project in the future.

FDA is aware of this information development project and is providing guidance as to the kind of information that would be useful in making agency decisions. The agency encourages industry to develop data bases that would be helpful in establishing reasonable guidelines for juices, in particular, the levels and types of nutrients, ranges for these levels, and effects of processing on nutrient content. Such data bases would facilitate decisions that promote fairness to both consumers and the industry.

39. Several comments expressed concern that the description of major modifications in § 101.30(k) would not be interpreted appropriately. One comment stated that if the phrasing "if its nutrient profile has been diminished" is strictly interpreted, juice made from concentrate would be excluded from the juice content declaration. The comment explained that there is some difference in nutrient content in any juice that is filtered and concentrated. Some comments stated that the language of § 101.30(k) should be clarified by adding: "at the time processing is complete" after "recognizable;" and "to a level below the naturally occurring nutritional range for the juice" after "diminished," so that minor modifications of juices do not preclude the juice from being included in the percentage juice calculation and declaration. They cited as examples of such minor changes acid adjustments and removal of naringin from navel oranges to facilitate production of a more uniform product.

The agency agrees with the comments and is clarifying the provision because it was intended to address significant modifications of organoleptic properties and significant modifications of nutritional values. Significant modifications in organoleptic properties would include removal of the typical color, taste or flavor, or aroma such that the juice is no longer recognizable as the typical juice of the fruit or vegetable. In the case of nutrient content of modified juices, significant nutritional modifications would include decreases in the content of any essential nutrient that is present in a measurable amount (excluding fat or calories), i.e., present at a level of 2 percent or more of the Reference Daily Intake (RDI) for any vitamin or mineral listed under § 101.9(c)(7)(iv). However, FDA recognizes that some nutrient losses can be expected as a result of heat treatment, filtration, and clarification used to make the modified juice product. FDA expects that such losses would be minor, and that the resulting modified juices will provide levels of essential nutrients comparable to the naturally occurring nutritional range published in recognized data bases, such as the USDA Handbooks on Food Composition (Refs. 5 and 6), for the unmodified juice product.

The agency is adopting the suggested changes to the regulation with one exception. It believes that the term "normal nutrient range" is more appropriate than "naturally occurring nutritional range." As stated in the comment, the naturally occurring nutrient range, i.e., nutrient levels in expressed juice, may be slightly different from the range of nutrients normally present in juice that has been processed, for example, filtered and concentrated. FDA believes these differences should be taken into account in determining which changes in a juice constitute major modifications.

Accordingly, FDA has revised new § 101.30(k) by adding the phrase "at the time processing is complete" after "recognizable" and the phrase "to a level below the normal nutrient range for the juice" after "diminished," to specify that comparisons of the organoleptic properties of the original juice and the modified juice will be made "at the time processing is complete" and to specify that the nutritional profile must not be diminished "to a level below the normal nutrient range."

40. Some comments requested clarification of how the percentage juice content of dehydrated juices should be determined. One requested that dehydrated fruit and vegetable powders be treated similarly to fruit and vegetable juice concentrates, i.e., based on the Brix value, and therefore, the percent of juice should be based on the soluble solids content of the rehydrated product.

Another comment questioned the status of dry drink mixes which are prepared from spray dried juices that have not been modified in any way other than that the water has been largely removed. The comment expressed the opinion that when these products are properly reconstituted, they should be considered to be a juice.

FDA is not providing for the declaration of the percent of juice from dehydrated fruit or vegetable juices. At this time, the agency does not have information on the manufacture of such products or on the properties of the finished products with which to determine whether dehydration is a minor modification that does not significantly change the juice. The agency believes that many dehydrated juices may contain ingredients other than simply juice solids. Maltodextrins are often added to prevent stickiness during juice drying operations. Fruit essence or flavors may be added to compensate for volatile flavor components lost during processing. However, according to the literature, processes are being developed in which juices may be dehydrated without the addition of additives such as maltodextrins or glucose syrups (Ref. 15).

The agency requests information on how the specific dehydrated juices are made, so that it can determine appropriate means of labeling dehydrated juice products in juice beverages. Until such time as FDA can establish rules governing the declaration of dehydrated juices in juice beverages, it will evaluate the labeling of such dehydrated products on a case-by-case basis to determine if it is misleading. However, FDA advises that in the meantime, any declaration of percent of juice made on a rehydrated juice should be based on the fruit or vegetable solids before any other soluble substances are added to the product.

41. One comment stated that it is possible to remove some or most of the sugar from a juice and not otherwise change the nutrient profile of the juice. The comment stated that, with an alternative sweetener, the product will have the color, taste, and other organoleptic properties consumers associate with the original juice. The reduced-sugars juice will have levels of ascorbic acid, citric acid, and minerals that are equivalent to those of the standard juice. The comment maintained that an alternate method to the Brix calculation will have to be used in calculating juice content for such products. Thus, the comment suggested that the regulation recognize this possibility and permit manufacturers to use an alternative method to calculate

the juice content, provided they have data to substantiate the method.

FDA recognizes that current technology is such that sugars or other components may be removed from juice. The agency recognizes that the reduction of sugars from a juice or a standardized juice, and the subsequent sweetening of the juice with a sweetener that provides an insignificant amount of calories, results in a modified juice. If the juice is a standardized juice, e.g., orange juice, that has been reduced in sugars so that it qualifies for use of a nutrient content claim and complies in all other aspects to new § 130.10, then the product is a food defined by new § 130.10 and must be labeled accordingly. The actual name of the food will depend on its nutrient content. Similarly, if the original juice is not a standardized juice, it may qualify to bear a nutrient content claim defined in part 101.

However, as stated above, when sugars are removed, the resulting product is a modified juice and not juice. Therefore, like other modified juices, it cannot be included in calculating the percent juice in the product.

III. Common or Usual Name Regulation

The 1990 amendments require that the percentage juice declaration for fruit or vegetable juice beverages be on the information panel of the label. Accordingly, FDA proposed to delete from the common or usual name regulation for diluted fruit or vegetable juice beverages (§ 102.33) the provisions that deal with percentage juice declaration as a part of the name of the product and to amend the regulation to pertain only to how these beverages should be named. The agency also proposed changes in the provisions for naming diluted juice beverages. The proposed regulation included a requirement that the name of a beverage that contains juice but that is less than 100 percent juice include a qualifying term like "beverage," "cocktail," or "drink," to indicate that the product is not 100 percent juice. In addition, the agency requested comment on whether the term "diluted" should be required for these products. Further, the proposed regulation addressed such issues as how individual juices in a multiple-juice beverage should be declared, and how modified juices should be declared.

42. One comment requested clarification of the applicability of § 102.33. It noted that there were differences in phrasing in proposed § 102.33(a), (b), and (c) with respect to the products covered. It said that in § 102.33(a), FDA addressed diluted juice beverages by saying, "* * * beverage that contains less than 100 percent and more than 0 percent fruit or vegetable juice." On the other hand, in § 102.33(b) the product is described as a "diluted, multiple-juice beverage or blend of single-strength juices," and in § 102.33(c), as a "multiple-juice beverage or blend of single-strength juices * * *." The comment stated that it was clear that § 102.33(a) applies to dilute beverages and does not apply to nondilute beverages, but that it was not clear whether both § 102.33(b) and (c) apply to dilute and nondilute beverages, or whether § 102.33(c) applies only to nondilute beverages.

The agency advises that the difference in phrasing in § 102.33(b) and (c) was inadvertent. Both provisions are intended to apply to both dilute and nondilute beverages. Accordingly, § 102.33(c) has been revised to refer to a "diluted multiple-juice beverage or blend of single-strength juices."

A. Identity of Diluted Juice Beverages

The agency proposed in § 102.33(a) that if a product contains less than 100 percent juice and uses the word "juice" in the common or usual name, then the word "juice" must be qualified by a term that indicates dilution, such as "beverage," "cocktail," or "drink," appropriate to advise the consumer that the product is less than 100 percent juice. In addition, FDA requested comments on whether the term "diluted," or a similar term, should be required as part of the common or usual name for juices that are less than full-strength (100 percent) juice.

43. Several comments supported the July 2, 1991, proposal to qualify the term "juice" on products containing less than 1080 percent juice, and none objected. However, the majority of comments addressing the issue objected to a requirement for the term "diluted" in the name of beverages containing less than 100 percent juice. The comments stated that the term would give consumers the impression that the product was "watered down." On the other hand, several comments expressed the belief that the term "diluted" should be used. Alternatively, these comments suggested that if the term "diluted" is not used, a declaration of the total percent of juice should appear on the principal display panel if the beverage is not 100 percent juice.

The comments requesting that the term "diluted" be required did not provide information to demonstrate that such a declaration was needed or would be useful to the consumer. Consequently, the agency has no grounds on which to base such a requirement at this time. Therefore, in accord with most of the relevant comments, while requiring use of a term that indicates dilution, FDA is not requiring that the term "diluted" be included in the name of juice products that contain less than 100 percent juice and is adopting § 102.33(a) as proposed.

Further, the agency disagrees with the alternative suggestion to require total percent juice declaration on the principal display panel of the juice beverage if it is not 100 percent juice and does not bear the term "diluted." Percentage juice is required to be declared on the information panel, and, as discussed in comment 12 of this document, the agency does not have an appropriate legal basis for requiring an additional percentage juice declaration on the principal display panel.

44. One comment stated that soft drinks (sodas) that purport to contain real fruit juice should have a common or usual name such as "imitation grape drink." This comment said that such a name is applicable when a product named "grape soda" bears vignettes or words indicating the presence of grape juice.

The agency disagrees. Under § 101.3(e), a food is an imitation if it is a substitute for, and resembles another food, and is nutritionally inferior to that food. However, if the food is not nutritionally inferior to the food for which it substitutes, it is permitted to be labeled descriptively and need not bear the term "imitation."

The requirements for labeling a beverage as an imitation are not evoked by use of vignettes or words suggesting that grape juice is present. These vignettes or words would, however, make the beverage subject to the requirements in § 101.30 for declaration of juice content. The agency finds that such a product with a percent of juice declaration would be informatively labeled and would not be misleading. Accordingly, FDA is not requiring beverages which purport to contain fruit juice to be labeled "imitation" unless the criteria in § 101.3(e) are met.

B. Identity of Multiple-Juice Beverages

FDA proposed to require in § 102.33(b) that if a product is a diluted, multiple-juice beverage or a blend of single-strength juices and declares, names, implies, or represents on the label, other than in the ingredient statement, one or more of the individual juices (represented juices), then the names of the represented juices must be included in the common or usual name in descending order of predominance by volume, unless the common or usual

name specifically shows that the juice with the represented flavor is used as a flavor (e.g., raspberry-flavored apple and pear juice drink).

In the July 2, 1991, proposal, the agency noted that blends or mixtures of several juices, with one or two juices present in only minor amounts giving them flavor, are difficult to label (56 FR 30452 at 30462). Therefore, FDA did not propose an exact labeling format for such products. The agency proposed in § 102.33(c) that if a diluted multiple-juice beverage or blend contains a represented juice and one or more that are not represented, i.e., not named or implied through words or vignettes other than in the ingredient statement, then the common or usual name for the product must state that the nonrepresented juices are present (e.g., "Raspcranberry: raspberry and cranberry juice in a blend of two other fruit juices").

45. Comments addressing the issue of which juices should be declared in the common or usual name when more than one juice is present in the product were markedly different. Some comments asserted that all juices (represented and nonrepresented) should be included in the common or usual name because consumers may be confused when the common or usual name reflects certain juices and the ingredient statement declares additional juices. One of these comments disagreed with FDA's proposed position that it was appropriate to exclude from the category of represented juices (and consequently from the requirement for declaration in the name) those juices whose presence in the product is disclosed only in the ingredient statement. The comment stated that the agency had offered no legal justification for this position. The comment provided no justification for its position that the presumption should be that juices declared only in the ingredient list are "represented."

Other comments stated that it would be unreasonably cumbersome for products that include many juices to list them all in the statement of identity. They said that the combination of a truthful, descriptive statement of identity, the ingredient list, the percentage total juice declaration and, optionally, a vignette would provide enough information about the juices present.

The first comments are not persuasive. The agency stated in the July 2, 1991, proposal that because all ingredients of a product must be declared in the ingredient statement, if the criteria for what is a "represented juice" included being listed anywhere on the label, all juices would be considered to be represented (56 FR 30452 at 30456). FDA stated that it was more appropriate to exclude juices listed only in the ingredient statement from the category of represented juices, so that a distinction can be made between those juices represented as being present in the product, through word or vignette, and those not so represented. The comment did not provide any information that would justify different position.

The basis for the agency's position is provided by the basic principles for common or usual names in § 102.5. It is not necessary to list all juices in the name of a beverage to adequately describe the product. The basic nature of the product can be described in various ways, e.g., as a blend of five juices, with a declaration of the name of the juice or juices that provide the characterizing flavor, as long as it is clear from the name that other juices are present. Under sections 201(n) and 403(a) of the act, the name of the food must not omit any material facts. The names of all the juices in the five-juice beverage example, however, are not necessarily material facts in this context. Consequently, FDA concludes that its position that a juice whose presence in the product is disclosed only in the ingredient list of a beverage product is not a "represented" juice is appropriate and consistent with the act.

The agency also concludes that it is not necessary to require that each juice in a beverage be named to ensure that the label is not be misleading. As discussed in the response to comment 10 of this document and in response to subsequent comments, there are several ways in which a multiple-juice beverage can be appropriately labeled. For example, for a product containing apple, grape, raspberry, and cranberry juice, the names "Raspberry and cranberry flavored juice beverage in a blend of two other juices" or "Raspcranberry; Raspberry and cranberry juice beverage, 10 to 15 percent cranberry juice and 3 to 8 percent raspberry juice" would be acceptable under the act.

However, while FDA is not requiring that each juice in a beverage be declared in the name of the product, it encourages such declarations. They may provide useful information for the consumer, provided that the declaration does not misrepresent the contribution of any individual juice to the product.

46. One comment suggested that for a multiple-juice beverage, the principal display panel should display by words, vignette, or other means each juice ingredient or the number of juices in the beverage. It stated that such a requirement would remove the need to distinguish between represented and nonrepresented juices and would assure clarity and uniformity in labeling.

The agency agrees that such labeling would be informative and encourages manufacturers to identify on the principal display panel each juice ingredient or the number of juices in the beverage. FDA is not convinced that it is necessary or appropriate to limit label declarations for all multiple-juice beverages to those described in this comment because there are other ways to adequately name these beverages. The agency has provided in response to other comments in this document, examples of other nonmisleading ways to name a multiple-juice beverage. Consequently, FDA is not adopting the requested requirement.

47. A number of comments objected to the requirement in proposed § 102.33(b) that each juice represented on the label be named in the statement of identity in descending order of predominance by volume. Some suggested that where all juices in a multiple-juice beverage are depicted in a vignette, naming all those juices in the common or usual name would not provide significant benefit to the consumers. They said that instead, naming all such represented juices would require excessive label space. A number of comments stated that in those instances where a blended juice product includes a juice that imparts the predominant flavor but that does not predominate by volume, the declaration of the name of the prominent or characterizing juice flavor should be made first, rather than being declared in order of predominance by volume, because the consumer needs to know the flavor to be expected in the product.

The agency has evaluated these comments and others discussed below and is revising the provisions of new § 102.33(b) so that it does not require declaration of all represented juices in the common or usual name of the beverage. Consistent with the approach discussed in response to comment 10 of this document, FDA concludes that while beverage labels are clearly misleading if they misrepresent the contribution of one or more individual juices to the nature of the product, not all multiple-juice beverage labels that bear representations of individual juices misrepresent their contribution to the total product. For example, a vignette that depicts all the fruits or vegetables in the product may not misrepresent the contribution of an individual juice to the nature of the product. Accordingly, the agency has revised new § 102.33(b) to clarify that all represented juices need not be named. In addition, FDA is

retaining the provision that juices that are declared in the name must be in descending order of predominance by volume unless the name specifically shows that the juice with the represented flavor is used as a flavor (e.g., raspberry-flavored apple and pear juice drink). The name of the characterizing juice may therefore be declared first although it is not the most predominant juice. However, as discussed below, this provision does not relieve the manufacturer of the obligation to label the product in a truthful and nonmisleading manner. The agency believes that this revision of new § 102.33 along with the others discussed below are adequate to prevent misleading labels on multiple-juice beverages.

48. Several comments supported proposed § 102.33(c), which states that when the represented juice is not the only juice present, the common or usual name of a multiple-juice beverage should reflect that fact. No comments objected. The agency is therefore retaining this provision. However, given other changes in the final regulation, FDA has used a different example to illustrate the requirement, so that there will not be confusion as to the completeness of the name provided in the example.

49. One comment noted the requirement in § 101.22(i) that the term "flavor" or "flavored" accompany the name of certain foods containing added flavors. The comment requested that juice products labeled as "——— flavor" be exempt from common or usual name requirements in proposed § 102.33. It requested clarification with respect to naming a diluted juice product containing three juices (cranberry, grape, and lemon) and a juice flavor (cranberry flavor). This comment stated that § 101.22(i)(1)(iii) requires such a product to be labeled as "cranberry flavor," however the proposed regulations in § 102.33 require the statement: "in a blend of ——— other juices." The comment stated that requiring this statement is not reasonable because the term "cranberry flavor" adequately informs the consumer in accordance with § 101.22, and the percent total juice and percent cranberry juice would be on the information panel.

The agency advises that an acceptable description of the product described in the comment would be "cranberry flavored juice in a blend of two other juices." Another adequately descriptive term would be "cranberry juice in a blend of two other juices, with added cranberry flavor." The agency has not specified the precise wording that must be used as the name of such a beverage. However, both §§ 101.22 and 102.33 are intended to ensure that the label communicates essential information to consumers. These provisions are intended to provide manufacturers with flexibility for labeling products while providing consumers with information that they need to determine the nature of the product. The agency concludes that both kinds of label information discussed here are essential to adequately describe the nature of the product. One type of information informs the consumer when flavoring substances have been added to the product. The other type describes other aspects of the basic nature of the product. Thus, FDA is not making the requested revision.

In addition, the suggestion in the comment included mandatory declaration of the percent of cranberry juice in addition to percent of total juice. As discussed in comment 10 of this document, declaration of percentage of individual juices represented on the label is not required as a part of the juice content declaration under this final rule. Therefore, not all the label information discussed in the comment's alternative approach will be required on the product.

50. Some comments that objected to mandatory declaration of the percentage of each individual juice represented on the label of a multiple-juice beverage suggested alternatives in the form of labeling schemes centered around the common or usual name of the product that they said would adequately describe multiple-juice beverages. These label schemes included statements of identity that: name the characterizing juice where needed to provide information on taste or flavor of the product; where appropriate, declare that the product was prepared from concentrate; and include terminology like "blended" or "blend of juices" to convey the multiplicity of juice ingredients. In addition, declaration of the presence of added flavors in accordance with § 101.22(i) would be required. The comments said that this information, together with the percentage of total juice and declaration in the ingredient list of all juices (or juice concentrates) in descending order of predominance by weight, would provide the consumer with sufficient information to make a product selection.

The agency agrees that the labeling schemes suggested by the comment would provide adequately descriptive labeling for some products and, as discussed in other comments, is requiring in the final regulation the declarations suggested. However, it does not agree that this scheme would ensure that all multiple-juice beverages would bear labels that are not misleading.

As discussed above, FDA finds that it is not necessary that all multiple-juice beverages identify each represented juice in the name of the product and declare the percentage of each represented juice. The agency has given examples of label statements that would not be misleading. However, FDA is not persuaded that the recommended schemes would ensure the labeling of multiple-juice beverages in which the named juice is not the predominant juice would provide enough information to describe the product for the consumer. FDA agrees with those comments that expressed concern that consumers are being misled into believing that named juices are present in greater amounts than is actually the case. The agency is aware of a number of products currently on the market for which the suggested labeling would not inform the consumer that the named juice is present in only a minor amount.

The agency notes that the regulation on the general principles for common and usual names provides in § 102.5(b) (21 CFR 102.5(b)) that when the proportion of a characterizing ingredient in a food has a material bearing on price or consumer acceptance, or when the label or labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient is present in an amount greater than is actually the case, the percentage such characterizing ingredient shall be declared as a part of the common or usual name of the food. This provision formed the basis for the requirement in the previous version of § 102.33 for declaration of percent of juice, both for total juice and for each individual juice represented on the label.

FDA agrees with comments that stated that declaration of the percentage of individual juices will provide informative labeling. While the agency has decided not to require percentage declaration of represented individual juices in all multiple-juice beverages, it concludes that for multiple-juice beverages that name one or more but not all of the juices present other than in the ingredient list, there is great potential for the label to misrepresent the contribution of the named juice to the product. When the named juice is the predominant juice in the product, FDA considers that the consumer will not be misled with regard to its contribution because naming it will not over emphasize its contribution. However, when the named juice is not the predominant juice, the consumer can be

misled. Therefore the final regulation, in § 102.33(d), requires that the common or usual name of the product specifically describe the contribution of the named juice if it is not the predominant juice. The agency has provided two ways for the common or usual name to include this information.

In § 102.33(d)(1), the agency has provided that manufacturers can use a product name that identifies the juice that provides the characterizing flavor and specifically shows that that juice is used to flavor the product (e.g., "raspberry flavored apple and pear juice drink" or "apple and pear juice drink flavored with raspberry juice"). The agency believes that using the term "flavor" with the name of the characterizing juice will inform the consumer that the juice is present in an amount sufficient to flavor the beverage but will not imply that the content of that juice is greater than is actually the case. This alternative is consistent with the agency's approach of not requiring percentage total juice declaration for bottled waters that contain juice for flavoring in small amounts (usually less than 2 percent) (see comment 4 of this document). Accordingly, FDA is providing in § 102.33(d)(1) that a multiple-juice beverage may use a product name that specifically shows that the named juice is used as a flavor.

Alternatively, consistent with § 102.5(b), the agency is providing in § 102.33(d)(2) for the declaration of the amount of the named juice in multiple-juice beverages that name one or more but not all of the juices in the product. As explained in the **Federal Register** of March 14, 1973 (38 FR 6964), the disclosure of the amount of a characterizing ingredient is a material fact.

Among the reasons given in comments that disagreed with the proposed requirement for declaration of percentage of individual juices was the need to have flexibility in the formulation of the beverage to accommodate variations in raw material juices and price changes. The comments included a report that documented that changes in formulation occur frequently and in a significant number of products. The agency is persuaded by the comments that an accommodation is warranted. It agrees that declaration of individual juice content in 1-percent increments is not practicable. Accordingly, FDA is providing in § 102.33(d)(2) that the juice content declaration of individual juices may be made using a 5 percent range, e.g., 2 to 7 percent raspberry juice or 5 to 10 percent cranberry juice. The agency considers that a 5 percent range is large enough to provide for changes in formulation for juices that are present in small amounts.

Comments did not provide specific information on individual juice content, but it is reasonable to assume that a minor juice in a multiple-juice beverage would not be present at greater than about 25 percent of the total product. The 5 percent range is one-fifth of this amount. The agency concludes that a 5 percent range would provide this kind of flexibility to accommodate minor fluctuations in amounts of juice needed to compensate for differences in raw material. In addition, some comments contended that declaration of percent of individual juices in 1-percent increments constitutes an inappropriate disclosure of proprietary formulation information. The agency believes that declaration of individual juice content in 5 percent ranges would in any case not reveal the product formula. Finally, the 5 percent range declaration will provide enough information for consumers to be able to understand the contribution to the product made by the named juice and not be misled into believing that the juice is present in an amount greater than is actually the case.

Accordingly, FDA has provided these two labeling alternatives for multiple-juice beverages that name one or more but not all of the juices in the product in new § 102.33(d). In addition, the final regulation requires in new § 102.33(d) that the percent individual juice declaration be a part of the name of the product and meet the type size requirements in § 102.5(b)(2).

51. Several comments stated that juice beverages may be made from dehydrated as well as fresh fruits and vegetables in products such as vegetable cocktail, vegetable juice cocktail, juice cocktail, and bloody mary mix. One comment requested clarification that the names "vegetable juice cocktail," "vegetable cocktail juice," and "vegetable cocktail" can be used interchangeably on such products, when they are made from any combination of expressed juice, juice concentrate, and dehydrated fruits and vegetables.

The agency does not have information with which to determine whether beverages made from dehydrated fruits or vegetables differ from beverages made from concentrated or expressed juice. The agency welcomes any data or other information on the nature of beverages made from dehydrated fruits and vegetables, particularly on how they differ from beverages made from expressed or concentrated juice. The agency advises that it will evaluate the labels of such products on a case-by-case basis to determine whether the labeling is misleading. However, FDA advises that irrespective of the form of the vegetable ingredients, the term "vegetable cocktail juice" may not be interchangeable with the other two terms. It uses the word "juice" without a term indicating dilution. Accordingly, it can be used only on beverages that are not diluted juice products. The terms "vegetable juice cocktail" and "vegetable cocktail" would apply to diluted vegetable juice beverages.

C. Vignettes

The agency did not propose a specific requirement regarding the relative amounts of the various fruits depicted in a label vignette but solicited comments on whether it should require that the vignette accurately reflect the quantity of the fruit present or the taste of the product, or whether some other requirement is appropriate.

52. Some comments, from both consumers groups and manufacturers, stated that vignettes should depict all juices in a product. Other comments stated that such a provision is not necessary because a descriptive name together with declaration of each juice by order of predominance in the ingredient list and the percent of total juice would provide enough information to ensure that the consumer is adequately informed.

The agency agrees that it is not always necessary that the label of a multiple-juice beverage depict each juice in a vignette. The agency believes that a vignette that pictures only some of the fruit or vegetables in the beverage would not be misleading where the name of the food adequately and appropriately describes the contribution of the pictured juice. For example, for a 100 percent juice product consisting of apple, grape, and raspberry juices, in which the raspberry juice provides the characterizing flavor, a vignette depicting raspberries would not necessarily be misleading if the statement of identity were "raspberry juice in a blend of apple and grape juice." Similarly, the vignette would not be misleading if the beverage were named "raspberry flavored fruit juice blend" or "raspberry juice in a blend of two other juices, 3 to 8 percent raspberry juice." Moreover, if these three juices were in a beverage containing 50 percent total juice, a vignette picturing raspberries would not be misleading in the presence of a name like "raspberry flavored juice beverage."

Accordingly, FDA is not requiring that vignettes depict the fruits or vegetables for all juices present. However, FDA believes that a vignette that pictures the fruit or vegetable

sources of all juices present in a product would provide useful information and thus encourages manufacturers to use such vignettes.

Conversely, vegetables or fruits not present in the beverage cannot be depicted in vignettes or other pictorial representations on the label. The agency considers that depicting a fruit or vegetable in a vignette on a juice beverage implies that the fruit or vegetable is in the product, either in the form of a juice or of a natural or artificial flavor of the depicted fruit or vegetable. A vignette that pictures a fruit or vegetable that is not present in the product results in a label that is false and misleading and therefore in violation of section 403(a) of the act.

53. Some comments that wanted all fruits and vegetables pictured in the vignette also requested that the fruits and vegetables be depicted in proportion to the amount of each juice present. However, most comments requested that the agency not impose a specific requirement regarding the relative amounts of the various fruits or vegetables because the relative size and shape of various fruits and vegetables make it difficult to portray by vignette. They stated that both the relative size and the quantity of those fruits and vegetables are difficult to represent in a manner that would allow the consumer to readily recognize the quantity relationship.

The agency did not propose a specific requirement regarding the relative amounts of the various fruits depicted in a vignette but solicited comments on whether it should require that the vignette accurately reflect the quantity of the fruit present or the taste of the product, or whether some other requirement is appropriate. While information in comments emphasized the difficulties in displaying fruits and vegetables quantitatively, there was no information on how useful quantitative displays could be devised. The agency, therefore, is not requiring that fruits and vegetables pictured in vignettes be depicted in proportion to the amount of each juice present.

54. Several comments requested that the agency not make specific requirements regarding flavor characterizations in vignettes. They stated that the taste of a product is best communicated to the consumer through means other than the label vignette alone, and that any requirement should rely on wording to describe product flavor, e.g., "raspberry (flavor) in a blend of ———— other juices."

The agency agrees with the comments that vignettes alone should not be required to communicate the flavor characteristics of the beverage and is not establishing such requirements. It also agrees that more explicit information is provided by the wording on the label, especially in the statement of identity of the product. However, FDA advises that in order for a beverage label to not be misleading, it is necessary that the vignette and other label statements on the beverage not conflict in any way. The agency has discussed above the circumstances under which the name of the beverage may be misleading. It will determine on a case-by-case basis whether a vignette is misleading because it is not consistent with other label information or for other reasons.

D. Modified Juices

In the July 2, 1991, proposal, the agency stated that the consumer must not be misled as to the nature of the juices used to make a juice or diluted juice beverage (56 FR 30452 at 30461). FDA stated that the appropriate common or usual name for a modified juice or a beverage containing a modified juice should be determined by the nature and extent of modification. For example, the appropriate common or usual name for frozen orange juice concentrate in which the acid content is reduced is "reduced acid frozen concentrated orange juice" (21 CFR 146.148).

However, FDA also acknowledged that beverages may contain modified juices that are markedly altered and added to beverages to increase the declared juice content but are actually "stripped" juices, i.e., juice derived, rather than sugar derived, sweetening ingredients, e.g., deflavored, decolored white grape juice.

The agency proposed in § 102.33(d) (redesignated as new § 102.33(e)) to permit a juice that has been modified to be referred to by a common or usual name that includes the word "juice" so long as the exact nature of the modification is specified in the common or usual name. The description of the modification would therefore appear as part of the name wherever it is used.

Further, the agency proposed that a product would be misbranded if a label vignette depicts the source fruit or vegetable of a juice whose color, taste, or other organoleptic properties have been modified to the extent that the original juice is no longer recognizable, or if its nutrient profile has been diminished.

55. One comment suggested three classifications for juice as the basis for developing labeling policy for modified juices:

First, minor modifications that do not alter the basic characteristics of the juice outside the normal range for that juice.

Secondly, more significant modifications that alter one or more basic characteristic of the juice but not to the extent that the juice would not still be acceptable if offered as a single juice product. The comment stated that such products would require a descriptive term as part of the product name to indicate the nature of the change but could still be identified as "juice."

Thirdly, products that have undergone major modifications that remove virtually all significant nutrients, resulting essentially in a sugar water product. The comment stated that while such products are acceptable as sweeteners, they should not be identified as juice or counted toward the juice content declaration.

The agency agrees that modified juices could be considered in three categories. It used a similar approach in the July 2, 1991, proposal (56 FR 30452 at 30460). The comment's first category is essentially the group of products that have undergone modifications so minor as to be within the normal range of properties of the original juice. These products do not require a modification of the name "———— juice," where the blank is filled with the name of the source fruit or vegetable.

The second category is illustrated in the July 2, 1991, proposal using "reduced acid frozen concentrated orange juice" and "acid-reduced pineapple juice" (56 FR 30452 at 30461). These products would require a name that describes the modification (§ 102.33(e)) but would not be prohibited under new § 101.30(k) from being included in the calculation of total juice percentage.

The third category described in the comment is clearly within the description in proposed § 102.33(e) (redesignated as new § 102.33(f)) and requires a name that fully describes the major modification. In suggesting that these products not be identified as "juice," the comment would prohibit the use of the word "juice" in the name of these modified juices. As discussed in the July 2, 1991, proposal and in response to comment 56 of this document, which follows, FDA disagrees and concludes that a name that fully describes the modifications made in the juice may include the word "juice" and its source.

56. A number of comments disagreed with the proposed provisions for naming juices that had undergone major modifications. They referred to these products as "stripped juices" and

"sugar water." They stated that the term "juice" should not be included in the name of such modified products. Some comments suggested alternative names such as "grape syrup," "apple syrup," or a similar term.

The agency proposed in § 102.33(d) (redesignated as new § 102.33(e)) that the common or usual name of a juice that has been modified shall include a description of the exact nature of the modification (e.g., "deflavored, decolored grape juice"). The agency believes that there is enough information in the description of the modification that consumers will be able to recognize the ingredient as different from the original juice.

Further, since juices with major modifications may not be included in the total percentage juice declaration, and the source fruit or vegetable from which the modified juice was derived may not be depicted on the label or other pictorial representation, consumers should not be misled by inclusion of the word "juice" in the name of juices in the ingredient list. Therefore, the agency is not granting the comments' request.

In addition, the suggestions for alternative names covered only some of the products in the category of juices that have undergone significant modifications. For example, other comments (comments 20 and 41 of this document) addressed juices from which the sugars had been removed. As discussed in response to those comments "reduced sugar ——— juice" may be an appropriately descriptive term for such a product with the name of the alternative sweetening ingredient appropriately declared.

Comments that addressed the issue supported the provision in proposed § 102.33(e) (redesignated as new § 102.33(f)) that the fruit or vegetable source of a modified juice may not be depicted on the label by vignette or other pictorial representation.

Accordingly, FDA concludes that except for conforming the wording of § 102.33(f) to reflect the decision made with respect to modified juices in comment 39 of this document, the provision should be retained. The agency wishes to clarify that the provision addresses juice products that have undergone major modification and as a result are no longer recognizable at the time processing is complete, or whose nutrient profile has been diminished to a level below the normal nutrient range for the juice. The prohibition against depicting the fruit or vegetable on the label does not apply to juices that have been slightly modified but that still retain the basic properties of the original juice, e.g., acid-reduced grape juice.

IV. Other Issues

57. One comment stated that where a beverage is prepared from one or more juice concentrates this fact should be declared as part of the common or usual name.

The agency agrees. FDA's longstanding policy with regard to juice beverages made from concentrate is that a term such as "from concentrate" or "reconstituted" must be a part of the name of the juice, in letters not less than one-half the height of the letters in the name of the juice, e.g., lemon juice (§ 146.114) and orange juice from concentrate (§ 146.145). Accordingly, FDA has added as § 102.33(g) a requirement that when one or more of the juices in a juice beverage is made from concentrate, the name of the juice must include a term indicating that fact, such as "from concentrate," or "reconstituted." Such term may either be included in the name of each individual juice where appropriate, or it may be stated once adjacent to the product name so that it applies to all the juices (e.g., "cherry juice (from concentrate) in a blend of 2 other juices" or "cherry juice in a blend of 2 other juices (from concentrate)"). The term shall be in type size no less than one-half the height of the letters in the name of the fruit or vegetable juice. This type size requirement is consistent with similar provisions in existing regulations (e.g., §§ 146.114 and 146.145).

58. One comment pointed out that under § 101.22(i)(1)(iii) the presence of added natural flavors is not required to be declared in the name of the beverage unless the declared juices alone do not characterize the product before the addition of the added flavors. It requested that § 102.33(b) be amended to clarify this.

The agency agrees that the requested clarification may be helpful to readers of the regulation and is revising § 102.33(b) accordingly. Because the provision is already a part of FDA's food labeling regulations, this amendment is not substantive. It simply conforms § 102.33(b) to § 101.22(i)(1)(iii).

59. Comments supported the proposal to revoke the common or usual name regulations for noncarbonated beverage products that contain no fruit or vegetable juice (§ 102.30) and for diluted orange juice beverages (§ 102.32). They agreed with FDA's position that because these products would be covered under new § 101.30 and the revised § 102.33, the separate regulations are no longer needed. Accordingly, as proposed, FDA is revoking these two regulations.

V. Effective Date

FDA proposed to make the percent juice labeling regulations effective on the same date as the mandatory nutrition labeling final rule (i.e., May 8, 1993). However, the agency pointed out that the 1990 amendments state in section 10(c) of the 1990 amendments that percent juice labeling was to take effect 1 year after enactment. Thus, on November 8, 1991, the statutory provision for percent juice declaration was to go into effect.

In response to the July 2, 1991, proposal many comments from the food industry strongly urged FDA to reconsider the effective date for percent juice labeling regulations. The comments argued that a November 8, 1991, effective date would not allow the food industry enough time to develop the required labeling and would significantly increase costs because present inventory would have to be discarded. The comments strongly urged FDA to establish a uniform effective date for the requirement for percent juice declaration with section 403(q) of the act (mandatory nutrition labeling) and section 403(r) of the act (health and nutrient content claims), which were added to the act by the 1990 amendments. Although FDA agreed with these comments, it had no authority to provide the requested exemptions or extend the effective date.

A technical amendment (Pub. L. 102–108) was enacted on August 17, 1991, in which Congress amended the 1990 amendments to delay the effective date of the percent juice labeling requirements. Notice of this change in the effective date was given in the **Federal Register** of November 27, 1991 (56 FR 60877). Under this amendment the new percent juice labeling requirements for fruit and vegetable juice beverages apply to labels attached to these products after May 8, 1993.

60. Many comments responding to this proposal objected to the proposed effective date of November 8, 1991, for compliance with the requirements of the percentage juice declaration provisions because of the cost and time involved in making the necessary labeling changes. The agency also received a comment requesting a temporary exemption from the May 8, 1993, statutory effective date established by the technical amendment. The comment requested that the requirement for percentage juice declaration on the labels of beverages purporting to contain juice be implemented concurrently with any later applicability date that the agency

may prescribe for the nutrition labeling regulations pursuant to section 10(a)(3)(B) of the 1990 amendments. The comment suggested that the effective date for the percent juice declaration be delayed until May 8, 1994, on the basis of the proviso in section 403(i) of the act which states that: "* * * to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary." The comment cited case law and previous FDA policy as precedent for the requested temporary exemption.

The agency is not persuaded by the arguments and assertions presented in the request for a temporary exemption from the statutory compliance date of May 8, 1993, for the requirement of percentage juice declaration. The agency acknowledges that section 403(i) of the act provides authority for exemption, and some such exemptions have been temporary. However, in light of the specific date (May 8, 1993) established by the technical amendment, and the failure of Congress to include provisions for a delay of the application of this provision, in contrast to the provision that it made for such a delay for the nutrition labeling and nutrient content claims provisions in the 1990 amendments, and without any indication in the legislative history that Congress wished to delay any longer the implementation of percentage juice declaration on beverages purporting to contain juice, the agency finds that a temporary exemption based on section 403(i) of the act is not sustainable. Therefore, the agency is not granting a temporary exemption from compliance with the percent juice declaration requirements or extending the effective date until May 8, 1994. However, because the amendments to part 102 are not directly responsive to section 7 of the 1990 amendments, and in order to minimize costs, FDA is making the amendments to part 102 effective on May 8, 1994.

VI. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857 and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

VII. Environmental Impact

The agency previously considered the environmental effects of the action being taken in this final rule. As announced in July 2, 1991, proposal, the agency determined that under 21 CFR 25.24(a)(11), that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required. No new information or comments have been received that would effect the agency's previous determination.

VIII. References

The following references have has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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4. Snyder, Carl S., and Lester D. Hammond, "Weights per U.S. Gallons and Weights per Cubic Foot of Sugar Solution," National Bureau of Standards, Circular 457, Table 1, pp. 3–26, 1946.

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7. Wallrauch, S. and W. Faethe, "Germany: RSK Values—Guidelines and Tolerances for Specified Constituents in Fruit Juices," in "Adulteration of Fruit Juice Beverages," ed., S. Nagy, J. A. Attaway, M. E. Rhodes, Marcel Dekker, Inc., New York, pp. 424–429, 446–452, 1988.

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13. Sale, J. W., "Interpretation of Chemical Analyses of Preserves and Jams," *Journal of the Association of Official Analytical Chemists*, vol. 21, No. 8, pp. 502–515, 1938.

14. Frederick E. Boland, Victor H. Blomquist, and Ben Estrin, "Chemical Composition of Fruits," *Journal of the Association of Official Analytical Chemists*, vol. 51, No. 6, pp. 1203–1205, 1968.

15. Monzini, A. and E. Maltini, "Production of Juice Powders without Additives by Vacuum Belt Drying," Flussiges Obst, vol. 57, No. 2, pp. 89–90, 1990.

16. Food and Drug Administration, State Cooperation Information Letter No. 48, June 26, 1950. Stutsman, Martin J., letter to City of Los Angeles Department of Aging, April 18, 1989. Scheineson, Marc J., letter to Bob Graham, United States Senator, May 14, 1992.

List of Subjects

21 CFR Part 101

Food Labeling, Reporting and recordkeeping requirements.

21 CFR Part 102

Beverages, Food grades and standards, Food labeling, Frozen foods, Fruit juices, Oils and fats, Onions, Potatoes, Seafood.

Therefore under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 101 and 102 are amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.30 is added to subpart B to read as follows:

§ 101.30 Percentage juice declaration for foods purporting to be beverages that contain fruit or vegetable juice.

(a) This section applies to any food that purports to be a beverage that contains any fruit or vegetable juice (i.e., the product's advertising, label, or labeling bears the name of, or variation on the name of, or makes any other direct or indirect representation with respect to, any fruit or vegetable juice), or the label or labeling bears any vignette (i.e., depiction of a fruit or vegetable) or other pictorial representation of any fruit or vegetable, or the product contains color and flavor that gives the beverage the appearance and taste of containing a fruit or vegetable juice. The beverage may be carbonated or noncarbonated, concentrated, full-strength, diluted, or contain no juice. For example, a soft drink (soda) that does not represent or suggest by its physical characteristics, name, labeling, ingredient statement, or advertising that it contains fruit or vegetable juice does not purport to contain juice and therefore does not require a percent juice declaration.

(b)(1) If the beverage contains fruit or vegetable juice, the percentage shall be declared by the words "Contains ———— percent (or %) ———— juice" or " ———— percent (or %) juice," or a similar phrase, with the first blank filled in with the percentage expressed as a whole number not greater than the actual percentage of the juice and the second blank (if used) filled in with the name of the particular fruit or vegetable (e.g., "Contains 50 percent apple juice" or "50 percent juice").

(2) If the beverage contains less than 1 percent juice, the total percentage juice shall be declared as "less than 1 percent juice" or "less than 1 percent ———— juice" with the blank filled in with the name of the particular fruit or vegetable.

(3) If the beverage contains 100 percent juice and also contains non-juice ingredients that do not result in a diminution of the juice soluble solids or, in the case of expressed juice, in a change in the volume, when the 100 percent juice declaration appears on a panel of the label that does not also bear the ingredient statement, it must be accompanied by the phrase "with added ————," the blank filled in with a term such as "ingredient(s)," "preservative," or "sweetener," as appropriate (e.g., "100% juice with added sweetener"), except that when the presence of the non-juice ingredient(s) is declared as a part of the statement of identity of the product, this phrase need not accompany the 100 percent juice declaration.

(c) If a beverage contains minor amounts of juice for flavoring and is labeled with a flavor description using terms such as "flavor", "flavored", or "flavoring" with a fruit or vegetable name and does not bear:

(1) The term "juice" on the label other than in the ingredient statement; or

(2) An explicit vignette depicting the fruit or vegetable from which the flavor derives, such as juice exuding from a fruit or vegetable; or

(3) Specific physical resemblance to a juice or distinctive juice characteristic such as pulp then total percentage juice declaration is not required.

(d) If the beverage does not meet the criteria for exemption from total juice percentage declaration as described in paragraph (c) of this section and contains no fruit or vegetable juice, but the labeling or color and flavor of the beverage represents, suggests, or implies that fruit or vegetable juice may be present (e.g., the product advertising or labeling bears the name, a variation of the name, or a pictorial representation of any fruit or vegetable, or the product contains color and flavor that give the beverage the appearance and taste of containing a fruit or vegetable juice), then the label shall declare "contains zero (0) percent (or %) juice". Alternatively, the label may declare "Containing (or contains) no ———— juice", or "no ———— juice", or "does not contain ———— juice", the blank to be filled in with the name of the fruits or vegetables represented, suggested, or implied, but if there is a general suggestion that the product contains fruit or vegetable juice, such as the presence of fruit pulp, the blank shall be filled in with the word "fruit" or "vegetable" as applicable (e.g., "contains no fruit juice", or "does not contain fruit juice").

(e) If the beverage is sold in a package with an information panel as defined in § 101.2, the declaration of amount of juice shall be prominently placed on the information panel in lines generally parallel to other required information, appearing:

(1) Near the top of the information panel, with no other printed label information appearing above the statement except the brand name, product name, logo, or universal product code; and

(2) In easily legible boldface print or type in distinct contrast to other printed or graphic matter, in a height not less than the largest type found on the information panel except that used for the brand name, product name, logo, or universal product code.

(f) The percentage juice declaration may also be placed on the principal display panel, provided that the declaration is consistent with that presented on the information panel.

(g) If the beverage is sold in a package that does not bear an information panel as defined in § 101.2, the percentage juice declaration shall be placed on the principal display panel, in type size not less than that required for the declaration of net quantity of contents statement in § 101.105(i), and be placed near the name of the food.

(h)(1) In enforcing these regulations, the Food and Drug Administration will calculate the labeled percentage of juice from concentrate found in a juice or juice beverage using the minimum Brix levels listed below where single-strength (100 percent) juice has at least the specified minimum Brix listed below:

Juice	100 percent juice[1]
Acerola	6.0
Apple	11.5
Apricot	11.7
Banana	22.0
Blackberry	10.0
Blueberry	10.0
Boysenberry	10.0
Cantaloupe Melon	9.6
Carambola	7.8
Carrot	8.0
Casaba Melon	7.5
Cashew (Caju)	12.0
Celery	3.1
Cherry, dark, sweet	20.0
Cherry, red, sour	14.0
Crabapple	15.4
Cranberry	7.5
Currant (Black)	11.0
Currant (Red)	10.5
Date	18.5
Dewberry	10.0
Elderberry	11.0
Fig	18.2
Gooseberry	8.3

Juice	100 percent juice[1]
Grape	16.0
Grapefruit	10.0
Guanabana (soursop)	16.0
Guava	7.7
Honeydew melon	9.6
Kiwi	15.4
Lemon	[2]4.5
Lime	[2]4.5
Loganberry	10.5
Mango	13.0
Nectarine	11.8
Orange	11.8
Papaya	11.5
Passion Fruit	14.0
Peach	10.5
Pear	12.0
Pineapple	12.8
Plum	14.3
Pomegranate	16.0
Prune	18.5
Quince	13.3
Raspberry (Black)	11.1
Raspberry (Red)	9.2
Rhubarb	5.7
Strawberry	8.0
Tangerine	11.8
Tomato	5.0
Watermelon	7.8
Youngberry	10.0

[1] Indicates Brix value unless other value specified.
[2] Indicates anhydrous citrus acid percent by weight.

(2) If there is no Brix level specified in paragraph (h)(1) of this section, the labeled percentage of that juice from concentrate in a juice or juice beverage will be calculated on the basis of the soluble solids content of the single-strength (unconcentrated) juice used to produce such concentrated juice.

(i) Juices directly expressed from a fruit or vegetable (i.e., not concentrated and reconstituted) shall be considered to be 100 percent juice and shall be declared as "100 percent juice."

(j) Calculations of the percentage of juice in a juice blend or a diluted juice product made directly from expressed juice (i.e., not from concentrate) shall be based on the percentage of the expressed juice in the product computed on a volume/volume basis.

(k) If the product is a beverage that contains a juice whose color, taste, or other organoleptic properties have been modified to the extent that the original juice is no longer recognizable at the time processing is complete, or if its nutrient profile has been diminished to a level below the normal nutrient range for the juice, then that juice to which such a major modification has been made shall not be included in the total percentage juice declaration.

(l) A beverage required to bear a percentage juice declaration on its label shall not bear any other percentage declaration that describes the juice content of the beverage in its label or in its labeling (e.g., "100 percent natural" or "100 percent pure[1]"). However, the label or labeling may bear percentage statements clearly unrelated to juice content (e.g., "provides 100 percent of U.S. RDA of vitamin C").

PART 102—COMMON OR USUAL NAME FOR NONSTANDARDIZED FOODS

3. The authority citation for 21 CFR part 102 continues to read as follows:

Authority: Secs. 201, 403, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 343, 371).

§ 102.30 [Removed]

4. Section 102.30 Noncarbonated beverage products containing no fruit or vegetable juice is removed from subpart B.

§ 102.32 [Removed]

5. Section 102.32 Diluted orange juice beverages is removed from subpart B.

6. Section 102.33 is revised to read as follows:

§ 102.33 Beverages that contain fruit or vegetable juice.

(a) For a carbonated or noncarbonated beverage that contains less than 100 percent and more than 0 percent fruit or vegetable juice, the common or usual name shall be a descriptive name that meets the requirements of § 102.5(a) and, if the common or usual name uses the word "juice," shall include a qualifying term such as "beverage," "cocktail," or "drink" appropriate to advise the consumer that the product is less than 100 percent juice (e.g., "diluted grape juice beverage" or "grape juice drink").

(b) If the product is a diluted multiple-juice beverage or blend of single-strength juices and names, other than in the ingredient statement, more than one juice, then the names of those juices, except in the ingredient statement, must be in descending order of predominance by volume unless the name specifically shows that the juice with the represented flavor is used as a flavor (e.g., raspberry-flavored apple and pear juice drink). In accordance with § 101.22(i)(1)(iii) of this chapter, the presence of added natural flavors is not required to be declared in the name of the beverage unless the declared juices alone do not characterize the product before the addition of the added flavors.

(c) If a multiple-juice beverage or blend of single-strength juices contains a juice that is named or implied on the label or labeling other than in the ingredient statement (represented juice), and also contains a juice other than the named or implied juice (nonrepresented juice), then the common or usual name for the product shall indicate that the represented juice is not the only juice present (e.g., "Apple blend; apple juice in a blend of two other fruit.")

(d) In a multiple-juice beverage or blend of single-strength juices where one or more, but not all, of the juices are named on the label other than in the ingredient statement, and where the named juice is not the predominant juice, the common or usual name for the product shall:

(1) Indicate that the named juice is present as a flavor or flavoring (e.g., "Raspcranberry"; raspberry and cranberry flavored juice drink); or

(2) Include the amount of the named juice, declared in a 5- percent range (e.g., Raspcranberry; raspberry and cranberry juice beverage, 10- to 15-percent cranberry juice and 3- to 8-percent raspberry juice). The 5-percent range, when used, shall be declared in the manner set forth in § 102.5(b)(2).

(e) The common or usual name of a juice that has been modified shall include a description of the exact nature of the modification (e.g., "acid-reduced cranberry juice," "deflavored, decolored grape juice").

(f) If the product is a beverage that contains a juice whose color, taste, or other organoleptic properties have been modified to the extent that the original juice is no longer recognizable at the time processing is complete, or if its nutrient profile has been diminished to a level below the normal nutrient range for the juice, then the source fruits or vegetables from which the modified juice was derived may not be depicted on the label by vignette or other pictorial representation.

(g) If one or more juices in a juice beverage is made from concentrate, the name of the juice must include a term indicating that fact, such as "from concentrate," or "reconstituted." Such terms must be included in the name of each individual juice or it may be stated once adjacent to the product name so that it applies to all the juices, (e.g., "cherry juice (from concentrate) in a blend of two other juices" or "cherry juice in a blend of 2 other juices (from concentrate)"). The term shall be in a type size no less than one-half the height of the letters in the name of the juice.

Dated: October 27, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 5, 20, 100, 101, 105, and 130

[Docket No. 91N-0219]

RIN 0905-AD08

Regulatory Impact Analysis of the Final Rules to Amend the Food Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Regulatory impact analysis statement.

SUMMARY: The Food and Drug Administration (FDA) is publishing the final regulatory impact analysis (RIA) that it has prepared under Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354). This study presents the costs and benefits of the food labeling regulations that FDA is issuing. FDA is issuing these final rules (published elsewhere in this issue of the **Federal Register**) in response to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) and as part of the Secretary of Health and Human Services' (the Secretary's) food labeling reform initiative. The agency has prepared this comprehensive RIA document for these regulations because, when taken together, they constitute a major rule.

FOR FURTHER INFORMATION CONTACT: Richard A. Williams, Jr., Center for Food Safety and Applied Nutrition (HFF-303), Food and Drug Administration,200 C St. SW., Washington, DC 20204, 202-205-5271.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 27, 1991 (56 FR 60366 et seq), FDA published a number of proposed food labeling regulations to implement the provisions of the 1990 amendments (Pub. L. 101-535). In the same issue of the **Federal Register** (56 FR 60856, November 27, 1991), FDA published an RIA (hereinafter referred to as the 1991 RIA proposal) which preliminarily estimated the costs and benefits of the various proposed regulations and on which FDA asked for comments. Interested persons were given until February 25, 1992, to comment. FDA received approximately 350 letters, each containing one or more comments, from health professionals, trade associations, Federal and State Governments, foreign governments, consumer advocacy organizations, consumers, professional societies, food manufacturers and distributors, and academia. Many of the issues addressed in the 1991 RIA proposal are covered in the separate final rules issued concurrently with this document.

Comments have not altered FDA's preliminary finding that the food labeling reform initiative, taken as a whole, will have associated costs in excess of the $100 million threshold that defines a major rule. Therefore, in accordance with Executive Order 12291, FDA has developed one comprehensive final RIA that presents the costs and benefits of all of the food labeling proposals taken together.

In addition, FDA is publishing elsewhere in this issue of the **Federal Register** a final rule to announce its decision to delay the application of the nutrition labeling and nutrient content claims provisions of the Federal Food, Drug, and Cosmetic Act (the act). In that rule FDA concluded that requiring compliance with section 403(q) or (r)(2) of the act (21 U.S.C. 343(q) or (r)) on May 8, 1993, would cause an "undue economic hardship" on the food industry in that there would be costs to the food industry that are excessive and more than Congress intended. All comments regarding the applicability date are addressed in that document.

FDA also published, as a component of the 1991 RIA proposal, a preliminary regulatory flexibility analysis which addressed the issue of small businesses. The 1990 amendments granted an exemption from mandatory nutrition labeling for small businesses. Under section 403(q)(5)(D) of the act, a small business is defined as a business with less than $500,000 annual gross sales or a business with annual gross sales of more than $500,000 but less than $50,000 in food sales. The exemption does not apply to those products that make nutritional claims or voluntarily provide nutrition information.

Comments concerning this exemption stated that this exemption was too low and are discussed more thoroughly in the mandatory nutrition labeling final rule published elsewhere in this issue of the **Federal Register**. FDA, in response to these comments, participated in a series of public forums that had been scheduled by the U.S. Department of Agriculture (USDA) to discuss the small business issue. In addition, FDA published a notice in the **Federal Register** asking for comments on this issue. As of publication of these rules and the final RIA, the exemption has not been changed. FDA will discuss in more detail the affect of the 1990 amendments on small businesses in a final Regulatory Flexibility Analysis published subsequent to these final rules.

II. Regulatory Options

Under the Regulatory Flexibility Act, FDA is required by law to consider ways to reduce the regulatory burden on small businesses. One conceivable regulatory option would be to allow product lines with fewer than 500,000 unit sales annually produced by small firms (firms with less than 500 employees) to make reasonable estimates of mean nutrient content rather than complying with the 80/100/120 rules.

Under the regulatory option currently selected, class I nutrients (added nutrients) including vitamins, minerals, protein, dietary fiber, and potassium are required to have at least 100 percent of the listed value within specified variances. Class II nutrients (naturally occurring), including vitamins, minerals, proteins, total carbohydrates, dietary fiber, other carbohydrates, polyunsaturated or monounsaturated fat, or potassium must have at least 80 percent of the value for the nutrient declared on the label within specified variances. Finally, a food with a label declaration of calories, sugars, total fat, saturated fat, cholesterol, or sodium is misbranded under section 403(a) of the act if the nutrient content of the composite sample is greater than 20 percent more than the declared amount, again within the variance specified for the appropriate test. In addition, in new § 101.9(g)(6), reasonable excesses over or under the labeled amounts are allowed where current good manufacturing practices (CGMP's) are used. This option would replace these values with a requirement to list the mean value within variances established for specific nutrient tests and allowing reasonable excesses over or under the labeled amounts where CGMP's are used. This option could either exist as a blanket exemption for small firms or one that is made by special request on a per firm basis to the agency.

Thus small firms could determine nutrient levels by analysis, by calculation using nutrient data bases of ingredients and recipes, or by other reasonable means that provide assurance that the value declared is the mean value of a particular nutrient in the food product. This option would reduce the burden on small business by allowing the use of means rather than values determined by analytical testing in the declaration of nutrient content.

Approximately 59 percent of all food products have fewer than 500,000 units sold annually and are produced by

small firms. This option would significantly reduce analytical costs by between $235 and $600 million depending upon the rate of retesting that would otherwise be done. In addition, this option will prevent small business failure which may occur for small firms with very low product volume. This option would result in virtually no loss in benefits because the occasional errors in labeling may offset one another. In addition, although this type of exemption would represent a large number of products, it represents only about 2 percent of the diet. Thus, for example, if these manufacturers were to approximate wrong (or intentionally misrepresent their products) concerning the amount of total fat in their product such that all of the products in this category underreported the amount of fat by 50 percent, and if all consumers were 100 percent mislead by such underreporting, it would only result in a 1 percent error in fat consumption. Given that such errors in reporting are: (1) Likely to balance out; (2) will probably be corrected by enforcement over time; and, (3) that it is unlikely that all consumers would be misled by gross errors, a significant loss of benefits as they have been calculated in this regulatory impact analysis seems unlikely.

An alternate standard for coverage of this option, such as exempting small firms (500 or less employees) with less than 100,000 units could also be chosen. This would exempt 51 percent of the products covered by the 1990 amendments, but it would exempt less than 2 percent of the diet.

Although FDA is allowing the "reasonable basis" standard in food service establishments making nutrient content claims and health claims, FDA believes that there is a significant difference between the criteria used to determine whether or not a claim is justified, and the criteria used to determine the quantified level of a nutrient to be reported on a food label. In addition, FDA believes that the option that it has chosen is also consistent with the other relevant sections of the act including sections 402(b) and 403(a) (21 U.S.C. 342(b) and 343(a)).

III. Costs of the Regulations

A. General

In the 1991 RIA proposal, FDA determined that about 17,000 domestic food manufacturers and 260,000 labels would be affected by the regulations promulgated in response to the 1990 amendments. Of these, approximately 160 dietary supplement manufacturers would alter approximately 3,400 unique dietary supplement products. In addition, 96,000 food service establishments would also be required to alter their menus if they are not in compliance with nutrient content and health claims regulations.

Categories of costs include administrative, analytical, printing, inventory disposal, and reformulation. In all cost categories, except administrative costs, the costs of relabeling products produced and labeled in foreign countries cannot be separated from those products produced and labeled domestically. Thus, the administrative costs considered are domestic costs only, whereas the printing, inventory, and analytical costs considered are multinational.

In the 1991 RIA proposal, mandatory ingredient labeling for standardized foods and certified colors were separated from the other actions because it was to take effect in November of 1991. Costs for these provisions, as proposed, were $128 million.

In the **Federal Register** of July 2, 1991 (56 FR 30452), FDA published a proposal on the declaration of percentage juice. FDA determined that the costs which would occur as a result of those proposed requirements would be $40 million, based on an effective date of November 8, 1991. When the 1991 RIA proposal was published, the proposed requirements regarding the declaration of percentage juice were to become effective concurrently with the requirements for mandatory nutrition labeling which would have resulted in lowering the incremental costs to $1 million. However, because those provisions are subject to being enforced 9 months before the agency will enforce the requirements for mandatory nutrition labeling, the costs are appropriately determined to be the original assessment of $40 million. FDA received no comments to the original proposal objecting to its determination of the costs. Therefore, the agency is not amending its original estimate of the costs of declaring percentage juice.

Voluntary nutrition labeling of raw fruit, vegetables, and fish is also separable from all other provisions of the 1990 amendments because it affects supermarkets, not food manufacturers. The agency estimated these costs to be between $117 to $155 million.

The costs to food manufacturers for all other labeling regulations, including percent juice labeling, mandatory nutrition labeling, nutrient content claims definition, health claim labeling, format changes, and others, were estimated in the 1991 RIA proposal to be as high as $1.3 billion, depending on the compliance period chosen.

In addition, FDA estimated that the costs to restaurants and other food service establishments to reprint menus not in conformance with nutrient content or health claim proposed regulations would be $116 million.

FDA estimated that total costs of the proposed rules to implement the 1990 amendments, excluding voluntary supermarket labeling, would be approximately $1.5 billion. The agency also determined that if the agency opted to allow an additional 6 months or an additional year to the compliance period provided for by the statute, total costs would decrease to $.8 billion and $.6 billion, respectively.

In October 1992, Congress passed the Dietary Supplement Act of 1992 (DS Act). This act prevents the agency from implementing the 1990 amendments as they apply to dietary supplements until December 1993. This act requires the agency to issue proposed regulations applicable to dietary supplements by June 15, 1993. Because this document is intended to determine the costs and benefits of all regulations implementing the 1990 amendments, the agency is responding to the comments regarding dietary supplements with tentative conclusions and is presenting preliminary estimates of those costs. The agency will address any alterations to these estimates when it issues regulations on the labeling of dietary supplements.

In response to its assessment of the costs in the 1991 RIA proposal, FDA also received several comments regarding costs from firms whose products are regulated by USDA, not FDA. The agency has forwarded these comments to USDA for consideration in their RIA.

1. One comment stated that FDA's cost analysis could not be correct because it is impossible to accurately estimate costs.

The agency disagrees with the comment. The agency recognizes that costs of regulation are complex and often difficult to measure with 100 percent accuracy. However, after studying the industries affected and considering the comments, FDA is confident that it has determined the costs of the regulations with reasonable accuracy. The agency will not amend its cost estimates based on this comment.

2. One comment stated that because it would take up to 30 years to see the benefits of the regulations, FDA should calculate the costs of nutrition labeling for 30 years. The comment criticized FDA for limiting the costs to a 5-year period.

FDA disagrees with this comment. FDA has determined that the benefits will occur sooner than 30 years. For calculation purposes, FDA assumed that the lag time for cancer is 10 years. Beyond 20 years, the discount rate drives the benefits too low to be significant. FDA, therefore, calculated benefits over 20 years for ease of computation. For the sake of consistency, FDA also calculated the costs over 20 years. FDA did not limit its determination of costs to 5 years as the comment mistakenly understood. FDA is calculating the final costs and benefits similarly.

B. Administrative Costs

In the 1991 RIA proposal, FDA determined that administrative costs would be approximately $177 million, of which $16 million are attributable to mandatory ingredient labeling of standardized foods and certified colors. FDA received one comment from an industry association that stated that FDA provided a fairly reasonable assessment of the administrative portion of total cost. This judgment was based on the association's evaluation of such costs for the firms it represents. However, FDA received several other comments criticizing its estimates.

3. Two comments stated that administrative costs are more closely related to the number of products or labels than to the number of firms. One firm stated that administrative costs will be high because of the number of units involved and the fact that the product is packaged at many different locations by third-party vendors. This situation, the comment stated, will necessitate additional administrative costs in the nature of man-hours for coordination.

FDA acknowledges that the comment may be correct but has no additional information to support this claim. In its original analysis, FDA assumed that administrative costs differed based on firm size. In part, this assumption is based not only on the bureaucratic difficulties inherent in larger companies, but also on the assumption that larger firms produce a greater number of products. The comment did not state nor supply data as to whether changing this assumption would increase or decrease administrative costs. Thus, FDA is not amending its final administrative cost estimates based on this comment.

4. Several comments stated the cost of increased errors should be included in administrative costs, especially for smaller firms. The comment stated that error rates will increase because of: (1) The unreasonably short timeframes in which all label changes will be made, (2) inexperienced short-term personnel hired to relieve the enormous strains on capacity, and (3) the novelty and magnitude of the changes themselves.

FDA agrees that firms may experience increased error rates which may increase administrative costs. FDA also agrees that these costs will be significantly reduced by allowing firms additional time to comply with labeling regulations. However, FDA is not amending its final cost estimates to account for increased errors because the final rule allows additional time, and the comments did not provide information regarding either the rate at which errors would be increased or the cost of such errors. Also, FDA believes that the cost of increased errors would not significantly increase total costs. Finally, by delaying the date that it will apply section 403(q) and (r)(2) of the act, the agency is relieving the time pressures that the comments said would contribute to the error rates.

5. Several comments provided estimates of administrative costs. FDA received only one estimate for small firms, $3,000 per firm. Estimates for medium to large firms range from approximately $6,500 to over $1 million per firm. One manufacturer of both FDA and USDA regulated products stated that additional man-hours and a part-time consultant would be required to implement the proposed label requirements at a total cost of $53,300. Some comments provided separate estimates for internal administrative costs and external administrative costs. Internal administrative costs include travel expenses, overtime expenses, and payroll expenses and benefit costs for added employees. External administrative costs include such items as legal fees, temporary help, and consultants.

FDA recognizes that the factors that determine administrative costs are very complicated. In the 1991 RIA proposal, FDA estimated that administrative costs for intricate regulations would be $9,000 for small/medium firms and $68,450 for large firms, assuming a compliance date of May 8, 1993. Administrative costs would be less with longer compliance periods. Final administrative estimates are based on a compliance period ending in May 1994. Administrative costs would be $3,375 for small/medium firms and $25,700 for large firms. The range of administrative cost estimates submitted in the comments was extremely broad. Also, there were no identifiable patterns to the estimates given. Therefore, FDA is not altering its original estimates. In the future, FDA would be interested in obtaining more detailed data concerning the nature and level of the marginal administrative costs of regulation.

6. One comment stated that the cost of reading, analyzing, and commenting on the proposals should be addressed. The comment stated that thousands of people are spending many hours reading, analyzing, discussing, and explaining FDA proposals and writing, typing, copying, collating, and sending comments.

FDA recognizes that many resources are spent in the process of reviewing and responding to proposals. Whether these costs should be attributed to the regulation or considered normal costs of doing business in a regulated industry is debatable. Nevertheless, FDA has no information to determine the amount and value of resources spent in reviewing regulations and is, therefore, not amending its estimates based on this comment.

7. One comment argued that FDA should consider the cost that the implementing regulations would have on the Government, e.g., extra FDA personnel, laboratory supplies, and tax increases to the American consumer.

FDA agrees with this comment. FDA estimates that approximately 85 Full-Time Equivalents (FTE's) have been utilized in the 2 years of development of the implementing regulations. In addition, FDA estimates that 135 FTE's will be used each year during the next 20 years in recurring activities related to the implementing regulations, e.g., enforcement and petition review. Each FTE is currently valued at $75,000. Therefore, FDA's labor costs are about $6.4 million for start-up and $127 million in recurring costs (discounted at 5 percent). In addition, FDA estimates that other costs to the Government to implement the 1990 amendments are approximately $4.4 million in start-up costs and an additional $2 million per year over the next 20 years, or $25 million (discounted at 5 percent). Therefore, total estimated costs to the Federal Government are $163 million. FDA notes, however, that these costs do not constitute increased cost to either consumers or industry in that they do not represent an increase in funding to the Federal Government. The development and enforcement of these regulations is funded primarily by replacing other Government programs.

8. One dietary supplement manufacturer stated that FDA should take into account the total cost of administrative time rather than incremental costs associated with the regulatory action being taken.

FDA disagrees with this comment. Executive Order 12291 requires that FDA calculate the cost of this regulatory

action. Therefore, only incremental costs—those costs associated with the additional administrative effort required to comply with the implementing regulations—are relevant. Accordingly, FDA rejects the comment on this point.

9. One dietary supplement manufacturer stated that FDA's estimate of administrative costs for supplement manufacturers was incorrect. The comment suggested that if one mid-level executive spends 1 week trying to read and understand these regulations, the cost would be in excess of the $850 per firm estimated by FDA.

FDA neither agrees nor disagrees with this comment. Although the assumptions FDA made regarding administrative costs for dietary supplements may have resulted in underestimates, comments did not provide FDA with information with which reasonable estimates could be made. FDA will continue to study the supplement industry and will alter its estimates, if necessary, when the regulations regarding dietary supplements are issued. FDA is not currently altering its original estimate based on this comment.

C. Analytical Costs

In the 1991 RIA proposal, FDA estimated analytical costs to be $195 million, of which $112 million are initial one-time costs. Although one firm stated that its cost estimates verify the numbers reported by FDA in its 1991 RIA proposal, several other comments argued FDA's estimates were too low.

10. Several comments questioned FDA's assumption that some products are already tested. These comments stated that the agency's assumption that 20 percent of products are already performing all newly required tests and would require no additional testing is arbitrary and not based on survey or other data. These firms argued that no products are currently undergoing all testing that would be necessary for compliance because the definitions for some nutrients or food components will significantly change.

FDA is persuaded by this argument. In its final estimate, the agency is assuming that all products will undergo at least some analytical testing and is adjusting the costs for analytical tests accordingly. FDA is assuming that the 40 percent of foods that currently provide nutrition information will require testing for only the newly required nutrients. The remaining 60 percent of foods are not currently undergoing testing for any nutrients. Therefore, the incremental costs for this 60 percent of foods will be the cost of performing all required tests. This change in assumptions also affects administrative costs because the regulation will be complex (requiring testing) for all firms, rather than for 80 percent of firms as originally assumed.

11. One comment requested that FDA make its laboratories available for testing at a small or no fee in order that firms may offset at least some of the cost of the regulations.

FDA does not have the resources to make its laboratories available to do testing, nor can FDA charge a fee to do testing. Therefore, FDA rejects this request. Although the choice may affect the company's expenses, whether testing is performed in-house, by independent laboratories, or by FDA laboratories, the societal costs of the regulation are the same.

12. Many comments stated that testing costs per product may increase because of the increased demand on laboratories. One firm estimated that analytical work on a priority basis will add about $2,000 per product. Similarly, many comments suggested that an increase in demand for printing services would create additional costs.

FDA agrees that the price of testing may increase in the short run because of increased demand. However, because firms will have 15 months to comply, not six months as assumed by the comments, any increase in costs will not be significant. FDA is not considering these costs in its final estimate.

13. One comment argued that FDA's estimate of the cost of analytical testing is wrong because it is based on the number of products, rather than the number of labels. The comment stated that it is not clear that a correlation exists between the number of labels needed to test and the number of products. For example, the comment stated that "manufacturing for private labels may require more testing of essentially the same product due to ingredient demands for retailers."

FDA believes that the comment did not understand FDA's definition of products and labels. FDA defined a product as an individual formulation regardless of size of container. Any change in ingredients constitutes a separate product formulation. When a private label manufacturer changes a product's ingredients in order to meet different demands of retailers, a different product is created, and additional testing is required. However, if the manufacturer merely changes the packaging for different retailers but does not change the product formulation, there is no new product, only a new label. FDA concludes after consideration of the contractor's (Research Triangle Institute (RTI)) report and comments to the 1991 RIA proposal, that for each distinct product formulation a separate analytical test must be performed. Tests for each individual label are unnecessary. Therefore, FDA is not modifying its estimate of analytical testing in response to this comment.

14. Many comments suggested that analytical costs as originally calculated are too low because the number of products on which they were based is too low.

FDA agrees that the estimate of the number of products contained in the 1991 RIA proposal was too low. FDA also agrees with comments that some firms use different formulations of the same product for different geographical areas because of varying ingredient demands. FDA's count of products and labels is based on Universal Product Code (UPC) codes that may not pick up these variations. Also, certain specialty items that are not sold through distribution channels using UPC codes would not be counted. Comments did not provide adequate information from which FDA can amend its original assessment of the number of products based on these considerations. However, FDA reviewed its source of the number of products (A. C. Nielsen) and found that its estimate was incorrect.

FDA originally used data collected in 1987 that was derived from grocery store warehouses. Because many products are not distributed through warehouses, FDA undercounted the number of products. A. C. Nielsen has since revised its method of data collection to account for this problem. Therefore, FDA now estimates that there are 196,000 products. The estimate of the number of labels, which was based on an up-to-date count of UPC codes, remains unchanged at 257,000. However, FDA recognizes that these estimates are still understated because Nielsen surveys 3,000 grocery stores and does not extrapolate to the remaining stores. FDA does not have any information with which such an extrapolation could be made. FDA also recognizes that these are still underestimates because: (1) Some firms use different formulations of the same product for different geographical areas due to varying ingredient demands; (2) FDA's count of products and labels is based on UPC codes which may not pick up these variations; and (3) certain specialty items which are not sold through distribution channels using UPC codes would not be counted. However, FDA does not have any better data, nor did the comments provide

better data. Therefore, the final estimates are based on these figures.

15. One comment argued that FDA's calculation of testing costs for those 32 percent of firms already performing the currently required tests was wrong. This comment argued that subtracting the $135 for tests not required was wrong because this is a sunk cost that was already being imposed by FDA. The comment did not object to the subtraction of $135 from the $354 cost required for analysis under the current regulations because this portion of the $354 will not be incurred by first-time testers.

FDA disagrees with the first point. FDA is not reimposing the costs for tests no longer required. The marginal cost is the cost of required tests ($376) less the cost of tests previously required by regulations but not required by these final rules ($135). FDA agrees with the second point made by the comment. The costs per test is not changed.

16. One comment argued that FDA's analytical cost estimates should have included employee time to prepare samples for testing, review laboratory reports, interpret the results, and determine resulting nutrition values that can be placed on labels. The comment stated an appropriate estimate would be 2–1/2 hours per product at an average salary and benefits figure of $85.

FDA agrees that the employee's time for preparing samples should be included as part of the analytical costs. However, the other activities cited by the comment are not analytical costs but administrative costs and are considered in that section of the document. Having concluded that the cost of preparing the sample should be added to its initial analysis, the agency, using the average hourly earnings calculated by the Department of Labor, has determined that an appropriate cost would be 1/2 hour per sample at an average salary and benefits figure of $19 per hour. These costs are included in the agency's final estimate.

17. One comment suggested that analytical costs should include the value of lost products and packages destroyed to run analyses, as well as the cost of freight to ship to the laboratory.

FDA agrees that for those products not undergoing any testing, the cited activities should be included in the analytical costs of complying with these regulations. Although FDA has no specific information on the amount of product and packaging that would be destroyed, or on the cost of that product, FDA can make crude estimates. These estimates suggest that such costs will be small relative to total costs. For example, if the cost of manufactured food products is approximately $2 per unit, and approximately 12 units per product are destroyed to conduct analytical testing, the total cost would be $4.7 million. Because these costs represent less than 1 percent of total costs, FDA is not attempting to accurately determine the cost of lost product and package and is not including these costs in its final estimates.

18. Several comments disagreed with FDA's assumptions regarding the frequency of retesting. One comment stated that partial, if not full, retesting will occur each time a product is reformulated. The comment noted that this occurs more frequently than every 5 years. Another comment stated that retesting would occur quarterly. A third comment was told by a laboratory that FDA would require testing 3 or 4 times a year. This latter comment recommended that FDA recommend laboratory analysis no more than once every 5 years or when the recipe changes.

FDA does not have a set number of times a product must be tested in a year, nor does FDA determine the frequency with which analytical information should be verified. The agency simply requires that the information on the label conforms to the regulations. Therefore, if a product is reformulated, the manufacturer should retest the product. The agency has no information regarding the average frequency of reformulation, nor was such information submitted by the comments. However, FDA is persuaded that many firms may retest their products more frequently than every 5 years. FDA, for its final estimates, calculated analytical costs based on a retesting frequency ranging from annual retesting to once every 5 years.

19. One comment stated that testing would almost always be duplicated and, in many cases, triplicated.

FDA believes that this comment confirms its assumption in the 1991 RIA proposal that initial tests will be performed three times to confirm the results. Thus, no change in the agency's original assumptions are necessary in response to this comment.

20. One comment suggested that analytical testing for new product introductions under the new proposals would be more expensive than otherwise.

FDA disagrees with this comment. Although initial testing costs to firms may go up because of queuing, FDA is not convinced that demand for testing will ultimately exceed the supply of testing services. However, FDA is including the incremental additional cost of testing new products in its final estimates of analytical testing costs which the agency did not do in the 1991 RIA proposal.

21. One comment suggested that the added cost of analysis would burden small companies because their work would be done by already overworked commercial laboratories which charge high fees for services, sometimes in excess of $900 for a full nutritional profile. Another comment agreed, arguing that the cost per product, estimated at $1,482, represents approximately 3 percent of the gross revenue per product for the average small/medium firm.

FDA agrees that because of the smaller volume under which small firms operate, the additional analytical testing could cause a burden on smaller firms. FDA believes that giving firms a longer time to comply with regulations, until May 8, 1994, will alleviate some but not all of this burden by reducing the impact of queuing costs. In addition, FDA believes that allowing firms the option of using nutritional data bases, instead of requiring analytical testing, will reduce the burden on small firms by providing a low-cost alternative to analytical testing.

22. One large firm stated that all costs incurred would be passed along to consumers almost immediately, not over a 20-year period. That comment explained that the cost of analytical work cannot be financed over a 20-year period.

FDA does not agree with this comment. The comment misinterpreted the agency's calculations. FDA did not state in the 1991 RIA proposal that costs would be financed over a 20-year period. FDA analyzed costs that will be incurred immediately. In addition, FDA also determined that firms would retest their products periodically, even without reformulating, to verify the accuracy of the nutrition information reported on the label and calculated the costs of this retesting over the next 20 years.

23. Several comments provided estimates of the costs of analytical testing. Estimates of analytical testing per product ranged from $500 to $2,000.

FDA, in the 1991 RIA proposal, calculated the analytical cost per product to be $723 for those products that have been tested and $1,785 for those products that have not been tested. Because these estimates are within the range reported by comments, FDA is using them in the final RIA.

24. One large firm stated that because testing for protein quality would be changed under FDA's proposed rules, the cost of this test should be included

with testing for cholesterol, fiber, fatty acids, and sugars. The comment also stated that under FDA's definitions, analysis for complex carbohydrate content would also be required.

FDA agrees with this comment that the cost of testing for protein quality would increase under FDA's rules. FDA has determined, based on information from existing independent testing laboratories' price lists, that a change in the definition of protein quality will add approximately $540 per product to the cost of analytical testing. Therefore, total costs would increase by approximately $159 million over the next 20 years assuming products would be retested every 5 years or $440 million assuming annual retesting (discounted at 5 percent). (FDA notes that these are maximum estimates. The agency is providing values in the final rule on mandatory nutrition labeling, published elsewhere in this issue of the **Federal Register**, that should significantly reduce the costs of calculating protein quality for many foods.) FDA is not, however, adding complex carbohydrates to the list of nutrients required to be listed in the nutrition label (see final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**). Therefore, no analysis for this nutrient is necessary.

25. One comment stated that the changeover to new Reference Daily Intake (RDI) values will require that all data bases be completely reprogrammed to reflect the new values, and that therefore the cost of reprogramming all data bases should be included as a cost to the regulations.

FDA agrees with this comment. Because RDI's differ from Recommended Dietary Allowance's and Daily Reference Value's, on which the nutrition label is based, data bases would need some new programming if the agency were to switch to RDI's. The comment did not provide any data regarding the additional costs resulting from such changes. FDA is not aware of the number of such data bases but notes that it would take a large number coupled with significant reprogramming costs to affect this cost estimate. Therefore, FDA believes that such costs will be small relative to the total costs of the regulation. However, because the DS Act prevents FDA from adopting revised RDI's at this time, the costs associated with switching to new RDI values will not occur.

26. One large firm commented that for most nutritionally-modified products, and for the foods for which they substitute, it is necessary to conduct a complete nutritional analysis to determine nutritional equivalence. The comment estimated the cost of testing for complete nutritional equivalence for one product to be $2,300 for the first lot and $1,200 for the remaining two confirmatory lots. Also, the comment stated that the agency's proposals require testing for several micronutrients not previously included in nutritional equivalency testing, such as Vitamin K and molybdenum.

The point of the comment is unclear. If the comment is referring to tests conducted when using nutrient content claims, FDA disagrees that such costs have not been considered. The costs associated with the use of nutrient content claims are the costs of obtaining the information to insure that the claim meets the definitions provided by FDA. All firms will obtain that information when performing analyses for the nutrition panel. Therefore, there are no incremental costs for using nutrient content claims. If, however, the comment is referring to substitute products, that policy is not changing, and the comment has no relevance. Finally, because of the moratorium under the DS Act, FDA has not adopted RDI's for Vitamin K or molybdenum. Therefore, no testing for these nutrients is necessary at this time. For these reasons, FDA will not change its estimates based on this comment.

27. Manufacturers of dietary supplements objected to FDA's assumption that, because of the nature of the product, full analytical testing is already performed on supplements. Comments stated that because full analytical testing is not currently done on dietary supplements, all dietary supplement products will undergo full nutrient content analysis.

FDA is persuaded by the comment. In the 1991 RIA proposal, FDA conceded that this assumption was merely supposition and requested information from industry sources on this point. FDA will develop an appropriate estimate of cost of analytical testing for dietary supplements as part of the rulemaking that the agency will complete in accordance with the DS Act.

28. Several dietary supplement manufacturers also stated that FDA's estimate of analytical costs was understated because the number of products was understated.

The agency's original analysis was based on a count of the number of unique supplement products reported in use during a small survey of consumers. Because of the small number of consumers sampled, FDA agrees that this was not an accurate source to determine the number of dietary supplement products. In comments to the 1991 RIA proposal, one association reported 25,000 products and 75,000 labels in use in the supplement industry. The association was unclear as to how these numbers were calculated, and how "supplement" was defined in order to arrive at these numbers. The agency believes these estimates seem large. However, because no better information currently exists, FDA is using these figures in calculating costs to dietary supplement manufacturers. FDA will further study the supplement industry and make any necessary changes to its estimates when regulations are issued in accordance in the DS Act.

D. Printing Costs

In the 1991 RIA proposal, FDA preliminarily determined that firms would spend approximately $112 million on printing costs to comply with mandatory ingredient labeling of standardized foods and certified colors, and approximately $750 million to comply with all other provisions, except labeling of raw fruit, vegetables, and fish. FDA received several comments criticizing the agency's calculation of printing and redesign costs.

29. One comment was concerned that FDA assumed that changes will occur only to the principle display panel (PDP) and to the information panel.

FDA is aware that mandated changes are so significant that the entire label will be changed. FDA accounted for this fact in the 1991 RIA proposal. In the model supplied by the contractor and used by FDA, label redesign was denoted as a "complex" label change which was used for all labels.

30. Several comments stated that capital costs associated with label printing are underestimated. The comments stated that for many firms, new labeling devices will be needed. One comment, for example, stated that food manufacturers may have to install new packaging or labeling systems if existing labels are not large enough to accommodate the new information. Comments stated labeling equipment would cost approximately $65,000.

FDA agrees that some firms may require new labeling devices but does not have enough information to determine how many new devices will be needed. Whether firms will need to increase package or label size to accommodate the new information will depend largely on the format selected. FDA is allowing a reduced format for small packages and very small packages may be exempt from nutrition information. The decision to purchase new machinery will also depend on how lengthy health claims are. FDA

does not believe that health claims will cause many firms to increase package size because health claims are voluntary. If a firm must increase package size and order new packaging equipment to accommodate a claim, many firms will not make the claim. Although FDA does agree that capital costs may be significant, inadequate information regarding the number of devices needed prevents the agency from quantifying these costs.

31. Several comments stated that FDA should include the cost of the first labels ordered under the new requirements because these initial label orders replace those labels that will not be in compliance.

In determining the impact of regulations, FDA is only concerned with incremental costs only. The cost of initial label orders is incremental only in the sense that labels are ordered to replace existing labels that are no longer in compliance. FDA included these costs in its calculation of the cost of label inventory disposal because disposed label inventory is valued at its replacement cost. To include both initial label orders and inventory disposal costs would be double counting. Therefore, FDA rejects these comments on this point.

32. One comment claimed that, as the compliance date nears, additional costs will be incurred as firms find it necessary to request smaller, less efficient print runs.

FDA agrees with this comment. However, the agency does not have information with which it can estimate these costs nor does it believe they will significantly add to the costs. FDA believes that giving firms a longer time to comply with these regulations will alleviate this burden.

33. Several comments provided estimates of printing costs ranging from $500 to $5,500 per label.

FDA believes its calculation of printing costs fits within this range. FDA calculated the cost of redesigning 257,000 labels within a 6-month compliance period at $862 million, or an average of $3,400 per product. FDA is using these same estimates, adjusted for a longer compliance period, in the final RIA.

34. Manufacturers of dietary supplements objected to FDA's analysis of printing costs as described in the 1991 RIA proposal. One manufacturer estimated redesign costs for all of its products to be $363,250 but did not provide the agency with the number of products that would be covered under this estimate. Other firms estimated relabeling costs per product to be between $400 and $5,000.

FDA tentatively concludes that its assessment of the redesign cost per label for dietary supplements was underestimated. FDA assumed that labels on supplement products were more similar to drug labels than conventional food labels. However, the comments were successful in convincing the agency that supplement labels are more similar to conventional food labels and would incur a similar cost of printing and redesign. FDA will revise its estimates for redesign cost per label for dietary supplements as part of the rulemaking that FDA will complete in accordance with the DS Act.

E. Label Inventory Disposal Costs

35. Many comments stated that FDA's estimate of inventory disposal costs were too low. One very large firm estimated its own cost of inventory disposal to be in excess of $10 million. Another comment estimated disposal costs for the dairy industry to be approximately $125 million. This comment stated that if the dairy industry represents 15 percent of food sales, then FDA's estimate must be understated.

FDA does not believe that it is possible to extrapolate disposal costs from one firm or industry to the aggregate. Inventory disposal costs are subject to too many different variables to make such comparisons. For example, smaller firms are known to hold larger inventories than large firms. However, large firms hold smaller inventories for a greater number of labels. The cost of inventory disposal is the value of replacing inventories. Costs will be higher per label for products for which the package is the label than for products with stick-on labels. Also, costs will be higher for those labels that are produced using expensive printing processes. Therefore, although an industry or firm may represent a certain percentage of food sales, that industry or firm will not necessarily represent the same percentage of label inventory disposal costs. FDA does not believe it understated label inventory disposal costs except in the case of dietary supplements as described below. Therefore, FDA is not amending its final estimates based on this comment.

36. One comment from a food manufacturer disagreed with the assumption that industry label inventories would not exceed 6 months.

The comment misunderstood FDA's calculations. Although FDA did make such an assumption in regard to manufacturers of dietary supplements, FDA used data provided in a study conducted by RTI to calculate inventory disposal costs applicable to conventional food manufacturers. These data showed that most firms would require longer than 6 months to deplete label inventories. Therefore, FDA is not changing its final estimates based on this comment.

37. Dietary supplement manufacturers objected to the assumption that existing label stock could be used up within the proposed compliance period. An association of supplement manufacturers stated that "the on-going recession has meant that production levels have been cut, resulting in greater than normal stocks of labels." The association stated that the cost of discarding inventory would be over $25 million in order to implement the new requirements by May 1993, $15 million by November 1993, and $8 million by May 1994.

FDA tentatively concludes that its estimates of inventory disposal for dietary supplement manufacturers were incorrect. FDA, in the 1991 RIA proposal, made an ad hoc assumption regarding disposal of dietary supplement labels. Based on information supplied by comments, the cost of inventory disposal for dietary supplement manufacturers is valued at $11.5 million for a compliance period ending May 1994. However, because the DS Act imposed a moratorium on implementation of the 1990 amendments with respect to dietary supplements, FDA is not including these costs in the final RIA.

F. Reformulation

38. Several firms criticized FDA for not including the costs of evaluating and executing changes in marketing strategies, searching and testing new brand names, and reformulating products. One association for supplement manufacturers estimated reformulation costs at $20,000 per product but did not state how many products would be reformulated. Another comment stated that new product introductions, of which there were 12,000 in 1991, typically cost between $5 and $7 million.

In the 1991 RIA proposal, FDA acknowledged that reformulation would take place because of these regulations but stated that it could not determine the costs of reformulation because of a lack of adequate information. FDA agrees that because of the changes in the market that these regulations induce, some products will be reformulated. However, FDA is not estimating either the costs or the benefits of such reformulation. The comments did not provide the agency with enough information to calculate the marginal costs of reformulation caused by these

regulations. Although it is known that new product introductions have grown at an annual rate of 15 percent since 1986, FDA cannot predict how these regulations might affect that rate. However, it seems likely that these regulations will encourage firms to offer more nutritious foods to consumers. FDA also questions the cost of $5 to $7 million as an average cost of new product introductions. FDA notes that many small gourmet and confectionery products reformulate often during the year and may have annual sales much lower than these figures. FDA believes the costs and benefits of reformulation will be significant but is unable to estimate either based on the comments received.

G. Costs to Food Service Establishments

39. One comment stated that the cost of providing nutrition information in food service establishments would be prohibitive. The comment stated that for a typical establishment offering 80 items, the cost of analytical testing would be $136,000.

FDA agrees that providing nutrition information in food service establishments would be costly and prohibitive for many firms. The 1990 amendments exempt food service establishments from providing nutrition information. However, the 1990 amendments do not exempt food service establishments that use nutrient content claims or health claims from meeting FDA definitions for nutrient content claims or health claims. FDA is not amending its final cost estimates based on this comment because the agency is not requiring nutrition labeling in food service establishments.

40. FDA received several comments stating that the estimates of costs to the food service industry is understated for the following reasons: (1) The number of establishments affected is understated, (2) the number of menus and menu boards is understated, and (3) the cost per menu is underestimated. An association for the restaurant trade stated that approximately 262,000 commercial establishments and 36,000 institutions have approximately 406,384 printed menus. The association determined that, based on analysis of entries in its annual menu contest, 89 percent of all printed menus include at least one nutrient content or health claim. Thus, nearly 362,000 individual menus and 233,000 establishments in the commercial sector are potentially affected by the regulations. Further, the association determined that at least 18 percent of printed menus would require revision of an entire section or symbol program. According to the association, the cost of changing printed menus requiring changes in terminology or individual menu items would be $500 per menu or $144 million. The cost of changing printed menus requiring changes to alter or replace sections or symbols would be $5,000 per menu, including the cost of analysis or data base use, or $366 million. Therefore, the costs to food service establishments would be $510 million. These cost estimates did not include costs associated with development of new menu items, costs of compliance for 178,355 commercial establishments likely to use menu boards, and costs of compliance for institutional establishments.

FDA has reviewed the calculations, data, and assumptions and is persuaded by the comments that certain costs to the food service industry as described in the 1991 RIA proposal were not accurately estimated. However, FDA notes that the association's estimates are overstated because of three issues: (1) The agency is requiring that food service establishments have only a reasonable basis to support nutrient content or health claims—no analyses or data bases are necessary; (2) the agency is deferring enforcement for small food service firms (10 or less individual establishments) for an additional year to facilitate compliance by this segment of the industry; and (3) the agency does not intend to include menus within its regulatory coverage.

The association estimated that analyses will cost between $700 and $950 for each of 4 recipes for 73,149 menus, or a total of $241 million. Total costs to food service establishments should be reduced by this amount. In the 1991 RIA proposal, FDA assumed that 30 percent of the establishments would normally change their food items during the proposed 6-month compliance period. FDA received no comments refuting this assumption. Extrapolating this assumption to account for the 9-month extension of the date of application of section 403(q) and (r)(2) of the act, indicates that 75 percent of all food offerings would normally be revised during the compliance period. For ease of calculation, the agency assumes that food service establishments make nutrient content claims only, not health claims for which the date of applicability has not been extended. In addition, the agency has determined that enforcement will be deferred on 75 percent of food service establishments. Therefore, the costs of compliance for food service establishments, adjusting for normal revisions and analytical testing, are $17 million. This cost is assumed to be an upper bound estimate as many claims made by restaurants may be consistent with the new definitions.

H. Other Costs

41. One comment stated that FDA overlooked the cost of advertising changes and related marketing expenditures that will be necessitated by these regulations. The comment stated that because most advertising in the visual media includes a picture of the product, the advertising will become obsolete because the label on the product will change. Also, marketing material such as recipe booklets, materials provided to the trade, and shelf tags will require revision or destruction.

FDA acknowledges that some firms may incur costs of changing advertising and marketing campaigns because of changes to the label required by these regulations. For example, in any instance in which a photograph of the product is shown in an advertisement, that advertisement will be made misleading if the label changes but the advertisement does not. Although advertising comes under the jurisdiction of the Federal Trade Commission, such changes will occur as an indirect result of FDA's regulatory actions, and the costs are attributable to these regulations. According to "Food Retailing Review" (The Food Institute, 1992 ed.) advertising budgets for food at home in 1991 were approximately $12 billion, or 4 percent of the total cost. It is unclear how much, if at all, advertising expenditures will increase because of these regulations. Also, it is likely that, within the 15 months firms have to comply with the mandatory nutrition labeling and nutrient content claims regulations, many of those advertisements would have been changed for other reasons. Therefore, FDA believes that the marginal costs of changing advertising because of these labeling regulations will not add significantly to total costs. Therefore, FDA is not amending its final estimates based on this comment.

42. One comment stated that FDA should include the costs of consumer education campaigns.

FDA agrees with this comment. Although not a direct component of these regulations, consumer education campaigns are an essential element of the 1990 amendments. In 1991, FDA and USDA initiated a multiyear food labeling education campaign to increase consumers' knowledge and effective use of the new food label and to assist consumers in making accurate and sound dietary choices. FDA and USDA themselves do not have adequate

resources to inform and educate the public effectively about the new food label and how to use it to plan a healthy diet. The agencies are working with other public and private sector organizations. FDA interprets its role as one of providing leadership in developing, and encouraging others to develop, programs that enable diverse audiences to use food labels effectively. The agency estimates that its efforts in this role may cost as much as $3 million in the next 5 years and in excess of 50 person-years. The agency, due to inadequate information, is not able to predict the costs to other Government agencies nor the multiplier effect on consumer groups, educators, mass media, the food industry, and other public and private sector organizations.

43. One comment concluded that much of the costs will be passed on to consumers, not borne by industry.

FDA does not have sufficient demand and supply information to estimate the amount of cost shifting that may occur as a result of the labeling costs. However, FDA has always considered costs to society without regard to who bears those costs. Therefore, FDA does not believe that it is important for the purposes of societal cost and benefit estimation to estimate the amount of cost shifting. However, for the purposes of estimating whether there is an "undue economic hardship" to industry, FDA does believe that this question is relevant, and this question has been addressed in the final rule published elsewhere in this issue of the **Federal Register** on the date of applicability of section 403(q) and (r)(2) of the act.

I. Summary of Costs

After examining the comments, FDA has recalculated the costs of the final rules. These final estimates are based on a 15-month compliance period ending in May 1994. Although some provisions of the 1990 amendments, i.e., health claims, will become effective on May 8, 1993, FDA received no comments regarding the separate costs of those provisions. Further, in the 1991 RIA proposal, FDA preliminarily determined that the costs of the labeling of ingredients in standardized foods and certified colors were $16 million for administrative costs and $112 million for printing. The costs of percent juice labeling have been estimated at $40 million. Comments did not result in a recalculation of these costs.

The comments mentioned many costs that FDA agrees could be included in the costs of food labeling regulations but cannot calculate because of a lack of information. These costs include the cost of increased errors, the resources spent in reviewing and commenting on proposed regulations, the cost of lost products and packages destroyed to run analyses, the capital costs associated with label printing, the costs associated with smaller, less efficient print runs, and the costs of reformulation. FDA believes that, with the exception of reformulation, these costs represent a small portion of the total costs and that not including them in the final estimates does not significantly alter FDA's conclusions.

Based on the information provided by the comments and the contractor's cost study, FDA now finds that administrative costs are $9,000 for small/medium firms and $68,450 for large firms when the compliance period is 6 months. Because FDA is extending the compliance to 15 months, costs will be $3,375 for small/medium firms and $25,700 for large firms, or $56 million for the 8,900 medium and large firms affected. Similarly, administrative costs to manufacturers of dietary supplements are $850 per firm with a 6-month compliance period. Adjusted to a 15-month compliance period, administrative costs to dietary supplement manufacturers are $320 per firm or $52,000. However, these costs may be greatly reduced depending upon the outcome of the proposals to be issued at a later date, as discussed above, in response to the DS Act. Thus, the costs to dietary supplement manufacturers are not being included at this time.

FDA has agreed with the comments that the costs to the Federal Government for implementing the 1990 amendments should be considered in its final estimates. As previously described in comment 7 of this document, FDA estimates that implementing the 1990 amendments will cost the Federal Government approximately $163 million in labor and capital over the next 20 years (5 percent discount rate). These costs will most likely not be incurred by increasing taxes on either consumers or industry as the food labeling information program will be funded by substituting efforts away from other Government programs. FDA did not attempt to estimate the costs to other governmental units or State governments.

FDA has determined that all products produced by medium and large firms will undergo some analytical testing. Approximately 40 percent of products will require full nutrient testing at a cost of $1,785 per product. The remaining 60 percent of products will require only partial testing because they have already been tested for some nutrients. The cost for testing these products is $723 per product. FDA is assuming a range of retesting from once every year to every 5 years on average. Analytical costs for mandatory nutrition labeling are $228 million in the first year. Total discounted analytical costs range from $466 million assuming retesting every 5 years and $1.1 billion assuming annual retesting (5 percent discount rate). The cost of collecting samples is between $17.9 and 22.8 million over the next 20 years (discounted at 5 percent) In addition, FDA estimates the cost of protein quality testing will be $540 per product or $185 million over the next 20 years assuming retesting every 5 years or $440 million assuming annual retesting.

The assumptions used to calculate printing costs for conventional foods remain unchanged by the comments. The cost of printing 257,000 food labels is estimated at $518 million for a compliance period ending in February 1994.

Review of the comments did not lead to any changes in the assumptions used to calculate inventory disposal costs except that FDA no longer assumes dietary supplement manufacturers will have enough time to dispose of all labels. Total costs for inventory disposal of conventional food labels is $6 million for a May 8, 1994, compliance date.

FDA has reviewed the calculations provided by food service establishments and has adjusted those calculations to account for a longer compliance period and normal menu revision. FDA is allowing food service firms the option of using a reasonable basis rather than analytical testing to support claims, further reducing costs. In addition, FDA is deferring enforcement for restaurants with 10 or less individual establishments. The cost to food service establishments, reflecting all adjustments, is $17 million.

The total costs of food labeling regulations range from $1.4 billion to $2.3 billion (discounted at five percent), depending on the frequency of reanalyzing products, excluding the cost of labeling raw fruit, vegetables, and fish, and assuming a 15-month compliance period ending in May 1994. In addition, costs of Government activities are estimated at $163 million.

IV. Benefit Estimation

As part of the 1991 RIA proposal, FDA published a labeling benefits model that examined the health benefits from consumer response to food labeling. In this model, FDA used economic theory to quantify the value of the reduction in coronary heart disease (CHD) and three types of cancer that

would result from modified diets in response to nutrition labeling. FDA received approximately 20 comments directly related to the benefits of nutrition labeling. Many comments addressed the benefits of specific rules. The agency is responding to these comments in the relevant individual final rules.

A. Benefits—General

44. Several comments questioned the credibility of the health benefit estimate, particularly as to whether risk reduction through change of dietary habits can be quantified.

FDA does not agree with this comment although FDA stresses that it views the benefit estimation of the 1990 amendments as a preliminary investigation into quantification of mandatory information disclosure. In addition, FDA notes that the agency is required by Executive Order 12291 to quantify benefits where possible and to use such estimates to select regulatory policy options that generate the largest net benefits. Therefore, FDA is not changing its estimate of the benefits based on this comment. FDA will continue to refine the methodology employed here as well as to seek alternative methodologies to measure these effects.

45. One comment noted that there will be reductions in health care and insurance costs that will result in cost savings to all consumers, whether disease afflicted or not.

FDA notes that health care estimates were included in the 1991 RIA proposal. FDA agrees that as demand for health care resources decreases, there will be price decreases that will affect all consumers and consequent reductions in insurance costs. However, benefit estimates are societal benefits which are real resource savings to all members of society, without regard to incidence. For example, estimates of the willingness-to-pay to reduce risk of illness and death reflect total societal values. Therefore, the benefits estimated in the 1991 RIA proposal reflect savings to all of society, whether disease afflicted or not, but this fact does not alter the quantitative total societal benefits and does not affect the final estimate of the benefits.

46. Another comment noted that there may be significant benefits from reduction in allergic responses to food.

The agency believes that the most significant additional ingredient information resulting from the 1990 amendments is the listing of ingredients in standardized foods. The agency believes, however, that the labeling of almost all standardized foods already contained this information before the passage of the 1990 amendments. Although the agency agrees that the required labeling of allergens such as hydrolyzed corn protein will have some benefits for preventing allergic responses, these benefits are expected to be small relative to the nutritional benefits of the final rules.

47. One comment suggested that because the agency accounted for the costs of product reformulations, it should estimate the benefits of reformulation.

Although FDA agrees that product reformulation will occur as a result of the 1990 amendments, FDA did not estimate either costs or benefits of product reformulation (see comment 38 of this document). The assumption underlying the benefit estimate is that firms did not reformulate foods just to participate in the shelf flag study (the FDA/Giant Special Dietary Alert (SDA) study cited in the 1991 RIA proposal) because the relative size of the market used in the study is small, and the time span was relatively short (1 year). The agency noted in the 1991 RIA proposal how difficult it would be to estimate the amount of reformulation that would take place.

48. Some comments addressed the purpose of the food label with respect to the projected benefits of the new labeling. One comment stated that the purpose of the food label is to inform consumers (presumably about nutritional values), while another stated that the purpose of the food label is to sell a product.

Compliance with the final regulations that respond to the 1990 amendments as well as with other regulations governing food labels will make the label, both the PDP and the information panel, more informative for consumers. Thus, estimated benefits derived from compliance with the 1990 amendments are not benefits to manufacturers from selling food but rather are benefits to consumers because manufacturers must comply with the law.

49. Another comment expressed concern that diet deficiencies might be a possible response to the new labeling information. This comment noted that some consumers may have negative benefits because they use food labels to modify their diet in a detrimental way. According to the comment, this result would occur because food nutrients are grouped in foods such that, for example, a product substitution may decrease fat intake slightly but result in a large increase in sodium intake.

As mentioned in the 1991 RIA proposal, FDA was aware of the possibility that these effects may occur and represent a potential bias towards overestimating benefits. However, FDA believes that it is unlikely that the provision of more information on food labels will lead to such effects. It is difficult to construe the labeling changes that respond to the 1990 amendments as being the cause of many ill-considered food choices. The disqualifying disclosure levels are intended to prevent such effects from occurring. Further, FDA believes that the consumer information campaigns now underway in response to the 1990 amendments will serve to further mitigate the chances of any such effect.

50. One comment stated that the only benefits that would arise from requiring restaurants to carry nutritional information would be for the chemical laboratories that do the testing.

The agency advises that it is not requiring full nutrition labeling for restaurants in these final rules. However, restaurants will be required to ensure that their judgments that a food has an appropriate level of a nutrient to qualify for a health claim or a nutrient content claim have a reasonable basis. There is no requirement for laboratory testing of such foods. Moreover, FDA does not agree that no other parties will benefit from these rules with respect to restaurants. Consumers will now have consistent, reasonably based signals from restaurant menus with regard to health claims and nutrient content claims that they can use to control their diets.

B. Consumer Response to Labeling

51. One comment contended that FDA's estimate of the consumer response to labeling was low. The comment argued that FDA's estimate of the percentage of consumers that read and understand labels, 45 percent, should be used as a measure of consumer behavior change in response to new labeling.

The agency rejects this view. The agency's estimate was based on actual consumer behavior measured in response to new labeling information (the FDA/Giant SDA study). As for the estimate of consumers who read and understand labeling, the agency notes that the cost of changing dietary behavior is greater than the cost of simply reading and understanding labels. The cost of changing dietary behavior includes search costs, costs of giving up some elements of taste, and possibly paying higher prices for the more nutritious foods. For this reason, it is likely that only a small percentage of consumers actually change their purchases in any meaningful way. In addition, FDA acknowledged factors

that would cause the benefit projections to be overestimated. For example, as noted in the 1991 RIA proposal, FDA does not have evidence that changes made in the FDA/Giant SDA program were lasting. Although FDA expects that consumers' diet/health link awareness will increase over time, it is not clear how much of an effect this increased awareness will have.

52. Other comments questioned whether consumers will use labels to actually change purchase behavior.

FDA believes that the SDA study supports its view that some consumers, although a small percent, will use labels to change their purchase behavior. In this study, shelf flags were used to alert consumers to the presence of desirable nutrient attributes. Netting out price changes, there were measurable shifts to more nutritious foods. Moreover, the SDA categories covered less than one-fourth of all of the food categories, and FDA believes it is likely that there will be responses in other categories of food because of the addition of other nutrients of concern as part of the 1990 amendments.

53. One comment to the RIA stated that the shelf flag highlighting in the SDA study overestimates benefits of the 1991 initiative because they do not apply to information required on the food label. The comment noted that, since shelf flag highlighting may have been used in addition to highlighting the product characteristics on the label, similar results will not be obtained unless retailers use shelf flags. The comment went on to say that it is unlikely that retailers will use shelf flags given disclosure requirements, type-size and placement requirements, and density-based requirements.

The agency notes that these final rules do not prohibit shelf flags from being used by manufacturers exactly as they were used by Giant Foods during the SDA study. The agency is announcing in the final rule on nutrient content claims, published elsewhere in this issue of the **Federal Register**, that it is encouraging retailers to use such devices consistent with the nutrient content claim definitions provided in that final rule. Thus, the agency believes that similar results will occur as a result of the 1990 amendments and is not changing its estimate based on this comment.

54. One comment expressed the view that the shelf flags in the SDA study are best related to regulations allowing health claims and nutrient content claims on labels, and that benefit estimates should be related to those provisions of the 1990 amendments.

FDA believes that all implementing regulations of the 1990 amendments will have benefits, although the bulk of such benefits may come with changes to the PDP where nutrient content claims and some health claims will be displayed. However, FDA is unable to separate the effects of the various aspects of the 1990 amendments on the basis of this comment or any other of the comments received. Therefore, FDA is not changing the benefits estimate based on this comment.

55. Another comment on the SDA study noted that FDA did not separate the effects of the shelf flags from other marketplace events such as price changes, advertising campaigns, price reductions, or couponing.

The agency notes that price changes were accounted for in the SDA study, although the other events mentioned represent a possible bias in the study. To the extent that such effects caused consumer purchase changes independent of the shelf flags, the agency agrees that such changes would result in the benefit estimate being an overestimate. However, no information was presented that would allow the agency to calculate the extent of this bias. The agency points out that this is one of several biases in the analysis that were noted in the 1991 RIA proposal.

56. One comment suggested that FDA examine microdata from SDA to determine whether Giant stores had a disproportionate number of people at risk for developing chronic diet-related diseases. They pointed out that if so, it would bias the outcome when the study is extrapolated to the entire U.S. population. Other comments noted that the Washington D.C. metropolitan area may not be representative based on demographic data.

The agency acknowledges these limitations of the data presented in the SDA study and recognizes that the benefit estimates provided in both the preliminary and the final RIA are soft because of the many assumptions made and the tenuous support for many of these assumptions. The agency believes, however, that it has made a novel first attempt at estimating the effects of this type of mandatory label information. A number of comments addressed the viability of the agency's assumptions in estimating these benefits but offered no data upon which to fashion better assumptions. The agency agrees that the Washington D.C. area may not be representative of the U.S. population as a whole but does not have any way to make the study representative. Thus, FDA is very aware of the imprecision of these benefit estimates. From these comments FDA has received no information that would alter its assessment of the expected change in dietary behavior from that reported in the 1991 RIA proposal.

C. Health Response to Improved Diet

57. One comment noted that FDA's estimate of the maximum preventable cases of cancer and CHD prevention from dietary changes was low relative to what was predicted by "significant scientific agreement." The comment used Table 13 in FDA's 1991 RIA proposal (56 FR 60856 at 60871, November 27, 1991), and estimated that, of the total cases estimated to be avoided, cancer cases represent 89.7 percent, and CHD the remaining 10.3 percent. Eliminating the years where 0 cases are expected to be prevented, the first 10 years for cancer and 2 years for CHD, the above percentages were applied to the total cases, 503,448 (Table 16, 56 FR 60856 at 60872). From these calculations, the comment noted that FDA's figures appear to show only 45,310 cancer cases and 2,797 heart disease cases are preventable through dietary intervention per year. These numbers were compared by the comment with other published numbers. For total preventable cancers, the comment updated a 1991 published estimate of 1,100,000 cases (per year in the United States) with an annual growth rate of 0.9 percent to obtain an average over the 10th to 20th years from the 1990 amendments of 1,258,230. The comment noted that FDA's estimate of preventable cancers (45,310) was only 3.6 percent of this figure, less than the 5 percent to 35 percent of cases preventable through diet. Another comment noted that the 2,797 estimated cases of CHD that would be prevented represent only 0.9 percent of the total cases, which it said was extremely low.

The agency disagrees that its figures are low. First, the agency's estimates were based on the difference between current dietary intakes and DRV's. DRV's are the U.S. Government recommendations for an achievable diet, not a maximal diet. A maximal diet would be much lower in fat content, for example, as well as containing other nutrient values much "stricter" than the RDI diet. The RDI diet might be construed to be "perfect," however, in the sense that it does not involve giving up all desirable foods to meet a reasonable health goal.

In addition, FDA notes that although there is significant scientific agreement that reductions in fat intake will reduce the risk of some cancers, the precise quantitative relationship has not been firmly established. It is unlikely, however, that the relationship between

fat intake and cancer will prove to be false.

Finally, it should be noted that FDA's figures from Table 16 in the 1991 RIA proposal (56 FR 60856 at 60872) are from reducing fat intake for FDA foods only, which does not include meat and poultry (regulated by USDA). Reductions of fat from consuming those foods will save additional lives and cases. Thus, FDA disagrees that its estimates are low and has not changed the benefit estimate of the 1990 amendments based on this comment.

58. One comment requested that FDA explain an apparent discrepancy. The comment took the number of total cases of illness estimated to be avoided for each scenario and divided them by the total number of deaths estimated to be avoided. The comment stated that the discrepancy arose because the total number of cases (cancer and CHD) avoided in the maximal FDA diet, approximately 42 percent resulted in lives saved, whereas in the scenario that applies to the benefit estimate, only 32 percent of cases avoided will result in lives saved.

The agency does not believe that this difference is a discrepancy. The explanation is that both total cases avoided and total lives saved are based on cancer and CHD. In the Browner model, which was used as a component of the FDA labeling benefits model, reducing fat intake changes the ratio of saturated fat to cholesterol intake. In the maximum health benefits scenario, this ratio is 2. As the amount of fat intake is reduced in response to labeling, this ratio declines to 1.3. The ratio of saturated fat to cholesterol changes are based on actual intake changes measured in the SDA study. In turn, as the ratio of saturated fat to dietary cholesterol decreases, the rate of CHD cases avoided (based on saturated fat) will decline relative to that of cancer cases avoided (based on total fat).

In the Browner model, it is assumed that all CHD cases result in death, but that only 45 percent of the cancer cases result in death. Thus, as there is no discrepancy, FDA concludes that no changes in the agency's benefit estimate are necessary in response to this comment.

59. One comment argued that it makes no sense to postulate that a perfect diet would only prevent 3.6 percent of cancer cases, but 42 percent of cancer deaths. Similarly, the comment stated that it is unlikely that there would be only a 0.9 percent reduction in incidence of heart disease but 4.5 percent reduction in deaths.

The agency disagrees with this comment. The comment is referring to the agency's estimate of the number of preventable cases of cancer and cases of death that would result from adoption of a perfect diet by all consumers (Table 15, 56 FR 60872). The comment appears to have incorrectly calculated the percentage of cancer deaths that will be avoided as a result of a perfect diet relative to the total number of cancer deaths in the United States. Rather than 42 percent as calculated by the comment, the agency calculates that 3.5 percent of all cancer deaths in the United States would be avoided if consumers adopt a perfect diet. This number, 3.5 percent, is calculated as follows: On average, it is expected, based on FDA calculations (56 FR 60872), that there would be approximately 18,985 cancer deaths avoided per year (following the 10-year lag from the beginning of a perfect diet). This number is obtained by multiplying the total number of deaths avoided (212,596) by 89.3 percent (the proportion of cancer deaths avoided) and dividing by 10, the number of years for which the model estimates cancer deaths being avoided. Therefore, if there are 545,718 total cancer deaths per year, then 18,985 deaths per year (3.5 percent) can be avoided as a result of adoption of a perfect diet. A similar calculation determines that CHD deaths avoided as a percent of CHD deaths per year (500,000) is about 0.3 percent.

60. Another comment states that the "total impact of the approved health claim on lipids and cancer will be a reduction of 0.28 percent of all cancer cases and an estimated prevention of 1,188 cancer deaths per annum, a total decline of 0.23 percent."

The agency's estimate of the benefits of the 1990 amendments apply to the whole of the 1990 amendments. Changes in dietary behavior, such as lipid reduction, are likely to be made by consumers in response to changes in the information panel including new nutrient and ingredient information, as well as to PDP changes such as new definitions for nutrient content claims and health claims. The agency is unable to separate out, based on this or any other comment received, the marginal change in consumer behavior solely in response to health claims and the resulting health effect. Thus, no change to the agency's benefit analysis has been made in response to this comment.

61. One comment noted that FDA has estimated a reduction in the consumption of fats by men and women to be 1.4 and 1.1 percent which translates to 1.49 and 0.67 grams, respectively. The comment went on to say that given that a "less" fat item will have a minimum of 3 grams less fat than a comparable choice, FDA's estimate would amount to only one improved serving choice every other day for an average male and every 4.5 days for an average female. The comment contended that this appears to underestimate the potential impact. The comment also noted that:

> The apparent use of a typical consumer, rather than of a bell distribution, would dramatically skew the impacts of the reduction on health * * * as minor reductions (1.1 to 1.4 percent) * * * cannot be expected to have a significant impact on risk reduction. Because actual reduction would be distributed across a curve, those whose reduction in cholesterol would be significant would experience a significant reduction in risk unrevealed by the FDA single, typical consumer model.

The agency did not use a typical consumer to estimate the benefits of the proposed regulations. In the Browner model, all age groups were used in 5-year increments (e.g., 40-to 45-year-olds) which would approximate the full distribution of age groups, not collapse all age groups into a typical consumer. This data (the actual distribution of intakes) came from the Continuing Survey of Food Intakes by Individuals. Furthermore, the agency is not persuaded by the argument concerning food choices. FDA agrees with the comment that rather than all consumers making small changes, what is more likely is that a small subset of consumers will make dietary changes, or that some consumers will only change a small portion of their diets. This pattern of response would explain the relatively modest changes that occurred in the SDA study. FDA notes that consumer response to new information has been shown to be modest in other studies, such as response to radon information provided by the Environmental Protection Agency. However, the agency believes that reformulation of foods, which were not estimated in this benefit analysis, will increase the size of the total benefits. FDA acknowledges that this bias exists in the estimate but, as noted elsewhere in this document, FDA does not have sufficient information to estimate these effects and FDA is not altering its estimate based on this comment.

Although the estimate of the number of deaths avoided will not be adjusted based on the comments received, FDA acknowledges that a letter to the Department of Labor from the Office of Management and Budget (OMB) returning a rule which would lower permissible exposure limits for 375 substances in the construction and maritime industries has implications for

its estimate of the number of lives saved (Ref. 2). In that letter, OMB took note of a series of papers and books that estimated the effect of wealth on health. They noted that, "Richer workers on average buy more leisure time, more nutritious food, more preventive health care, and smoke and drink less than poorer workers." Thus, money spent by society to improve nutrition labeling will not be spent in other areas such as smoke detectors and airbags which will reduce risk. OMB cited a U.S. Court of Appeals decision which in turn cited research showing that each $7.5 million in additional regulatory expenditures may result in one additional death from lowered income.

The relationship between income and death is still somewhat controversial. In a recent article, researchers found that the effect is likely if the income reduction is permanent, as opposed to transitory (Ref. 3). Keeney has examined the extent to which the mortality effects on income changes are greater for poorer people than for richer people (Ref. 7). As the expenditure on nutrition labeling is a one-time expenditure affecting all consumers very slightly, it is likely that it is a transitory expenditure. On the other hand, because food expenditures account for a significantly larger share of the family budget for poorer families, the cost of these regulations are likely to have larger impacts on those families. Thus, it is unclear whether or not these expenditures will, in fact, increase some deaths while saving others. Nevertheless, FDA has estimated the possible effects this potential bias could have on the benefit estimate.

FDA's final estimate of additional regulatory costs resulting from the 1990 amendments is $1.6 to $2.7 billion. This would result in between 216 and 360 additional deaths which should be subtracted from FDAs estimate. Based on the Keeney estimate of one death for each $7.5 million of cost, the final estimates for the total deaths avoided as a result of the 1990 amendments are between 12,542 and 12,689 (from 12,902 estimated in the 1991 RIA proposal, Table 13, 56 FR 60856 at 60871). Life-years gained are reduced to between 78,672 and 79,577 (from 80,930, also in Table 13). The results of these changes affect the total benefits very slightly with the new range being $4.5 to $21 billion.

D. Quantification of Health Response

62. One comment argued that the average medical care costs estimated in Table 14 (56 FR 60856 at 60871) should not be discounted at a 5 percent inflation rate because the rising costs of medical care have been increasing 10.5 percent in recent years.

The agency agrees that the costs of medical care have been rising at approximately 10.5 percent. If this trend were to continue, however, a net of 5.5 percent increase (10.5 percent medical care cost inflation minus 5 percent general inflation) could be added to these costs, although future cost increases are difficult to predict, and the agency does not wish to infer that great precision accompanies these estimates. The agency notes that medical care costs estimated in the 1991 RIA proposal may be over or underestimates of actual medical care costs. That is, because some people who will not get cancer or CHD will get other illnesses that will result in medical care costs, using the total cost savings from reduced cancer and CHD cases is an overestimate. Because the agency was unable to net out increases in medical care from other diseases, it overestimated medical care cost savings. Thus, the agency acknowledges that there is a bias in both directions for the medical care cost estimate. Because it is not possible to estimate the net direction of these biases, however, the agency will not make further adjustments in these numbers. Finally, the agency's estimates of the benefits of nutrition labeling derive primarily from the willingness-to-pay for increased longevity, not from nonfatal medical care costs.

63. One comment expressed the view that the willingness-to-pay generated benefits of the 1990 amendments of $3.6 to $21 billion are for nonmedical outlays only.

FDA disagrees with this comment. In fact, the willingness-to-pay estimates of health benefits in the 1991 RIA proposal are individual dollar amounts that market studies demonstrate consumers (and workers) will pay to reduce the probability of death from these illnesses. Many people are willing to pay to reduce the probability of death and illness, and these payments include expected expenditures on medical care as well as other types of disability, such as pain and sickness. As noted earlier in this document, however, the total benefit estimates do not cover the cost savings from illnesses that do not result in death, which are estimated in the section on medical care cost savings. Thus, no change in the benefit estimate will be made as a result of this comment.

64. One comment pointed out that a willingness-to-pay model is not anchored in any real occurrence in the marketplace and reflects only a subjective valuation of good health. This comment added that risk is not traded in the marketplace.

The agency disagrees with this comment. The agency believes that willingness-to-pay estimates represent the individual's valuation of loss of productivity, medical care costs, pain and suffering, and other utility losses as demonstrated in economic literature. In this case, the decisions reflect payments to reduce the risk of death rather than using those resources for other goods.

FDA also believes that risk, including health risk, is ubiquitously traded in the marketplace. For example, expenditures on seatbelts, airbags, airline safety, safety caps on medicine, preventive check-ups, suntan lotion, and a multitude of other factors represent market expenditures on risk reduction. Many of the studies conducted to estimate willingness-to-pay to avoid death were based on the workplace transactions by estimating wage differentials for jobs with varying levels of risk and wages. Therefore, the willingness-to-pay figures for reductions in the probability of death are strongly grounded in economic theory such that the agency will not change the benefit estimate based on this comment.

65. One comment suggested that "hard figures" such as lost productivity should be used instead of willingness-to-pay estimates.

FDA disagrees with this comment because the use of such "hard figures" alone (productivity) will ultimately undervalue the total utility of reducing risk to the individual as it does not include the utility derived from reduced medical care costs and pain and sickness. The agency believes that the willingness-to-pay methodology is strongly grounded in economic theory and is the conceptually correct method to estimate these health benefits. Therefore, no change will be made to the benefit estimates based on this comment.

66. One comment contended that the quantitative estimate provided in the 1991 RIA proposal for the amount and value of reduced risk were too low because: (1) The estimate chosen for the value of risk reduction (value of life) from secondary studies was low because the mean of these type of studies was not chosen; (2) the estimate for value of risk reduction did not include the impact of recent inflation; (3) the estimate for the value of risk reduction did not include growth in real income before 1990; and (4) the estimate for value of risk reduction did not include future real growth of income.

FDA does not agree that the estimates chosen for the value of risk reduction, $1.5 to $3 million, from secondary

studies is necessarily low. Market studies of willingness-to-pay to avoid death have produced a range of values—some higher and some lower than the values used in this study. In order to capture this diversity, FDA used a wide range of benefits. Thus, FDA is unconvinced that sufficient data are either available in the literature or were in the comments to warrant changing these estimates.

As to the second point, FDA agrees that some inflation has occurred since the publication of the study that the agency used to estimate the value of risk reductions. The study's results were calculated in 1986 dollars (Ref. 4) and inflation from 1986 to 1991 was 16.5 percent (not 15.5 percent as mentioned in the comment). In addition, the comment noted that there have been increases in real personal disposable income since 1986. Real personal disposable income has increased from 1986 to 1990 by 8.5 percent, not 10 percent as cited in the comment (Table B–25 in the Economic Report to the President (Ref. 6)). To the extent that individuals can now purchase 8.5 percent more goods than they could in 1986, it is likely that they would be willing to pay more for risk reduction as well. Updating the range of estimates noted above of $3.5 to $21 billion to account for inflation and real personal disposable income yields the new range of $4.4 to $26.5 billion.

The comment also noted that FDA should include in the benefits estimates future real growth of income because if income continues to grow, people in the future will purchase more risk reduction. FDA disagrees with using long-term real growth of income to increase benefits. The benefits estimate derives from the choice that is made by individuals today. That choice reflects the amount of money people are willing to give up today to reduce risk in the future. Those estimates reflect individuals subjective evaluation of both their future health states as well as their assessment of their future income changes that will occur as a result of the regulation. If FDA were to forecast future growth in personal income and estimate the income/risk trade-offs (income elasticity of demand for risk reduction) that would be made for each future period, it would result in double counting. Again, this would be true as people implicitly account for future income growth in decisions made today. Furthermore, as income rises, people may choose to add even more labeling information at some time in the future but that would represent a separate choice with separate marginal costs and benefits.

FDA concedes, however, that choices that are made in most, if not all, willingness-to-pay studies associated with risk reduction are reflective of individuals valuation of their own change in probability of risk of death. They do not include the individual's altruistic expenditures to reduce risk for future generations. This effect is expected to be small for this regulation, however, as benefits and costs are estimated for over 20 years.

E. Health Claims

67. One comment expressed concern that FDA had ignored some fundamental findings from consumer behavior studies and the economics of information. It also stated that approval of health claims should be done on a cost-benefit basis rather than by consensus. The comment noted that allowing partial information produces a more efficient marginal adjustment process in the market than requiring full information. The comment noted that it did not believe there was such a thing as "Gresham's Law" (which essentially says that "bad" money drives out "good" money) of health claims in advertising.

The agency does not necessarily disagree with this assessment of the state of the economics of information. However, section 403(r)(3) of the act requires "substantial scientific agreement" for approval of a health claim for conventional food. The standard for substances in dietary supplements under section 403(r)(5)(D) of the act will be determined in accordance with the DS Act. The agency believes that the final rules for health claims are as flexible as is possible. Also, the agency notes that there is a set period of time for Government review of petitions for authorization to make additional health claims.

On the issue of whether or not there is a "Gresham's Law" with respect to advertising, the agency notes the widespread persistent use of the misleading "percent fat free" advertising. Thus, it is not clear whether or not "good" advertising in terms of being truthful and not misleading will ultimately drive "bad" advertising from the marketplace without regulation. Thus, FDA does not believe that this comment affects the ultimate benefits from the 1990 amendments and will not change its assessment based on the comment.

There is an opportunity cost of the choices made with respect to health claims and nutrient content claims. Opportunity costs of the regulation of these claims include the benefits foregone by not choosing an alternative option. Some of these costs arise from the statute itself, and some arise from the interpretations made in these regulations. If firms are either prohibited from making certain kinds of claims, or if the incentives are such that firms make fewer valid health claims or nutrient content claims, there is a cost imposed on society in that some valuable information may not be conveyed to consumers. For instance, if firms find that the required disclosures surrounding health claims are too cumbersome, they may find that this adversely affects the marketing of their product and fail to make a valid health claim.

In fact, FDA has no data to evaluate the potential market outcomes that would arise with alternative regulatory choices with respect to health and nutrient content claims. Although FDA has benefited from numerous comments on the subject, including a lengthy comment from the Federal Trade Commission, no comments have been able to show the quantitative outcomes of allowing more health claims in a different format or allowing more flexible use of nutrient content claims. However, although these rules are final, FDA will continue to evaluate information that will help refine these rules and encourages interested parties to submit such information.

V. Summary

FDA has evaluated comments on the costs and benefits of the impact of the changes in the food label occurring as a result of the 1990 amendments. The benefits of the 1990 amendments and the implementing regulations include decreased rates of cancer, CHD, osteoporosis, obesity, hypertension, and allergic reactions to food. As consumers are given more informative labeling in an improved format, uncertainty and ignorance concerning the ingredient and nutrient content of the foods they eat will decrease, and some consumers will select more nutritious, healthier foods. Also, the creation of consistent metrics and definitions, such as standardized serving sizes and nutrient content claim definitions, that consumers can use to judge the nutritional aspects of foods will encourage manufacturers through competition to reformulate their products into healthier foods. Thus, even those consumers who may be unaware of the effects of diet on health will inadvertently eat a better diet.

The model chosen to estimate these benefits focused on the two largest health problems, cancer and CHD (Ref. 5). This model involved the following three-step estimation process:

(1) Estimate changes in consumer purchase behavior and resulting changes in nutrient intakes as a result of receiving new nutrient information about foods. Some comments stated that consumers will not use labels at all, and some comments asserted that many more changes will come about than those that FDA estimated. A number of comments noted particular bias in the FDA/Giant SDA study. Although FDA agrees that there is bias both in the SDA study and in applying the results of the SDA study to the benefits of the 1990 amendments, no comments provided a sufficient basis either to replace or amend the study's result in this RIA.

(2) Estimate the changes in health states that would result from consumers' changes in nutrient intakes, particularly for reduced incidence of cancer and CHD. Again, FDA was presented with a number of comments on the changes that will result from changed diets, but none were convincing. Many comments were directed at the Browner model which was incorporated into FDA's benefit estimate in this section of FDA's analysis. The comments focused on the fact that nutrition labeling and other components of the 1990 amendments are estimated in FDA's model to make only a relatively small decrease in the number of cases of CHD and cancer and the deaths associated with them. However, FDA is unpersuaded by these arguments. The Browner model is well documented and contains realistic health assumptions. However, FDA did account for studies cited by OMB that demonstrated that regulatory expenditures may cause increased death. This resulted in FDA's estimate of lives saved and life-years saved decreasing by very small amounts, to between 12,542 and 12,689 (from 12,902 estimated in the 1991 RIA proposal, Table 13, 56 FR 60856 at 60871) and to between 78,672 and 79,577 (from 80,930, also in Table 13) for the number of life-years saved.

(3) Estimate the value of changes in health states in terms of life-years gained, number of cases and deaths avoided, and the dollar value of such benefits. FDA has been persuaded by some of the arguments that the benefits are underestimated in this component of the analysis. Specifically, the agency has adjusted for inflation and for the growth of real personal disposable income that occurred in the 4 years between when the estimates were cited in the economic literature and the time the 1991 RIA proposal was concluded. Coupled with changes made to the number of life-years and lives saved mentioned above, these adjustments change the benefits to $4.4 to $26.5 billion (discounted at 5 percent over a 20-year period).

FDA also evaluated comments on costs of the 1990 amendments and has amended its cost estimates based on these comments. The total costs of food labeling regulations range from $1.4 billion to $2.3 billion (discounted at 5 percent), depending on the frequency of reanalyzing products, excluding the cost of labeling raw fruit, vegetables, and fish, and assuming a 15-month compliance period for nutrition labeling and nutrient content claims ending in May 1994. If a discount rate of ten percent is used, total costs are estimated between $1.3 and $1.8 million. These costs include costs to food manufacturers and food service establishments. Costs to Government entities are estimated to be $163 million. Costs to dietary supplement manufacturers were not included in this estimate because of the moratorium imposed by the DS Act.

FDA believes that the study of the costs and benefits of food labeling is as accurate as possible for a forward looking study of the costs and benefits of regulatory action. FDA published the initial study in the **Federal Register** and received over 300 comments on it. As a result of the comments and new information, FDA revised its figures upward for both costs and benefits. In addition, FDA acknowledges that many deficiencies remain in these estimates because there are elements of both costs and benefits that remain unquantified. Nonetheless, the purpose of the RIA is to estimate the general magnitude of these effects in accordance with Executive Order 12291 and to determine whether the benefits of this action exceed the costs, and FDA has met that burden. With the exception of reformulation, FDA has examined the unquantified costs and benefits and believes that they are likely to be small relative to those that have been quantified and are not likely to change the estimates significantly.

Furthermore, the analysis contains assumptions that are subject to challenge, and many of the comments did so. However, where neither data nor convincing evidence were submitted to contradict the assumptions, FDA has not changed them. Finally, FDA advises that the dollar amounts estimated in the final RIA are not exact amounts but rather reasonable estimates of the impacts of nutrition labeling on U.S. society. The final RIA demonstrates that although this action is expensive, the likely benefits to U.S. consumers substantially exceed the costs that shareholders, taxpayers, and consumers will ultimately bear.

VI. References

The following references have been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Peto, Richard, "Cancer Around the World: Evidence for Avoidability," in *Diet and Prevention of Coronary Heart Disease and Cancer*, B. Hallgren et al., editors, Raven Press, New York, 1986.

2. MacRae, James, B. Jr., Acting Administrator and Deputy Administrator of the Office of Information and Regulatory Affairs, OMB, letter to the Honorable Nancy Risque-Rohrbach, Assistant Secretary for Policy, Department of Labor, March 10, 1992.

3. Graham, John D., Bei-Hung Chang, and John S. Evans, "Poorer is Riskier," *Risk Analysis*, vol. 12, No. 3, 1992.

4. Fisher, A., L. Chestnut, and D. Violette, "The Value of Reducing Risk of Death: A Note on New Evidence," *Journal of Policy Analysis and Management*, vol. 8, No. 1, 1989.

5. RTI, "Estimating Health Benefits of Nutrition Label Changes," April 1991.

6. Economic Report of the President, transmitted to Congress February 19, 1992, p. 327, U.S. Government Printing Office, Washington DC.

7. Keeney, R.L., "Mortality Risks Induced by Economic Expenditures," *Risk Analysis*, vol. 10, No. 1, 1990.

Dated: December 17, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

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Wednesday
January 6, 1993

Part V

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 101, et al.
Food Labeling; Misleading Containers; Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 91N-384H]

RIN 0905-AD08

Food Labeling: Nutrient Content Claims, Definition of Term: Healthy

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its food labeling regulations to establish a definition for the term "healthy" under the Federal Food, Drug, and Cosmetic Act. Elsewhere in this issue of the **Federal Register**, the agency is publishing a final rule to revise 21 CFR part 101 which establishes provisions for general principles, petitions, and definition of terms for nutrient content claims. This proposal will provide a definition for the implied nutrient content claim "healthy" for individual foods and for meals and main dish products and provide for its use on the food label. This action is in response to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments).

DATES: Written comments by March 8, 1993. The agency intends that any final rule that may issue based on this proposal become effective on the same date as the final regulations for the General Principles for Nutrient Content Claims, promulgated under the provisions of the 1990 amendments and published elsewhere in this issue of the **Federal Register**.

ADDRESSES: Written comments may be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Elizabeth J. Campbell, Center for Food Safety and Applied Nutrition (HFS-155), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5229.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of November 27, 1991 (56 FR 60421), FDA published a proposal entitled, Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms (hereinafter referred to as the general principles proposal) that would, among other things, establish general principles for the use of claims describing the nutrient content of foods and define certain nutrient content claims and provide for their use on food labels.

In the same issue of the **Federal Register** (56 FR 60478), FDA also published a proposed rule entitled "Food Labeling: Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food" (hereinafter referred to as the fat/cholesterol proposal) to define and provide for the proper use of the nutrient content claims for fat, saturated fatty acids, and cholesterol.

Both the general principles proposal and the fat/cholesterol proposal were issued in response to the 1990 amendments (Pub. L. 101-535). With respect to nutrient content claims, the 1990 amendments amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 403(r)(1)(A) (21 U.S.C. 343(r)(1)(A)), which states that a food is misbranded if it bears a claim on its label or in its labeling that either expressly or implicitly characterizes the level of any nutrient of the type required to be declared as part of the nutrition labeling, unless such claim is made in accordance with section 403(r)(2) of the act.

In the general principles proposal, the agency proposed that an implied nutrient content claim is one that describes the food or an ingredient therein in such a manner that leads a consumer to assume that a nutrient is absent or present in a certain amount (e.g., "high in oat bran"), or that the food because of its nutrient content may be useful in achieving a total diet that conforms to current dietary recommendations (e.g., "healthy") (56 FR 60421 at 60423).

The agency stated that because of the large variety of statements that could be considered to make implied claims and because of the resource constraints and strict timeframes under which the rulemaking was proceeding, it was not proposing to adopt regulations that authorize any implied claims at that time. However, the agency solicited comments and information concerning specific implied claims. The agency stated that if it received sufficient information in comments, it would consider providing for specific implied claims in the final regulation. Alternatively, it said, the agency might defer action on implied claims until after the rulemaking required by the 1990 amendments was complete.

In response to the general principles proposal, the agency received a number of comments on implied claims, including some specifically on the term "healthy." Elsewhere in this issue of the **Federal Register** FDA is publishing a final rule (the general principles final rule) based on the general principles proposal and the fat/cholesterol proposal. In the general principles final rule, the agency has determined that the term "healthy" is an implied nutrient content claim when it appears on the label or in labeling in a nutritional context, that is, when it appears in association with an explicit or implicit claim or statement about a nutrient, such as "healthy, contains less than 3 g of fat." Alternatively, use of the term "healthy" when not an implied claim will be reviewed under the general misbranding privisions. Such a statement suggests that the food may be useful in maintaining healthy dietary practices. Because of the complex nature of the term, the agency has determined that it was not possible to arrive at a final regulation for a definition of the term "healthy." Therefore, the agency is proposing a definition of the term. The agency advises that it intends to make any final rule that derives from this rulemaking effective on the same date as the general principles final rule and the final rule on mandatory nutrition labeling. If for some reason, however, the final rule has not been issued, "healthy" would be subject to the general nutrient content claim requirements for implied claims or the general misbranding clause.

II. Comments and Agency Response

1. Some comments asserted that the term "healthy" may be understood by consumers in some contexts to convey an implied health claim and should, in those instances, be regulated as an implied health claim. One of these comments asserted that the extent to which the term "healthy" implies health benefits depends on the context of the entire label. The comment specifically asserted that the term "healthy," when it is standing alone or is in a brand name, definitely implies to the consumer that the food has a direct beneficial effect on one's health.

Many other comments asserted that the term "healthy" is an implied nutrient content claim. Some comments stated that the context surrounding the use of the term "healthy" frequently conveys a strong message to consumers about the nutrient content of a food. However, one of these comments further stated that the term "healthy" can also appear in a context that does not imply nutrient content. The comment urged FDA, therefore, to consider the textual use of the term when determining whether it constitutes an implied nutrient content claim.

A similar comment asserted that the term "healthy" is misleading when it appears in a brand name of a food but is combined with a descriptor (nutrient content claim) or used in a context that is susceptible to a "unique" inference (e.g., "Healthy One"). The comment stated that the implication is not only that this labeled food is healthy, but that it is the only healthy product and other products of a similar type are unhealthy. The comment supported this argument by citing the results of a poll in which people were presented with two brand names of soup and asked which soup was "better for you." The soups were equivalent in nutritional content. When presented with one brand name that contained the term "healthy" in conjunction with a descriptor implying that the product was unique and one brand name that made no reference to "health" or "healthy," 67.7 percent of the respondents stated the soup whose brand name contained "healthy" was "better for you." The comment suggested that the term "healthy" not be allowed to appear in any context that suggests that the food is uniquely "healthy" as compared to similar products, unless such a claim is true.

FDA agrees with the comments that asserted that the context in which the term "healthy" is used is a critical factor in determining whether the term constitutes an implied nutrient content claim. As discussed in the general principles final rule, FDA believes that the term "healthy" constitutes an implied nutrient content claim only when it appears in a nutritional context. Such a context is established when the term "healthy" appears in association with an explicit or implicit claim or statement about a nutrient. Accordingly, the label or labeling statement "a healthy, low fat meal" would constitute an implied nutrient content claim. Likewise, the statement "low in saturated fat" on the label of a food with the brand name "Healthy Mountain" would place the term "healthy" into a nutritional context and subject it to the provisions of section 403(r) of the act.

On the other hand, FDA believes that in a context that refers to general dietary guidance, "healthy" is not an implied nutrient content claim. For example, in the statement "eat lots of fruit and vegetables for a healthy diet," the term "healthy" does not imply the absence of a nutrient or the presence of a nutrient in a particular amount and would therefore not be a claim subject to the requirements of section 403(r) of the act.

Further, FDA is not convinced that brand names in which "healthy" appears in a phrase with a term that suggests that the product is uniquely healthy, such as "Healthy One," invariably imply that the specified product is superior to products of a similar type, or that the consumer should choose that product because it conforms to current dietary guidelines. The comment's interpretation of its survey is that some brand names that include the term "healthy" should be prohibited because of their context. However, FDA is not convinced that this interpretation of the study is appropriate. Because the study included only one sample involving "healthy," the agency has no way to distinguish between uses of "healthy" in various names. Accordingly, FDA is not granting the comment's request that "healthy" not be allowed to appear in a context that suggests that the food is uniquely healthy. FDA will evaluate such uses of the term on a case-by-case basis and take appropriate action if a particular use is false or misleading.

In addition, FDA advises that a statement containing references to both nutrient levels and a disease or health-related condition would constitute a health claim. As discussed in the final rule on general principles for health claims, published elsewhere in this issue of the **Federal Register**, a health claim is made when a label or labeling statement refers explicitly or by implication both to a nutrient present in the food and to a disease or health-related condition. The agency does not believe that the term "healthy" inherently implies that a food contains certain nutrients, or that the term inherently implies that the consumption of the product may reduce the risk of a disease or health-related condition. Instead, such implications are likely to be made only if the term "healthy" is accompanied by additional language or graphic material (e.g., logos, symbols, vignettes) that explicitly or implicitly suggests both a disease-related benefit and a nutrient context. For example, the statement "a low fat, heart-healthy food" on a food label or labeling implies that the food is useful in reducing the risk of heart disease because of its low fat content and would, therefore, be considered an implied health claim.

Consequently, the agency concludes that when the term "healthy" appears on a food label without the additional label statements that render it either a health claim or a nutrient content claim, it is not subject to the requirements of section 403(r) of the act. Instead, under such conditions, the use of the term "healthy" is subject to section 403(a) of the act, and whether it is misleading will be determined on a case-by-case basis. However, FDA advises that even though it is not establishing a regulation on use of the term "healthy" on labels and in labeling of foods under section 403(a) of the act, it believes that there are some foods on which the term would be misleading. These include foods in which the level of a nutrient exceeds the disclosure level established in new § 101.13(h) published elsewhere in this issue of the **Federal Register**. The agency considers that it is misleading for a label to include the term "healthy" when the food contains a nutrient at a level such that the food would not assist consumers in maintaining healthy dietary practices.

FDA seeks comment on whether it should adopt a regulation using its authority under the general misbranding sections of the act (201(n) (21 U.S.C. 321(n)), 403(a), and 701(a) (21 U.S.C. 371(a))), that provides further guidance on the circumstances under which use of the term "healthy" might be false or misleading and thus misbrand the product. The agency is concerned that when a label bears the term "healthy," even in the absence of statements that render the term an implied claim subject to the requirements of section 403(r) of the act, its implications about the consequences of consumption of the food will be misleading unless the food complies with some understood criteria. If comments support adopting such a regulation, FDA will consider doing so in the final rule that results from this proposal.

2. Some comments asserted that the term "healthy" should either be clearly defined or be prohibited to ensure that the term is used consistently and truthfully. Others asserted that the word "healthy" should be prohibited on food labels because it is misleading to consumers. One of these comments asserted that establishing a definition for "healthy" is impractical because what is "healthy" for one individual is not necessarily "healthy" for another. The comment noted that many of the nutritional needs of children are markedly different than the needs of adults. The comment also asserted that the scientific understanding of "healthy" is continually evolving.

Many comments suggested that the agency should define the term "healthy." A comment from industry stated that the term "healthy" should be defined to curtail the wide variety of products that are marketed as "healthy," when in fact the benefits that they provide in comparison to benchmark products are minimal. One comment asserted the agency should define and allow the use of the term "healthy" to give manufacturers who wish to use the term an incentive to improve the nutritional quality of their products.

One comment asserted that use of the word "healthy" as a descriptor should be encouraged and facilitated because it allows an evaluation of a total product, while it precludes unjustified focus on one nutritive aspect. The comment stated that promulgation of a standard will ensure a quality product, used in an informed way, by a consumer who has accurate information and justified reliance on the product as labeled.

A number of comments stated that there is little or no consistency in the way the term "healthy" is used in the marketplace today. One of these comments asserted that the term is used to describe a low sodium content in some instances and a low fat or saturated fat content in others. The comment noted that some products described as "healthy" may in fact contain a low level of one of these nutrients but still contain high levels of another (e.g., a peanut butter which contains less sodium than other brands but just as many calories and just as much fat). The comment further noted that, in some instances, the nutrient of concern is actually present in greater amounts than it is in similar products that are not described as "healthy" (e.g., one brand of frozen desserts labeled as "healthy" contains more sodium than regular ice creams and more fat than fat free ice creams). Another comment pointed out that the term "healthy" is also understood by some consumers to indicate that a food is free of pesticides.

Some comments stated that the uncontrolled use of the term "healthy" diminishes consumer confidence in FDA and in the truthfulness of the food label. One of these comments cited the results of a national survey conducted in February 1992, in which 1,007 individuals were interviewed concerning their interpretation of the word "healthy" as it appears on food labels. The comment reported that when asked what the word "healthy" on a food label says about an unspecified product, 33 percent responded that it means nothing, 24 percent responded that it means the product is good for you, 9 percent responded that it is an advertising ploy. Additionally, 9 percent of the respondents indicated that they don't believe that the product is actually healthy.

Several comments objected that the grandfathering of brand names that include the term "healthy" would create additional confusion in the marketplace. Some of these comments stated that unevenly restricting usage of the term "healthy" would allow one company to use a term like "healthy" in a brand name and preclude other manufacturers with equivalent or superior products from using the term. One comment also asserted that allowing the use of the term "healthy" through the grandfathering process would perpetuate a "good food/bad food" distinction. Another comment stated that such a policy would allow manufacturers of products with grandfathered brand names to continue to mislead consumers. One comment stated that leaving the term "healthy" undefined allows companies that used the claim in brand names before October 25, 1989, to continue using the term on foods that may not meet appropriate standards.

Some comments encouraged FDA to define "healthy" in a separate supplemental proceeding on an expedited basis, with an effective date that coincides with other implementing regulations. One comment suggested that such a rulemaking be done in conjunction with the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service.

FDA has carefully reviewed these comments and tentatively concludes that a definition of the term "healthy" should be included in the implied nutrient content claim regulations. The number and variety of comments received in response to the appearance of the term "healthy" in the proposed definition of "implied nutrient content claim" has made the agency aware of the overwhelming interest that both consumers and industry have in regulating the use of this term. The agency agrees with those comments that asserted that there is little consistency in the way the term "healthy" is currently used in the marketplace and is concerned that this inconsistency is confusing to consumers. Because concern over the use of the term "healthy" is so great, and because there is a wide divergence of opinion on appropriate criteria, the agency is proposing a definition for this term.

In reaching this tentative conclusion, FDA considered the option of not defining the term "healthy." Under section 403(r)(2)(C) of the act, all undefined nutrient content claims will be prohibited except when they appear in the brand names of products that were initially marketed before October 25, 1989. Thus, if FDA did not define "healthy," it could continue to be used in grandfathered brand names as long as such use was not false or misleading under section 403(a) of the act. This would have meant that the inconsistent use of this term among grandfathered brand name foods would also continue. The agency believes that the situation that would have resulted would not only not be in the interest of consumers but would be inequitable, because one product would be able to bear the claim but a nearly identical product could not. (The agency emphasizes that this discussion does not apply to uses of "healthy" that are not implied nutrient content claims.)

FDA tentatively concludes that a more appropriate resolution to the problems cited by the comments is to define the term "healthy." The agency believes that, by providing a definition, it will ensure that the term is used consistently by various manufacturers, and that all manufacturers who market similar products are able to use the term "healthy" if the product meets the definition.

3. Some comments asserted that the term "healthy" is more appropriately applied to overall diets which include fresh fruits, vegetables, low fat dairy products, and grains rather than an individual food or "meal/main dish" product. These comments suggested that FDA prohibit the use of the term on food labels. One such comment stated that allowing the use of the term "healthy" on individual foods contradicts the Department of Health and Human Services and USDA "Nutrition and Your Health, Dietary Guidelines for Americans" 1990 (Dietary Guidelines) which states that almost any food that supplies calories and nutrients can be incorporated into a nutritious diet, and that it is the overall diet that is significant. While most comments that discussed "healthy" did not distinguish between its use on individual foods and its use on meals and main dishes, other comments asserted that allowing individual foods to be described as "healthy" perpetuates a "good food/bad food" image. A comment from a foreign government advised that its policy is not to allow food products to be described as "healthy," although their labeling may bear statements that the food can be consumed as part of a healthy overall diet. Another comment expressed concern that the representation of single foods or "meal/main dish" products as "healthy" could easily lead a consumer to over consume those products rather than consuming a variety of foods and thereby reduce the nutrient quality of his/her diet.

The agency tentatively concludes that it should not limit the use of the term "healthy" to reference the total diet. FDA believes that foods labeled with the term "healthy," whether they are individual foods, main dishes, or meals, can be used with a variety of foods to assist consumers in maintaining healthy dietary practices, that is, to achieve a total diet that conforms to current

dietary guidelines. One of the goals of the 1990 amendments was to encourage manufacturers to provide a wider selection of foods with improved nutrient content to facilitate diets that conform to guidelines. The agency tentatively concludes that appropriate criteria for use of the term "healthy" can be established to both encourage innovation and ensure that the term is not misleading.

While FDA is proposing a definition for "healthy" that includes the same criteria for all types of foods, the agency requests comments on whether it is more appropriate to establish criteria for the use of "healthy" on individual foods that are different from those for meals and main dishes, or whether use of "healthy" should be limited to meals and main dishes. Comments should suggest criteria appropriate for the recommended use and include data or other information to substantiate their recommendations.

4. The agency received numerous comments that suggested definitions for use of the term "healthy" on food labels. Several of those comments addressed the issue of what the term "healthy" is understood to mean or should be defined to mean when it appears on food labels. One comment stated that consumers associate the term "healthy" with fat, saturated fat, cholesterol, and sodium. The comment cited the results of a national survey that showed that 81 percent of the respondents thought that a food labeled as "healthy" was low in sodium and fat, 79 percent thought it was low in cholesterol, and 74 percent thought it was low in saturated fat and calories. Many of the comments that offered definitions for the term "healthy" included requirements for the levels of fat, saturated fat, cholesterol, and sodium. One of these comments stated that foods labeled with the term "healthy" should contain no more than 30 percent calories from fat, 10 percent calories from saturated fat, 60 milligrams (mg) or a significantly reduced amount of cholesterol, and 480 mg or a significantly reduced amount of sodium. A few comments suggested that FDA allow the term "healthy" to appear on foods that do not contain nutrients at levels exceeding the disclosure levels for sodium, fat, saturated fat, and cholesterol. Many comments asserted that a product labeled as "healthy" should additionally be "low" in at least one of these nutrients.

Many other comments suggested a stricter definition of "healthy" that would require that a product meet the "low" definition for sodium, fat, saturated fat, and cholesterol. Some comments also suggested additional criteria that a "healthy" product should be required to meet. One of these comments suggested that such a product be "low" in calories. Another suggested that such a product meet the "low" definition for sugars.

The agency has evaluated these comments. It tentatively agrees with those comments that stated that FDA should define the term "healthy" in a way that restricts the levels of those nutrients whose consumption should be limited in the total daily diet to levels that do not exceed the Daily Reference Values (DRV's) for those nutrients. The agency also tentatively agrees with those comments that suggested that the definition for "healthy" should focus on restrictions for fat, saturated fat, sodium, and cholesterol because these nutrients are of particular significance to public health. High intake of total dietary fat is associated with increased risk for obesity, some types of cancer, and possibly gall bladder disease. Excessive saturated fat consumption is a major contributor to total blood cholesterol levels, and the consumption of dietary cholesterol also contributes to total blood levels. An extensive body of evidence has established a relationship between high blood cholesterol and increased coronary heart disease. Accordingly, many health organizations have made recommendations for modifying dietary intake of fat, saturated fat, and cholesterol for the purpose of improving the public health (56 FR 60478 at 60482). According to the Dietary Guidelines, excessive dietary intake of sodium is one of several factors that may increase the risk of hypertension in some individuals. Hypertension currently affects one in three Americans and is associated with heart disease and stroke when uncontrolled (56 FR 60825 at 60834).

The agency has tentatively concluded that a definition of "healthy" that allows the term to appear on foods that contain amounts of fat, saturated fat, sodium, and cholesterol above the disclosure level would not assist consumers in maintaining healthy dietary practices and could result in an overall diet inconsistent with current dietary guidelines. Accordingly, FDA has tentatively concluded that a definition of "healthy" that permits levels of fat, saturated fat, sodium, and cholesterol that are above the disclosure levels would not be approiate. FDA believes that labeling of such products as "healthy" would be misleading to consumers.

Likewise, the agency is concerned that a definition of "healthy" that requires that a food be "low" in fat, saturated fat, sodium, and cholesterol may be too restrictive. Such a definition could disqualify many products that would be useful in maintaining a diet that conforms to current dietary guidelines. FDA also believes that although restricting the percentage of calories derived from fat and saturated fat to no more than 30 percent and less than 10 percent, respectively, is appropriate for overall diets, it is not appropriate for individual foods and is, therefore, not appropriate as a criterion for "healthy" on individual foods. However, as discussed in the general principles final rule in the definition for "low fat" and "low saturated fat" for meal and main dish products, no more than 30 percent of calories from fat and less than 10 percent of calories from saturated fat are used as a second criterion for the definitions for "low fat" and "low saturated fat," respectively. Therefore, under this proposal the criterion of no more than 30 percent of calories from fat or less than 10 percent of calories from saturated fat will apply to meal and main dish products bearing the term "healthy."

FDA is therefore proposing to amend new § 101.65 by redesignating paragraph (d) as paragraph (d)(1) and by adding new paragraph (d)(2) which provides that for the purposes of new § 101.65, the term "healthy" may be used to describe foods that do not exceed the disclosure level for sodium or cholesterol and are "low" in fat and saturated fat. This proposed definition of "healthy" limits fat and saturated fat in a "healthy" food because of the recommendations from leading health authorities that lowered consumption of fat and saturated fat is of importance in reducing the risk of certain diet-related diseases that are discussed above.

The agency believes that the foods that will be able to bear the term "healthy" under this definition will be of a sufficient number and variety to help consumers achieve a total diet that is consistent with current dietary recommendations.

FDA specifically solicits comments for evaluating whether this definition of "healthy" is appropriate.

The agency requests comments on whether the definition for "healthy" should include a requirement that the food be "low" in a third nutrient, i.e., cholesterol or sodium. Among other things, comments should address: whether a "low cholesterol" criterion is needed; if such a requirement is included in the definition will such foods as shellfish and crustaceans qualify to be labeled "healthy;" should such foods be labeled "healthy" in light of their cholesterol content?

In addition, comments should consider whether a "low calorie" criterion should be a part of the definition of "healthy." The agency has not included a calorie criterion in its proposed definition because there was not enough information in comments for FDA to determine that such a criterion is needed. However, dietary guidelines recommend that Americans maintain appropriate caloric intake for their body weight, and that overweight is a major public health problem. In light of these facts, FDA is seeking comment on what, if any, calorie criterion should be included. Should calories be a part of a requirement for a third nutrient at a "low" level, i.e., the food must be "low" cholesterol, sodium, or calories in addition to fat and saturated fat? Alternatively, should a "low calorie" criterion be required in addition to "low" in cholesterol or sodium?

FDA acknowledges that the definition of the term "healthy" that it is proposing in this document differs from the definition for the term proposed elsewhere in this issue of the **Federal Register** by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS), which regulates the labeling of meat and poultry products. The Dietary Guidelines for Americans recommend choosing lean meat and poultry as part of a balanced diet. The agency requests comments on whether a definition of healthy which excludes lean meat and poultry will help consumers to achieve a total diet that is consistent with current dietary recommendations. Comments should suggest appropriate criteria for a single definition for all foods or separate definitions for foods of animal origin such as meat and poultry and provide rationale and other information to substantiate their suggestions. The agency also requests comment on whether it is necessary that the two agencies provide uniform criteria for use of this term or whether different definitions may be appropriate.

5. Some comments suggested that a product labeled as "healthy" should provide key nutrients in addition to being "low" in sodium, fat, saturated fat, and cholesterol. Another such comment specified that the product should be "high" in two of the four micronutrients (i.e., Vitamin A, Vitamin C, calcium, and iron). Another of these comments suggested that a "healthy" food contain either at least 5 percent of the Reference Daily Intake (RDI) of at least two vitamins or minerals required to be included in the nutrition label or at least 10 percent of the RDI of at least one such vitamin or mineral. One such comment suggested that FDA require that the food provide 10 percent of the reference levels of fiber and two other vitamins or minerals. The concept that a definition for the term "healthy" should include a requirement for fiber was also supported by the results of the national survey that is discussed above in greater detail. That survey found that 72 percent of the respondents believed that the term "healthy" implied that the food was a source of fiber.

FDA specifically requests comments on the appropriateness of including a requirement in the definition of "healthy" that the food supply a certain amount of specified essential vitamins, minerals, or other nutrients (e.g., protein). There is not significant agreement among the comments as to the specific nutrients that should be included in such a requirement. The agency does not believe that it currently has enough information to conclude that such a requirement would be useful if a definition for use of the term "healthy" were to be adopted.

6. Some comments specifically addressed use of the term "healthy" to describe meals and main dish products (referred to in the general principles proposal as meal-type products). One comment suggested that the term "healthy" be allowed to appear in the labeling of a meal-type product that contains not more than 19 grams (g) of fat, 6 g of saturated fat, 75 mg of cholesterol, or 600 mg of sodium per product. The comment also stated that these criteria would reflect 25 percent of the proposed DRV for each of the nutrients and would provide an adequate amount of nutrients when considering that consumers have approximately four important eating occasions on a daily basis.

Another comment asserted that in addition to nutrient criteria, the use of the term "healthy" to describe meal products should be restricted to foods that: (1) Provide at least 500 calories per serving, and (2) are composed of foods from at least three of the major food groups.

After reviewing these comments, the agency has tentatively concluded that there is a need to provide for use of the term "healthy" to describe the levels of multiple nutrients in a meal or main dish product.

FDA tentatively agrees with those comments that suggested that the definition for "healthy" on meals and main dish products should focus on restrictions for fat, saturated fat, sodium, and cholesterol, because these nutrients are of particular significance to public health. Moreover such a definition is consistent with the definition of "healthy" that FDA is proposing for individual foods. The agency does not agree, however, with the comment that suggested that the definition for "healthy" on meal products should be restricted to those products that provide at least 500 calories per serving and are composed of foods from at least three of the major food groups. Such a criterion would preclude many products that otherwise meet the requirements for "healthy" and are beneficial in assisting consumers in maintaining diets within current dietary guidelines from bearing a "healthy" claim. Thus, the agency has tentatively concluded that the proposed definition for "healthy" on individual foods can also be applied to meal and main dish products, because, as discussed in section II. of this document (comment 4) such a definition places emphasis on the limitation of fat and saturated fat in a "healthy" meal or main dish product. Therefore, the proposed definition conforms to recommendations from leading health authorities to limit total daily consumption of fat and saturated fat. Accordingly, FDA is proposing to define the term "healthy" in new § 101.65(d)(2) to describe a meal product as defined in new § 101.13(l) or main dish product as defined in new § 101.13(m) that meets the definition for "low" for fat and saturated fat and that does not exceed the disclosure level for cholesterol or sodium.

The agency believes that the meal and main dish products that will be able to bear the term "healthy" under this definition will be of a sufficient number and variety to help consumers achieve a total diet that is consistent with current dietary recommendations. FDA specifically solicits comments for evaluating whether this definition of "healthy" is appropriate for meal and main dish products.

In addition, as discussed in the general principles final rule, because of the unique nature of restaurant foods, the agency requests information on the extent to which such a definition for "healthy" would be appropriate for meals, main dishes, and individual foods served in restaurants. Specifically, the agency requests information on: (1) Whether such foods have characteristics which would make such a definition for "healthy" difficult to meet, and (2) if a different definition for "healthy" on such foods would be confusing to consumers.

7. One comment requested that FDA specifically include in the language of the regulation on "healthy" that a food need not be specially processed, altered, formulated, or reformulated to qualify for use of the term on its labeling.

The agency advises that the requirement that a food be specially processed, altered, formulated, or reformulated compared to other foods applies to "free" and "low" claims (new § 101.13(e)). The requirement is triggered when these claims appear before the name of the food to prevent the consumer from being led to believe the product differs from others of that type when that is not the case. FDA is not aware of a similar use of the term "healthy." The comment did not provide information on or examples of misleading labels. Therefore, the agency tentatively concludes that a provision similar to that in new § 101.13(e) is not needed for "healthy." However, it requests comments on this issue. If information in comments demonstrates that such a provision is warranted, FDA will consider including it in the final regulation.

III. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the Federal Register of November 27, 1991 (56 FR 60656), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the Federal Register. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (address above), and a notice will be published in the Federal Register announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

Because any changes that result from this proposal will not need to be made until the same date as the other changes required by the nutrient content claims final rule (May 8, 1994), this proposal will not add any additional meal costs to those considered in the RIA.

IV. Environmental Impact

The agency previously considered the environmental effects of the action being taken in this final rule. As announced in its nutrition labeling proposed rules published in the Federal Register of November 27, 1991 (56 FR 60366 et al.), the agency determined that under 21 CFR 25.24(a)(8) and (a)(11), these actions are of a type that do not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

V. Request for Comments

Interested persons may, on or before March 8, 1993, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.65 is amended by adding new paragraph (d)(2) to read as follows:

§ 101.65 Implied nutrient content claims and related label statements.

* * * * *

(d) * * *

(2) For purposes of this section, the term "healthy" may be used on the label or in labeling of a food, including a meal as defined in § 101.13(l) or a main dish as defined in § 101.13(m), provided:

(i) It meets the definition of "low" for fat and saturated fat;

(ii) Neither cholesterol nor sodium is present at a level exceeding the disclosure levels as described in § 101.13(h) for an individual food, meal product, or main dish product, as appropriate; and

(iii) The food complies with definitions and declaration requirements established in this part for any specific nutrient content claim on the label or in labeling.

Dated. October 26, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 101, 102, and 161

[Docket No. 90N-361M]

RIN 0905-AD08

Food Labeling; Declaration of Ingredients—Common or Usual Name Declaration for Protein Hydrolysates and Vegetable Broth in Canned Tuna; "and/or" Labeling for Soft Drinks

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to: (1) Amend the standard of identity for canned tuna (21 CFR 161.190) to require the term "(includes soybeans)" as part of the name used to declare the ingredient vegetable broth when soybeans are one of the vegetable extractives used to make the vegetable broth; (2) amend the common or usual name regulations for protein hydrolysates (new § 102.22) to require the term "contains glutamate" as a part of the common or usual name of autolyzed yeast extracts and certain hydrolyzed proteins; and (3) amend the food labeling regulations in § 101 4 (21 CFR 101.4) to allow "and/or" labeling for the declaration of sweeteners in soft drinks. These proposed requirements are in response to issues that were raised in comments to the proposed rule on ingredient labeling that was published in the **Federal Register** of June 21, 1991 (56 FR 28592).

DATES: Written comments by March 8, 1993. The agency proposes that any final rule that may issue based on this proposal, become effective May 8, 1994.

ADDRESSES: Written comments may be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Elizabeth J. Campbell, Center for Food Safety and Applied Nutrition (HFS-155), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5229.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 21, 1991 (56 FR 28592), FDA published a proposed rule (hereinafter referred to as the 1991 ingredient labeling proposal) to implement certain amendments to the Federal Food, Drug, and Cosmetic Act (the act) that were made in section 7 of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101-535). These amendments require the listing of the ingredients of standardized foods and the declaration of certified color additives in foods. In the 1991 ingredient labeling proposal, FDA also proposed other actions concerning ingredient labeling in response to written and oral comments received on an advance notice of proposed rulemaking published in the **Federal Register** of August 8, 1989 (54 FR 32610), as part of the food labeling initiative of the Secretary of the Department of Health and Human Services. The agency received over 700 letters in response to the 1991 ingredient labeling proposal, each containing one or more comments. Elsewhere, in this issue of the **Federal Register**, the agency is publishing a final rule (the declaration of ingredients final rule) responding to the majority of those comments. However, some comments to the 1991 ingredient labeling proposal presented new information on two matters that the agency had addressed in the 1991 ingredient labeling proposal: the declaration of glutamate when a component of certain protein hydrolysates and the use of "and/or" labeling for sweeteners in soft drinks. Other comments raised a new issue that had not been addressed in the 1991 ingredient labeling proposal: the declaration of vegetable extractives in vegetable broth in canned tuna.

After reviewing the information provided in these comments, as well as other information available to the agency, FDA has tentatively concluded that additional labeling requirements are necessary and appropriate to ensure that ingredient labeling with regard to these issues is accurate, not misleading, and assists the consumer in making informed purchase decisions. With respect to each of the three issues, however, FDA has concluded that it would not be appropriate to simply include the regulations that it is proposing in the final rule on declaration of ingredients. The agency had not specifically addressed the appropriate declaration of the vegetable extractives in vegetable broth when present in canned tuna in the 1991 ingredient labeling proposal. Moreover, in that proposal, FDA had flatly asserted that declaration of glutamate would not be possible, and its only action with regard to the use of "and/or" labeling of sweeteners in soft drinks was to deny a longstanding petition. Thus, the agency determined that the best approach to addressing these issues was to publish a proposed rule and to permit an opportunity for comment on its tentative decisions to establish additional labeling requirements with regard to these three matters.

II. The Proposal

A. Declaration of Soybeans as Ingredients of Vegetable Broth Used in Canned Tuna

The standard of identity for canned tuna (§ 161.190 (21 CFR 161.190)) permits the inclusion of several optional ingredients. One of the optional ingredients provided for in § 161.190(a)(6)(v) is designated as "vegetable broth" and is permitted to be declared in the ingredient list as "vegetable broth." As required by the standard, vegetable broth consists of two or more of the vegetable extractives as specified in § 161.190(a)(6)(v). In accordance with the 1990 amendments, FDA proposed in the 1991 ingredient labeling proposal to amend the standard of identity for canned tuna (56 FR 28592 at 28634) to require that all mandatory and optional ingredients be declared in the ingredient list in accordance with the requirements of the applicable sections of parts 101 and 130 (21 CFR parts 101 and 130). Previously, only declaration of optional ingredients in standardized foods was required by the act

One comment interpreted the agency's implementation of the 1990 amendments to mean that FDA will require the listing of each vegetable that is in the vegetable broth in the order of predominance parenthetically following the term "vegetable broth" in the ingredient statement on the label of canned tuna. The comment stated its opposition to this approach. In support of its position, the comment pointed out that this method of listing the ingredients comprising vegetable broth in canned tuna would "intensify label crowding" and "create confusion as to whether or not whole pieces of vegetables are contained therein." This comment also stated that FDA should not require the listing of the components of vegetable broth in canned tuna.

As discussed in the declaration of ingredients final rule, FDA agrees that the listing of each ingredient comprising vegetable broth on the label of canned tuna could be lengthy and cumbersome. Furthermore, as stated above, the standard of identity for canned tuna permits the ingredient vegetable broth to be listed as "vegetable broth." Hence, the new regulations do not require full declaration of all of the ingredients of which the vegetable broth is comprised.

However, the agency notes that some manufacturers have interpreted the provision in § 161.190(a)(6)(v) that permits the use of "beans" as one of the vegetables extractives in making the vegetable broth used in canned tuna as including soybeans (Ref. 57). Soybeans generally are not classified as "vegetables" but as grains and belong to the general category of oilseeds. Thus, it is not likely that the term "vegetable broth" would be understood by most consumers to be a product that has been made from soybeans. Because some individuals have food sensitivities (including possible life-threatening reactions) to soy proteins (Ref. 58), consumers should be informed of the presence of soybean extractives in the broth. Therefore, FDA is proposing to amend the standard of identity in § 161.190(a)(8)(vi) to require that when soybeans are used in vegetable broth, this fact be declared parenthetically following the listing of "vegetable broth" in the ingredient statement of the label, as follows: "vegetable broth (includes soybeans)". If the vegetable broth serves as a flavor and has no flavor enhancing function in the food, the vegetable broth containing soybean extractives will be listed in the ingredient statement as "flavoring (includes soybeans)." (In the declaration of ingredients final rule the agency discusses its conclusions with respect to the functional effect of vegetable broth as a flavoring or flavor enhancer when used in canned tuna and the appropriate label declarations for such use.)

The proposed requirement to list soybeans as a constituent of vegetable broth is consistent with FDA's past policy regarding the listing of soybeans on canned tuna labels. In a letter to Protein Technologies International, FDA stated that when soybeans are used in the vegetable broth, their presence must be identified parenthetically following the term vegetable broth because of possible allergic reactions in some individuals to soy proteins (Ref. 57). FDA continues to believe that such information is essential to individuals with sensitivities to soybeans, and that the industry should continue to list soybeans on the label when it is contained in the vegetable broth.

FDA encourages, where practicable, the full disclosure of all ingredients on the labels of food products to promote clarity and to prevent confusion and misunderstanding on the part of consumers. The agency believes that listing of all the components of vegetable broth would be informative and useful to consumers.

B Label Declaration of Glutamate as a Component of Protein Hydrolysates

FDA stated in the 1991 ingredient labeling proposal that the agency was not aware of scientific evidence establishing that monosodium glutamate (MSG) causes severe adverse or life-threatening reactions (56 FR 28592 at 28600). Therefore, the agency tentatively found that there was no public health basis for requiring the declaration of free glutamates (i.e., salts of free glutamic acid such as MSG, monopotassium glutamate, etc.) that occur as components of protein hydrolysates.

Many comments to the ingredient labeling proposal urged the agency to reconsider its position and require declaration of the MSG component in protein hydrolysates for health reasons. (The agency notes that the glutamic acid portion of a protein hydrolysate may be present as salts other than the monosodium salt. Hence, the agency will use the generic term, "glutamate," to refer to all the salts of glutamic acid.) Most of these comments alleged that many people have allergic reactions, food intolerance, or sensitivity to glutamate and, therefore, want to avoid consumption of any amount of glutamate in food. One comment stated that its request for declaration of glutamate in hydrolyzed protein was based on some of the same information on which the agency had relied. The comment disagreed, however, with the agency's conclusion that glutamate as a component of a protein hydrolysate is safe. The comment also disagreed with the agency's belief that there is no scientific evidence to support a finding that glutamate in such amounts as may result from the hydrolysis of a protein can cause or trigger an allergic reaction, food intolerance, sensitivity, or any other measurable adverse health effect.

The agency disagrees with these comments. As the agency indicated in the 1991 ingredient labeling proposal, there is some evidence in case reports and in the scientific literature that dose-dependent, mild reactions to glutamate occur in a limited portion of the population. However, no verifiable scientific data have been presented to the agency that establish that low doses of glutamate, as found in protein hydrolysates, cause severe adverse or allergic reactions in sensitive individuals. Further, none of the comments provided scientific data to support allegations of allergic reactions, food intolerance, or sensitivity responses due to the ingestion of glutamate as a component of protein hydrolysates.

Thus, there is no public health basis for requiring declaration of glutamate present in a food as a component of hydrolyzed protein and the agency's tentative decision to require the declaration of glutamate is not based on any failure of the labeling to reveal material facts regarding consequences that may result from the customary or usual use of the ingredient.

However, some comments to the 1991 ingredient labeling proposal raised other issues not related to public health concerning the declaration of glutamates. These comments urged that FDA require declaration of the glutamate component in protein hydrolysates because of public confusion, misunderstanding, and suspicion caused by lack of informative labeling of protein hydrolysates. Most of the comments expressed concern that foods that do not have glutamate declared in the ingredient label or are labeled "no added MSG" do indeed contain some form of glutamate. Several comments stated that MSG could conceivably be a component of any ingredient in the finished food. Other comments stated that all protein hydrolysates, regardless of the degree of hydrolysis, contain high levels of glutamate. Finally, some comments indicated that consumers believe manufacturers add protein hydrolysates that contain high levels of glutamate to food but do not declare the presence of glutamate on the label.

FDA did not consider these issues in the 1991 ingredient labeling proposal. After evaluating the information presented in these comments, FDA has tentatively concluded that the phrase "(contains glutamate)" is necessary to describe adequately the basic nature of certain protein hydrolysates and, thus, is proposing that this phrase be part of the common or usual name of certain protein hydrolysates.

The agency has tentatively decided to define specific situations (i.e., when the protein hydrolysate used is an autolyzed yeast extract or a highly hydrolyzed protein hydrolysate) in which the label declaration of free glutamate formed during the production of protein hydrolysates is required.

The tentative decision to require declaration of glutamate as a component of certain protein hydrolysates is in response to information reviewed by the agency that suggests that the proposed common or usual name for protein hydrolysates used for flavor-related purposes does not accurately describe the basic nature or characterizing properties of the ingredient. Specifically, some protein hydrolysates with high levels of glutamate are

functionally equivalent to MSG when added to food, while other protein hydrolysates, added to food for nonflavor related purposes, contain inadequate levels of glutamate to mimic MSG in food.

Literature reviewed by the agency (Ref. 4) indicates that protein hydrolysates from different sources may contain very different levels of free glutamate based on the amino acid profile of the source protein and the degree of hydrolysis of the protein hydrolysate. These technical differences are important in deciding which protein hydrolysates will be used in which foods.

Two basic methods for producing protein hydrolysates used for flavor-related purposes were identified in the 1991 ingredient labeling proposal (56 FR 28592 at 28596): Acid hydrolysis and enzyme hydrolysis (including hydrolysis by endogenous proteolytic enzymes as occurs in the preparation of autolyzed yeast extract). The high degree of hydrolysis that occurs as a result of the acid digestion of the source protein results in a 75 to 95 percent free amino acid content. Enzyme hydrolysis, on the other hand, is less complete, and the resulting free amino acid content can be as little as 45 percent (Ref. 4).

The major contributors to the flavor and flavor enhancement properties of protein hydrolysates are the many amino acids and their derivatives (Ref. 4). Glutamic acid, although well-known for its flavor enhancing properties, is only one of several amino acids contributing to the desirable flavor profile of a hydrolyzed protein. Nevertheless, it is the predominant amino acid in all of the protein sources currently subjected to hydrolysis for flavor-related uses (i.e., autolyzed yeast extracts and highly hydrolyzed proteins) (Ref. 4). Furthermore, data show that, as the free glutamate component of the protein hydrolysate is increased, the effectiveness of the protein hydrolysate as a flavor enhancer is also increased (Refs. 4, 59, and 60). Moreover, the amount of free glutamate in protein hydrolysates commonly used for flavor-related purposes is at a level such that the glutamate is capable of functioning as a flavor enhancer independently of the protein hydrolysate (Refs. 4 and 60).

The concern expressed in the comments by consumers who desire to know whether a protein hydrolysate has a significant glutamate functionality, but are unable to determine the nature of the protein hydrolysate from the information in the ingredient list, led the agency to consider further current labeling practices as they relate to commonly used levels of highly hydrolyzed proteins and autolyzed yeast extracts. In addition, the comments the agency has received on the various types of protein hydrolysates used in foods (i.e., flavor and nonflavor types) and the consumer confusion that surrounds the current terms used to declare protein hydrolysates have convinced the agency that additional provisions for common or usual name declaration of flavor type protein hydrolysates are required in the regulations to ensure that the common or usual names accurately describe the nature and characterizing properties of these ingredients.

Under the declaration of ingredients final rule, for example, both a highly and a partially hydrolyzed soy protein may be declared as "hydrolyzed soy protein." This form of declaration provides no means of distinguishing between the lightly hydrolyzed ingredient, which does not contain a level of free glutamate sufficient to cause the ingredient to function as a flavor enhancer; and the highly hydrolyzed ingredient, which does contain functionally effective free glutamate. In order to ensure that the common or usual names of protein hydrolysates used for flavor-related purposes accurately describe the basic nature of the particular ingredient and its characterizing property distinction as required by § 102.5(a), the agency tentatively concludes that the common or usual names of protein hydrolysates used for flavor-related purposes (i.e., autolyzed yeast extracts and highly hydrolyzed proteins) should include the parenthetical phrase "contains glutamate." Highly hydrolyzed proteins can be defined as those with a ratio of α-amino nitrogen (AN) to total nitrogen (TN), determined by using the tests for "Acid Hydrolyzed Proteins" set forth in the "Food Chemicals Codex", 3d ed., 1st Supp. (1983), greater than 0.62 (AN:TN ≤ 0.62) (Ref. 53). Proteins that are not highly hydrolyzed would have an AN:TN ratio of less than 0.62 (AN:TN < 0.62) and may be declared by using such terms as "partially," "mildly," or "lightly" (e.g., "Partially hydrolyzed (source) protein"), as discussed in the declaration of ingredients final rule.

Thus, FDA is proposing to require declaration of glutamate in the common or usual names of highly hydrolyzed proteins and autolyzed yeast extracts because it is essential to describe accurately the basic nature and characterizing property of the particular ingredient. The agency is proposing to add new § 102.22(b) to include this requirement. For example, a common or usual name required by this proposed regulation would be "hydrolyzed soy protein (contains glutamate)" or "autolyzed yeast extract (contains glutamate)." The agency believes that this provision will provide fully informative labeling for hydrolyzed proteins used for flavor-related purposes. It will also preclude the misleading practice, alleged in many comments, of manufacturers using protein hydrolysates as substitutes for MSG in order to circumvent the requirement that MSG be declared in the ingredient list.

The agency requests comments on its tentative decision to require "contains glutamate" as part of the common or usual name of these protein hydrolysates.

C. Use of "and/or" Labeling

The food labeling regulations allow the use of "and/or" labeling in certain situations when manufacturers are unable to adhere to a consistent pattern of use of specific ingredients in their products (§ 101.4(b)). Such labeling provides a manufacturer with the flexibility to list together in the ingredient list of a food product all the ingredients of a particular type (e.g., fats or oils) that it sometimes uses to make the product, without having to specify the ingredients that are actually present in the product. To make clear that not all of the ingredients identified are actually present, the entry in the ingredient list must include the words "or," "and/or," or "contains one or more of the following."

In the 1991 ingredient labeling proposal, the agency denied the citizen petition of the National Soft Drink Association (NSDA) (January 20, 1984—Docket No. 84P–0029) that had requested that FDA allow for the use of "and/or" labeling for sweeteners in soft drinks.

NSDA submitted a comment and additional information requesting that FDA reconsider its denial of its petition and provide for the use of "and/or" labeling for sweeteners in soft drinks. These comments maintained that the option of using different sweetener formulations (e.g., sucrose, high fructose corn syrup (HFCS), or a blend of the two), in conjunction with meeting consumer demands during peak selling periods, obtaining product labels from a national supplier, and the huge sales volume of the bottler system, necessitates the flexibility of an "and/or" labeling system. These comments asserted that, in contrast to sweeteners used in other foods, sugar and HFCS are used in soft drinks exclusively to produce desired sweetness. Furthermore, in contrast to other foods, nondiet soft drinks contain only these

two sweeteners. A single intense (i.e., artificial) sweetener is used solely in diet soft drinks. The comments did not request inclusion of intense sweeteners in "and/or" labeling. They stated that HFCS and sugar are completely interchangeable in soft drinks. One sweetener can be substituted for the other without otherwise altering the formulation or changing the order of predominance of the total amount of the two sweeteners in the ingredient label. The comments reported that, consequently, a current practice in the soft drink industry is for different bottlers of the same brand of soft drink to use different sweetener formulations (i.e., either HFCS, sugar, or a blend of HFCS and sugar) when HFCS, the primary sweetener used, is in short supply for the bottler.

Furthermore, the comments reported that the franchise company typically provides "standard copy" labels to all of the bottlers of a particular brand of soft drink. This practice ensures consistency, uniformity, and accuracy for all of a company's product labels throughout the nation. The comments asserted that because the franchise company provides labels to the bottlers, each individual bottler does not have the flexibility of using labels specific to its unique formulation of HFCS, sugar, or an HFCS-sugar blend. Without "and/or" labeling, problems with compliance may arise when these bottlers need to change their labels in response to necessary adjustments in their specific sweetener formulations. The comments contended that, furthermore, without the flexibility of "and/or" labeling, many bottlers would be forced to maintain, at a minimum, dual inventories of packages (for soft drinks packaged in cans, the label is printed on the can during can manufacture) and labels, which could not only double or triple their operating cost but also make it unlikely that soft drink can manufacturers which, commonly, already operate at 97 percent of capacity would be able to meet the demand for additional packaging.

These comments stated that even though problems of availability of HFCS do not occur routinely, situations do arise from time to time every year in many different parts of the country that necessitate altering the sweetener formulation or completely substituting sugar for HFCS. The comments stated that the demand for soft drinks is seasonal, and that there is not enough flexibility in the supply system to accommodate spot shortages of HFCS during peak demand season. They stated that there were limits to the ability to stockpile HFCS in anticipation of shortages. The storage life of HFCS is only 90 to 120 days. After that period of time, it changes color, decreases in sweetness, and is not suitable for use. Without "and/or" labeling, the flexibility of using sugar to compensate for shortages in HFCS would be lost unless multiple inventories of labels were maintained.

These comments further stated that "and/or" labeling would allow certain soft drink manufacturers to use "kosher for Passover" claims on shrink wrap, bottle lids and caps, or cardboard enclosures, without changing the ingredient label, to indicate to the consumer that the product has been sweetened with sugar rather than HFCS and meets kosher requirements. Without "and/or" labeling, bottlers wishing to market kosher soft drinks would have to obtain completely new packaging, listing only sugar in the ingredient list. The comments contended that the considerable expense associated with maintaining different packaging in order to offer a product in conformity with religious requirements would discourage bottlers from producing such products.

The comments strongly urged FDA to reconsider its position and to allow the use of "and/or" labeling of sweeteners in soft drinks.

At the time that the agency developed the ingredient labeling proposal, it was"not aware that sweetener formulations may be different for the same soft drink brand. In light of this information, FDA has reconsidered its denial of NSDA's petition on the use of "and/or" labeling for sweeteners in soft drinks. Based on its reconsideration, FDA finds substantial merit on both sides of this issue.

The petition and comments allege that a constant pattern of use of sweeteners does not exist among soft drink bottlers because individual bottlers are sometimes required to change their sweetener formulation in response to shortages in supply. FDA finds, however, that this reason does not justify establishing a provision for "and/or"labeling. The agency has traditionally dealt with such emerging shortages by informally granting temporary labeling exceptions to the manufacturers. This approach fully addresses this aspect of the problem.

The second basis for "and/or" labeling that the petition and comments assert is that different bottlers around the country use different formulas. As a result, the labels for some would need to list only HFCS in the ingredient list, the labels for others HFCS and sugar. Moreover, at Passover, a third label would be required that lists only sugar. Having to prepare and maintain three labels would add to the costs of the franchise company and would limit its ability to ensure the consistency and uniformity of its product labels throughout the nation. The individual bottlers would have the costs of maintaining a label that reflects their regular formula plus the Passover label. Thus, the question that the agency must consider is whether the additional costs to the franchise company and bottler make it impracticable for soft drinks to satisfy section 403(i)(2) of the act (21 U.S.C. 343(i)(2)) and to declare each ingredient by its common or usual name.

Granting an exemption for sweeteners in soft drinks would represent a significant departure from the circumstances in which FDA has granted "and/or" exemptions in the past. FDA has only granted "and/or" exemptions when the manufacturer has been unable to adhere to a constant pattern of ingredient use. As explained above, FDA questions whether the claim has credibly been made here. Moreover, all "and/or" labeling exemptions in § 101.4(b) have been for minor ingredients, such as leavening agents, yeast nutrients, dough conditioners, firming agents, and ingredients that are less than 2 percent of the foods. Furthermore, such "and/or" labeling exemptions are provided for these ingredients in all foods and is not restricted to a specific food type. Thus, FDA has significant concerns about the precedent that it would create by granting this exemption.

However, in the interests of advancing the administrative process in the most expeditious manner, FDA is proposing to grant the exemption. The agency is proposing to add § 101.4(b)(21) to allow the use of "and/or" labeling for sweeteners in soft drinks.

The agency wishes to make clear, however, that its final decision on the exemption will be based largely on the comments that it receives. To justify adoption of proposed § 101.4(b)(21), industry will have to produce data to demonstrate that it is in fact impracticable to produce the very limited number of versions of a label that would be necessary if an exemption is not granted. Those who oppose granting the exemptions will have to come forward with strong reasons why the requested exemption should not be granted in the face of data from the industry that establishes significant costs from strict compliance with section 403(i)(2) of the act. Is there data to show, for example, that consumers are less willing to buy a product that contains HFCS than sugar? Is there

reason to believe that the use of "and/or" labeling in this instance is to obscure the nature of the sweetener used rather than to minimize labeling costs? FDA will consider the comments that it receives.

III. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the Federal Register of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the Federal Register. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (address above) and a notice will be published in the Federal Register announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

Because any changes that result from this proposal will not need to be made until the same date as the other changes required by the other rulemakings undertaken in response to the 1990 amendments (May 8, 1994), this proposal will not add any additional costs to those considered in the RIA.

IV. Environmental Impact

The agency has previously considered, in the 1991 ingredient labeling proposal, the environmental effects of the type of action being taken in this proposed rule. No new information or comments have been received that would affect the agency's previous determination under 21 CFR 25.24(a)(8) and (a)(11) that there is no significant impact on the human environment and that an environmental impact statement is not required.

V. Effective Date

The proposed effective date of any final rule based on this proposal is May 8, 1994. FDA intends to publish the final rule on this proposal as soon as possible after the comment period to ensure that any labeling changes necessitated by the final rule can be accomplished by the proposed effective date.

VI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Congressional Record—House, July 30, 1990, H5842.
2. FDA Compliance Policy Guide 7127.01.
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21. Tollefson, L., FDA memorandum, March 12, 1990.
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23. Committee on Diet and Health, Food and Nutrition Board, Commission on Life Sciences, National Research Council, "Diet and Health, Implications for Reducing Chronic Disease Risk," National Academy Press, Washington, DC, 1989.
24. U.S. Department of Agriculture (USDA) and DHHS, "Nutrition and Your Health, Dietary Guidelines for Americans," *Home and Garden Bulletin*, No. 232, U.S. Government Printing Office, Washington, DC, 1985.
25. National Heart, Lung, and Blood Institute, "National Cholesterol Education Program Report of the Expert Panel on Population Strategies for Blood Cholesterol Reduction (Population Panel)," draft, February 2, 1990.
26. DHHS, PHS, National Institutes of Health (NIH), Office of Medical Applications of Research, "Lowering Blood Cholesterol to Prevent Heart Disease," consensus development conference statement, vol. 5, No. 7, NIH, Bethesda, MD, 1984.
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52. FDA opinion letter, Kay Holcombe, Acting Associate Commissioner for Legislative Affairs, to David Tabar, July 29, 1991.
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VII. Comments

Interested persons may, on or before March 8, 1993, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

21 CFR Part 102

Beverages, Food grades and standards, Food labeling, Frozen foods, Fruit juices, Oils and fats, Onions, Potatoes, Seafood.

21 CFR Part 161

Food grades and standards, Frozen foods, Seafood.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 101, 102, and 161 are amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.4 is amended by adding new paragraph (b)(21) to read as follows:

§ 101.4 Food; designation of ingredients.

* * * * *

(b) * * *

(21) Each individual sweetener in a soft drink (soda) shall be declared by its specific common or usual name in its order of predominance in the soft drink (soda) except that, if the manufacturer is unable to adhere to a constant pattern of nutritive sweeteners in the soft drink (soda), the nutritive sweeteners may be designated in their order of predominance in the soft drink (soda) by words indicating that the sweeteners may not be present, such as "and/or," "or," or "contains one or more of the following:".

* * * * *

PART 102—COMMON OR USUAL NAME FOR NONSTANDARDIZED FOODS

7. The authority citation for 21 CFR part 102 continues to read as follows:

Authority: Secs. 201, 403, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 343, 371).

8. Section 102.22 is amended by adding new paragraph (b) to read as follows:

§ 102.22 Protein hydrolysates.

* * * * *

(b) The parenthetical declaration "(contains glutamate)" when the protein hydrolysate is an autolyzed yeast extract, or a highly hydrolyzed protein (i.e., hydrolyzed proteins whose ratio of α-amino nitrogen (AN) to total nitrogen (TN), using the tests for "Acid Hydrolyzed Proteins" set forth in the "Food Chemicals Codex", 3d ed., First Supp. (1983), is greater than 0.62). "Hydrolyzed soy protein (contains glutamate)" or "autolyzed yeast extract (contains glutamate)" are examples of acceptable names.

PART 161—FISH AND SHELLFISH

9. The authority citation for 21 CFR part 161 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

10. Section 161.190 is amended by adding two sentences to the end of paragraph (a)(8)(vi) to read as follows:

§ 161.190 Canned tuna.

(a) * * *

(8) * * *

(vi) * * * If the vegetable extractives used in manufacturing the vegetable broth include extractives of soybeans, the designation of vegetable broth in the ingredient statement shall be followed by a parenthetical listing as follows: "vegetable broth (includes soybeans)." Alternatively, if vegetable broth containing soybean extractives serves as a flavor and has no flavor enhancing function, it may be listed in the ingredient statement as: "flavoring (includes soybeans)."

* * * * *

Dated: October 26, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 92-31527 Filed 12-28-92; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 100

[Docket No. 92N-0383]

Misleading Containers; Nonfunctional Slack-Fill

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA), in accordance with the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), is proposing to amend its regulations to define the circumstances in which a food is misbranded under section 403(d) of the Federal Food, Drug, and Cosmetic Act (the act). Among other things, the proposed regulation defines the circumstances in which the slack-fill within a package is nonfunctional and, therefore, misleading. FDA is taking this action to remedy the inadequate implementation of section 403(d) of the act.

DATES: Written comments by March 8, 1993. The agency intends to issue a final rule by May 8, 1993.

ADDRESSES: Written comments may be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Michelle A. Smith, Center for Food Safety and Applied Nutrition (HFS-158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5106.

SUPPLEMENTARY INFORMATION:

I. Background

A. Section 403(d) of the Act

Section 403 of the act (21 U.S.C. 343) defines conditions under which a food is deemed to be misbranded. Section 403(d) of the act deals with misleading containers. This section states that a food is misbranded "if its container is so made, formed, or filled as to be misleading." The misleading container provisions in section 403(d) of the act may be triggered by misleading packaging practices, misleading containers themselves, or by misleading fill. Examples of packaging and filling practices that would cause a food to be misbranded under section 403(d) of the act include: (1) Packages made of yellow cellophane that make plain or water noodles appear to be rich in egg; (2) containers formed with a false bottom, ridges, or other device whose sole purpose is to create empty space (i.e., space devoid of product) within a container; and (3) opaque packages filled to substantially less than capacity, i.e., packages containing an unnecessary amount of empty space (slack-fill) that is significant in proportion to the volume of the container, and that consumers may not be aware of when they purchase the product. The first two examples refer to containers that are "made" or "formed" as to mislead consumers regarding the quality or quantity of the contents of such container (hereinafter referred to as "deceptive packaging"). The third example refers to deceptive fill even though the net quantity of contents may be accurately stated.

B. The 1990 Amendments

The 1990 amendments (Pub. L. 101-535) provide, among other things, for the Federal preemption of certain food standards and other labeling requirements issued by a State or political subdivision of a State. Section 6 of the 1990 amendments, entitled "National Uniform Nutrition Labeling," adds new section 403A to the act (21 U.S.C. 343-1). Section 403A(a)(3) of the act prohibits States from directly or indirectly establishing any requirement for the labeling or packaging of any food in interstate commerce of the type required by sections 403(b) (offered for sale under the name of another food), 403(d) (misleading container), 403(f) (appropriate prominence of information), 403(h) (standards of quality and fill), 403(i)(1) (common or usual name), or 403(k) (declaration of artificial flavoring, coloring, or preservatives) of the act that is not identical to the requirement of such section. However, sections 6(b)(3) and 10(b)(1)(C) of the 1990 amendments provide that the six provisions listed in section 403A(a)(3) of the act do not become preemptive until FDA determines that each is being adequately implemented by Federal regulations.

To implement section 403A of the act, section 6(b) of the 1990 amendments mandates that the Secretary of Health and Human Services (the Secretary) (and, by delegation, FDA) contract for a study to determine whether the above six misbranding sections of section 403 of the act are adequately being implemented by Federal regulations. The 1990 amendments further mandate that FDA publish in the **Federal Register** lists of sections that are (or are not) being adequately implemented by Federal regulations. Finally, the 1990 amendments require that FDA propose revisions to its regulations for any sections that the agency determines are not being adequately implemented.

C. The IOM Report

In accordance with section 6(b) of the 1990 amendments, FDA entered into a contract with the National Academy of Sciences, Institute of Medicine, Food and Nutrition Board (hereinafter referred to as "the IOM") to conduct a study of State and local food labeling and packaging requirements of the types required by section 403(b), (d), (f), (h), (i)(1), and (k) of the act and to report on whether these sections of the act, and the regulations issued by FDA to enforce them, adequately implement the purposes of such sections. On April 23, 1992, the IOM submitted to FDA the final draft manuscript reporting its findings. A copy of the report, entitled "Food Labeling: Toward National Uniformity" (hereinafter referred to as "the IOM report"), is on file with the Dockets Management Branch (address above) under the above-referenced docket number. Copies of the IOM report may be purchased from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418.

Based on information collected at a public meeting (May 8, 1991), written comments to the public meeting notice, and discussions with State and local regulators, industry representatives, and consumer groups, the IOM reported that all but section 403(d) of the act (misleading container) are being adequately implemented.

The IOM report acknowledged that there was a wide divergence of views among State officials, industry, and consumer groups as to whether section 403(d) of the act is being adequately implemented. All groups that expressed an opinion to the IOM about the adequacy of implementation of 403(d) of the act felt very strongly about their position.

Industry generally supported the adequacy of implementation of 403(d) of the act. However, some State officials and consumer groups testified that the absence of Federal regulations and the small number of enforcement actions under section 403(d) of the act are evidence that this section is not being adequately implemented.

The IOM found that relatively few States have taken independent action to establish more specific requirements related to container fill or deceptive packaging. One State official testified that his State has not encountered problems with container fill and deceptive packaging, and that, if it did, section 403(d) of the act was more than adequate if enforced. Of the States with

regulations prohibiting misleading containers, two have adopted "formed or filled" language similar to section 403(d) of the act.

One State regulation cited by the IOM addresses variance from net weight which may be more relevant to section 403(e) than to 403(d) of the act. Another State regulation cited by the IOM deals with the practice of "downsizing," i.e., reducing the amount of product in a container without a substantial change in the size or shape of the container. For example, a manufacturer may decide (with an appropriate change in the declared net weight) to sell 14 ounces (oz) of coffee in a container similar in appearance to one that has traditionally held 16 oz of product. The potential problem with downsizing lies in the fact that consumers, familiar with a product and its packaging, may receive an amount of product that is less than they expect based on a history of purchases.

FDA notes that reducing the amount of product in a container without reducing the volume of the container will increase the amount of slack-fill in that container. To the extent that some portion of this slack-fill would be nonfunctional, the practice would constitute misleading fill under § 100.100, as proposed. However, proliferation of sizes, of which downsizing may be a part, comes under the jurisdiction of the Department of Commerce as provided for in section 5(d) of the Fair Packaging and Labeling Act (FPLA) (15 U.S.C. 1454). Therefore, the practice of downsizing is outside the scope of this proposed rulemaking, although the package that results is not.

Four States have chosen to issue regulations that establish specific fill-of-container provisions or that define misleading fill beyond the provisions of section 403(d) of the act. Several State officials provided the IOM with examples of packaged foods that are currently being marketed and that represent, in their view, objectionable practices that have occurred under FDA's current policies.

The IOM reported that there was disagreement among the members of the committee that it used to study about the adequacy of the implementation of 403(d) of the act. According to the IOM report, some members of the committee saw no problem with implementation of section 403(d) of the act and did not feel consumers were being disadvantaged by deceptive packaging or slack-filled containers. These members believed that the more blatant examples of misleading containers presented to the IOM could be addressed quite readily under current law. In addition, these members maintained that, because the IOM had determined that the level of enforcement activity was not a criterion in determining adequacy of implementation, new regulations should not be suggested to FDA on the basis of the level of enforcement of this section.

The IOM report stated that other committee members were impressed by the examples of packaging presented by State officials and believed that deceptive or slack-filled containers should be considered a matter of national importance. One example cited in the IOM report involved two varieties of a hot beverage mix in single-serving packages within an outer container. One variety was a "light" version of the regular mix. It contained 40 percent less product by weight but was packaged in the same size envelopes and external package as the regular mix. The IOM believed that packaging the "light" product in the same way as the regular product could potentially mislead consumers as to the quantity of food that they were purchasing. Ultimately, the IOM decided that the perception of inadequacy on the part of some State officials and consumer groups was sufficiently strong to justify a finding that section 403(d) of the act is not being adequately implemented.

D. Agency Determination of Adequacy of Implementation of Section 403(d) of the Act

In a document published in the **Federal Register** of July 28, 1992 (57 FR 33283), based on the IOM report, the agency proposed to find that of the six misbranding sections listed in section 403A(a)(3) of the act, all but section 403(d) are being adequately implemented. The document provided for the submission of comments by interested persons by September 28, 1992.

In a final rule published elsewhere in this issue of the **Federal Register**, the agency is announcing its conclusion, based on comments submitted in response to the July 28, 1992, proposal and other relevant material, that all but section 403(d) of the act are being adequately implemented. The agency notes that three of the six letters received in response to the July 28, 1992, proposal maintained that section 403(d) of the act is being adequately implemented. However, as discussed in the final rule, none of the comments provided a factual basis to support a determination that 403(d) of the act is being adequately implemented.

In its consideration of whether section 403(d) of the act is (or is not) being adequately implemented, the agency gave significant weight to evidence cited by the IOM that a number of States have addressed fill-of-container matters that are not addressed by FDA's regulations. As discussed in the final rule, FDA believes that a strong Federal regulatory system is a prerequisite of the Congressional mandate for uniformity. FDA currently has no regulations to implement the provisions of section 403(d) of the act. The agency determination that section 403(d) of the act is not being adequately implemented is discussed further in the final rule.

FDA acknowledges the lack of consensus expressed in the IOM report with respect to section 403(d) of the act (see section I.C. of this document) and in the comments to the proposed list. The agency is also concerned that, because of the time constraints imposed by the 1990 amendments, there may not have been sufficient time for interested parties to fully develop evidence to support a determination that section 403(d) is being adequately implemented.

FDA advises that, should it receive evidence during the comment period on this proposal that establishes that section 403(d) is being adequately implemented, the agency would be willing to reconsider its contrary determination. Thus, one possible outcome of this rulemaking would be a determination that section 403(d) is adequately being implemented by FDA and is thus preemptive, even in the absence of a new regulation. However, absent information to support such a finding, FDA advises that it tentatively concludes that the regulation proposed in this document would ensure adequate implementation of section 403(d) of the act.

II. The Issue of Slack-Fill

A. Introduction—The IOM Report

Most of the discussion in the IOM report, and much of the information that the IOM received, regarding the adequacy of section 403(d) of the act centered around whether consumers are being adequately protected against slack-filled containers. Furthermore, of the States cited by the IOM that have established more specific requirements than section 403(d) of the act related to misleading containers, most have chosen to focus on misleading fill.

The IOM cited the California Sherman Food, Drug, and Cosmetic Law (California Health and Safety Code Section 26437) that adopted the language of section 5(c)(4) of the FPLA as an approach for prohibiting misleading fill. The IOM also stated that no single State regulation was adequate for adoption as a Federal standard. The IOM suggested that FDA consider

promulgating regulations to prohibit misleading fill based on the definition of nonfunctional slack-fill provided for in the FPLA. The IOM report concluded that the definition of nonfunctional slack-fill in the FPLA provides FDA with a means of implementing the intent of section 403(d) of the act and suggested that FDA consider promulgating regulations to prohibit misleading fill based on that definition. In concluding that section 403(d) of the act was not being adequately implemented, the IOM did not recommend that the agency promulgate regulations with regard to the deceptive packaging ("made" or "formed" as to be misleading) provisions of section 403(d) of the act.

B. Definition of "Slack-fill"

For the purposes of this rulemaking, "slack-fill" is defined as the difference between the actual capacity of a container and the volume of product contained therein. For example, when a round or cup-shaped candy bar is packaged in a square container, the empty space in the corners of the package is considered slack-fill. In the case of cereal or potato chips, the empty space external to the bulk of the product (i.e., at the top of the bag or box) would be considered slack-fill. Slack-fill includes space within a container that is empty of product but that may contain secondary packaging materials (e.g., bag-in-box packaging, cardboard dividers, or molded plastic trays).

Air space within the bulk of the food (e.g., the space between adjacent corn flakes, the "holes" in swiss cheese, or the air in whipped cream) is generally not considered to be slack-fill, although a portion of this space could become slack-fill as some products settle. The agency tentatively concludes that interstitial space in a food that results from the physical characteristics of the food (e.g., the shape of the food particles), that would be included in any common household measure of the food (e.g., a cup of sugar or a cup of corn flakes), and that cannot be excluded from the food without changing its physical characteristics is part of the body of the food rather than slack-fill. The agency believes that it is both inappropriate and impracticable to quantify as slack-fill the interstitial space that can not be separated from the bulk of a food without altering the character of the food. The agency invites comment on this interpretation.

C. The Fair Packaging and Labeling Act

The FPLA was promulgated, in part, to elaborate on and to reinforce the misbranding provisions in section 403 of the act. In section 2 of the FPLA (15 U.S.C. 1451), Congress clearly states that "Informed consumers are essential to the fair and efficient functioning of a free market economy. Packages and their labels should enable consumers to obtain accurate information as to the quantity of the contents and should facilitate value comparisons." Section 5(c)(4) of the FPLA provides for the promulgation of regulations necessary to prevent the deception of consumers or to facilitate value comparisons of consumer commodities, including regulations to prevent nonfunctional slack-fill. Section 5 of the FPLA states:

> For the purposes of paragraph (4) of this subsection, a package shall be deemed to be nonfunctionally slack-filled if it is filled to substantially less than its capacity for reasons other than (A) protection of the contents of such package or (B) the requirements of machines used for enclosing the contents in such package.

During 1970 and 1971, following enactment of the FPLA, FDA contracted with 11 State regulatory agencies to determine the extent to which slack-fill occurs in food packages at the retail level. Analysis of 11,000 samples revealed many packages with significant levels of slack-fill. In some instances, the empty space occupied as much as 80 percent of the volume of the container. However, this survey did not differentiate between functional and nonfunctional slack-fill.

The agency subsequently (from 1974 through 1976) initiated surveys at the manufacturing level to determine the extent to which slack-fill was justified by factors such as: Requirements of the filling machine, physical properties of the product, and normal product settling. These surveys focused on commodities that had: (1) Exhibited substantial slack-fill in the earlier State surveys, (2) significant production volumes, and (3) the highest incidence of consumer complaints. The commodities surveyed included: Candy, cookies, crackers, pretzels, potato chips, macaroni, spaghetti, cereal, dry dessert mixes, and prepared mixes.

Agency personnel, in cooperation with industry, observed various commercial manufacturing and filling operations and measured the degree to which product settled during shipping. They also collected data on variations in bulk density (weight per unit volume) for individual products and for product classes. In some instances (e.g., cereal and dry dessert mixes), FDA field personnel adjusted filling equipment or manually added additional product to containers in order to determine the effect of "overfill" on product quality. In other instances (e.g., a candy bar on a cardboard support with an outer wrap), the level of slack-fill was reduced by increasing the dimensions of the product. Overfilling packages to various degrees allowed FDA to identify the levels of slack-fill necessary for proper package closure and protection of the product and to determine the amounts of slack-fill that were likely to result from variations in the physical characteristics of the product and normal product settling. For the purposes of these studies, it was often easier to reduce slack-fill by increasing the fill of the container rather than altering the dimensions of the container.

Although the study was terminated before slack-fill had been fully studied in all the target commodities cited above, and no formal report was published, FDA collected sufficient data to determine that it is possible to distinguish between functional and nonfunctional slack-fill on a plant-by-plant basis for specific products in given container sizes.

At the same time, the agency noted that differences in the physical characteristics of a given product, including the need to protect the product from breakage, and precision of filling equipment result in a high degree of variability in the level of functional slack-fill within commodity classes. For example, functional slack-fill for macaroni products ranged from a low of 3.7 percent at manufacture and packaging to as much as 23.0 percent after shipping. Functional slack-fill levels for cereal products after shipping were even higher, ranging from 8.6 to 43.1 percent of the container volume. FDA concluded that many consumer commodities may have large levels of slack-fill that, although justified, might appear to be deceptive to consumers. FDA also observed that some products had greater slack-fill than could be justified by protection of the food or by requirements of the filling machine. A copy of the draft Compliance Program Evaluation for fiscal years 1975 and 1976 nonfunctional slack-fill surveys (7320.40 and 7320.65) is on file with the Dockets Management Branch (address above) under the above-referenced docket number.

The agency notes that some manufacturers employ label statements such as "Contents may settle during shipping" or "Contents sold by weight, not volume" to inform consumers that a package will probably appear to be less than full. Statements such as "A certain amount of air is packaged in each bag to act as a cushion against breakage" alert consumers as to the presence of slack-fill and provide

information on the function of the slack-fill.

Although section 5(c)(4) of the FPLA provides for the promulgation of regulations to prevent nonfunctional slack-fill in packages containing consumer commodities, FDA chose not to promulgate such regulations. Based on the preceding studies, FDA believed that establishing specific limits on the level of slack-fill of consumer commodities would, in many cases, involve values that were so high (e.g., as much as 63.8 percent for candy bars) that the regulations would serve no useful purpose. FDA also believed that such regulations could, in fact, encourage or legitimize a failure to minimize slack-fill on the part of some manufacturers. For example, a manufacturer with sophisticated equipment, capable of producing a product with a relatively low level of slack-fill, might decide to increase slack-fill in the product, taking advantage of a maximum slack-fill level that had been established based on less sophisticated packaging equipment. The agency also concluded that determining maximum allowable levels for functional slack-fill on a commodity-by-commodity basis would require considerable agency resources. Based on the preceding studies, FDA determined that it would not be appropriate to expend limited agency resources to develop regulations that would probably contribute little to improve implementation of section 403(d) of the act.

However, as stated above, the 1990 amendments require FDA to promulgate regulations to implement any provision listed in section 403A(a)(3) of the act that it determines is not being adequately implemented. Thus, in light of its determination that section 403(d) of the act is not being adequately implemented (see I.D. of this document), FDA has reconsidered its position on the need for regulations on nonfunctional slack-fill.

III. FDA Proposed Response

A. Introduction

As mentioned in section I.D. of this document, FDA has determined that section 403(d) of the act is not being adequately implemented. That section states that a food is misbranded if its container is so made, formed, or filled as to be misleading. Although FDA is addressing each of these aspects of section 403(d) of the act in proposed § 100.100, this rulemaking is primarily concerned with defining the circumstances in which the slack-fill within a package is nonfunctional and, therefore, constitutes misleading fill. The agency has tentatively decided not to elaborate on ways in which a container may be "made" or "formed" as to be misleading. The agency has tentatively concluded that these terms are straightforward and thus require little elaboration. This approach is consistent with that of several States that have chosen to establish regulations prohibiting misleading containers by elaborating only on what constitutes misleading fill. Furthermore, the IOM did not point to any particular problems emanating from the "made" or "formed" aspects of 403(d) of the act, nor did it recommend that the agency promulgate regulations with regard to these provisions. The agency invites comment on its approach and on whether it is necessary to elaborate on when a container is so made or formed as to be misleading to fully implement section 403(d) of the act.

B. Misleading Fill

The agency has long been aware of consumer dissatisfaction with slack-filled containers. FDA advises that, in many products, a certain level of slack-fill has a functional purpose (e.g., protecting the product) and, therefore, can be justified even though some consumers may perceive it to be misleading. The agency acknowledges that some products being marketed under existing Federal regulations may contain amounts of slack-fill exceeding that necessary to protect the product or required by the filling machine. The agency also acknowledges that in the cases that it has brought to enforce section 403(d) of the act, such as the *United States* v. *174 Cases * * * Delson Thin Mints*, 195 F. Supp. 326 (D.N.J. 1961), aff'd 302 F.2d 724 (3d. Cir. 1962), the phrase "misleading fill" has proven to be too vague to permit successful resolution.

Although FDA has established fill-of-container standards for a number of standardized foods such as canned oysters (21 CFR 161.145) and canned wet pack shrimp in transparent or nontransparent containers (21 CFR 161.173), the agency believes that standards of fill are not a practical way to implement the intent of section 403(d) of the act for all consumer commodities. Establishing specific limits on the level of slack-fill on a commodity-by-commodity basis would require considerable agency resources, much more than the agency has available. On the other hand, FDA believes that the action suggested by the IOM, i.e., to establish by regulation a general definition for nonfunctional slack-fill using the FPLA for guidance, has merit.

FDA believes that by establishing under section 701(a) of the act (21 U.S.C. 371(a)) a regulation that implements section 403(d), it could provide a general definition for nonfunctional slack-fill that would serve to define the circumstances in which fill is misleading under the act. By doing so, the agency would provide the guidance about the meaning of misleading fill that was requested by State officials and consumer groups in testimony before the IOM. This approach would also allow enforcement based on the capabilities of individual processing and packaging facilities and on the specific physical properties (e.g., bulk density, uniformity, tendency to settle, and need for protection) of individual products, rather than establishing maximum slack-fill values for classes of commodities that are necessarily too high to have any meaning. The agency believes that this proposed action will: (1) Provide guidance for consumers and manufacturers regarding what is functional slack-fill and what is not, (2) encourage industry to evaluate the amount of slack-fill in existing products and aid it in choosing the most appropriate processing and packaging methods for new products, and (3) increase consumer confidence that the amount of slack-fill in consumer commodities has a function. By ensuring adequate implementation of section 403(d) of the act, the proposed regulation will reduce those instances of misleading fill that may exist under current Federal regulations.

FDA tentatively finds that appropriate levels of slack-fill are those no greater than necessary to accomplish the intended functional effect in the packaged food product. For example, a candy bar may be packaged so that it is resting on a cardboard support with both candy bar and support within an outer wrapper. The support will determine the minimum length and width of the outer packaging, while the height of the package is determined by the height of the candy bar. The dimensions of the cardboard support and the outer wrapper must be such as to accommodate normal variations in the size and shape of the product. The cardboard support needs to be of sufficient size and strength to protect the product during shipping and handling. It may also be necessary for the outer wrapper to be longer than the support, so that neither the support nor the candy bar interferes with the efficient closure of the outer wrapper.

When a candy bar is packaged in this manner, some slack-fill is inevitable. The amount of slack-fill in the package will vary depending on factors such as the uniformity of the product and the capabilities of the packaging equipment. The proposed regulation is not intended to require manufacturers who are operating under current good manufacturing practices to change the physical characteristics of a food, nor is it intended to require manufacturers to purchase more sophisticated packaging equipment (proposed § 100.100(a)(2)).

FDA tentatively finds that slack-fill or the practice that results in slack-fill is justified to the extent that it performs such appropriate functions as protecting the contents of the container or meeting the necessary requirements of the filling machine. Slack-fill in excess of that required to perform a function, e.g., using a 6-inch cardboard support to hold a candy bar that is 3 inches long, however, is nonfunctional slack-fill and, therefore, misleading fill, even though the support may continue to perform a function such as protecting the product.

To address this situation, FDA is proposing to define "nonfunctional slack-fill." The agency tentatively finds that the definition of this term that appears in section 5(c) of the FPLA is adequate to differentiate between functional and nonfunctional slack-fill of the types described above. However, slack-fill may serve additional purposes (e.g., allowing a package to accommodate tamper resistant devices or modified atmosphere packaging to extend shelf-life) that were not anticipated when the FPLA was enacted. FDA believes that slack-fill related to modified atmosphere or tamper resistant packaging is covered by that portion of the proposed definition that allows slack-fill to protect the contents of a container (proposed § 100.100(a)(1)).

FDA notes that some slack-fill, e.g., slack-fill resulting from normal product settling, does not perform a function in a food. As such, it could be considered nonfunctional slack-fill. However, product settling is a normal, unavoidable process for many types of food (e.g., cereal and potato chips). Thus, slack-fill that results from product settling is a function of the physical properties of the product (e.g., the shape of the pieces of food), and of the way in which the product is filled into the container (e.g., loosely packed). For the purposes of this proposed rule, FDA tentatively proposes to exclude unavoidable slack-fill that results from normal product settling from the definition of nonfunctional slack-fill (proposed § 100.100(a)(3)).

In addition, advances in food technology and product development have resulted in a number of products with slack-fill that may be justifiable (i.e., performs a specific function) but may not be addressed by the definition of nonfunctional slack-fill in the FPLA. For example, consumer demand for convenience has led to the development of food products that may be cooked in, or eaten out of, the containers in which they are purchased. Thus, packaging for an instant soup must not only allow efficient closure of the package and protect the product during shipping, it must also have sufficient empty space to hold the hot water added by the consumer to hydrate the product. A package of microwavable brownies may contain a disposable tray in which the product is both mixed and cooked. Thus, the package would need to be large enough to accommodate a tray whose size was based, in part, on the size of the cooked brownies, not the amount of dry mix in the container.

FDA notes that convenience foods often require an increase in the size of the container relative to the amount of product within the container. For example, a box containing hot chocolate in single serving packages is usually larger than a box containing the same amount of bulk product without the secondary packaging. In addition, such products would be clearly labeled as to their contents (e.g., "Contains 6 single-serve packages" or "Package contains baking tray"). Therefore, the agency tentatively concludes that reasonable levels of slack-fill resulting from the practices described above perform a function in that they are necessary for convenient preparation or consumption of the product. However, such functions are not covered by the definition of nonfunctional slack-fill in the FPLA. Therefore, the agency is proposing to exclude, from the definition of "nonfunctional slack-fill," slack-fill that results from practices that are necessary for a package to perform a particular function (e.g., to aid in the preparation and consumption of a specialty food product), where such function is clearly declared on the label and is an integral part of the nature of the food (proposed § 100.100(a)(4)).

Gift products represent another category where packaging may serve functions other than to simply contain and protect the food. For example, some gift products (e.g., cheese and jellies in a basket or assorted biscuits in a teapot) consist of a food contained in a reusable household article that is itself part of the gift. In some instances, the food component of the gift product is packaged in a predetermined or standardized quantity before being placed in the reusable gift container. At the same time, the size of the reusable gift container (e.g., a teapot) may be a function of its intended use after the food component of the gift has been consumed.

Depending on the nature of the food and the type of gift container used, manufacturers will have varying degrees of control over the amount of slack-fill in such containers. For example, baskets are available in a wide range of shapes and sizes, allowing manufacturers to choose a basket that is appropriate for the amount of food contained therein. Other household items that may be desirable gift containers (e.g., coffee cups or teapots) are available in a more limited number of sizes. Furthermore, because part of the purchase of a gift product is the continued utility of the reusable container, and part of the purchase may include intangibles (e.g., aesthetics or sentiment resulting from the way in which the product is packaged), it is more difficult to differentiate between functional and nonfunctional slack-fill in these items as compared to conventional foods.

FDA tentatively finds that, in the case of such gift products, reasonable differences between the volume of the reusable gift container and the amount of food contained therein that result from the role of the gift container in the presentation of the food would not constitute misleading fill, even though such slack-fill might not have a specific functional effect such as protecting the product. FDA tentatively finds that exempting reasonable amounts of slack-fill in such gift products (i.e., food packaged in a reusable household item) from the definition of nonfunctional slack-fill would provide manufacturers with flexibility in packaging such products, while providing consumers with product choices. The agency invites comment on these tentative findings. Specifically, FDA requests comment on the appropriateness of establishing an exemption from the definition of nonfunctional slack-fill for gift products consisting of a food item combined with a gift container (i.e., a reusable household item) where the gift container serves to contain and protect the food, is part of the presentation of the food, and is to be usable after the food is consumed (proposed § 100.100(a)(5)).

FDA advises that the preceding discussion is concerned only with gift products that are packaged in reusable containers. The agency acknowledges that other types of gift products may also be packaged in containers that are designed to do more than simply

contain and protect the food. For example, when candy is packaged in a heart-shaped box, the shape of the box conveys a message to the receiver. Other products, e.g., chocolate covered cherries, may be packaged in a decorative plastic tray that not only protects the product but plays a role in the presentation of the food. The agency believes that manufacturers of such products have greater control over package design and filling operations with respect to minimizing slack-fill in these products as opposed to gift products in a reusable container whose size and shape is, in part, a function of its intended use after the food has been consumed. The agency also notes that, in the absence of a reusable gift container, the distinction between gift products, luxury items, and conventional food products appears to be subjective. Furthermore, although packaging such as a heart shaped box appears to play a role in the presentation of a food, the agency lacks sufficient information to establish criteria for distinguishing between functional and nonfunctional slack-fill in such products.

The agency invites comment on whether it would be appropriate to provide more latitude in determining that slack-fill in gift products is functional if the slack-fill is attributable to packaging that serves to contain the food and that plays a role in the presentation of the food but that is not intended for reuse after the food is consumed. The agency invites comment on criteria that it could use to distinguish between functional and nonfunctional slack-fill in such products and for such purposes. Comments should provide specific examples of products whose packaging includes slack-fill associated with the presentation of a food that should, or should not, be excluded from the definition of nonfunctional slack-fill as misleading fill. Comments should provide substantive arguments for or against such an exclusion and, if appropriate, contain criteria to be used in determining such exclusion.

FDA notes that product reformulations may change the density, weight, or volume of a product, sometimes drastically. For example, a package of gelatin mix sweetened with sugar may contain 3 oz of product. The same product sweetened with a high intensity sweetener may weigh only 0.5 oz. If the manufacturer uses the same package for both products, the package containing gelatin sweetened with the high intensity sweetener will contain a significantly greater amount of slack-fill. The agency notes that the increased slack-fill in the package containing 0.5 oz of product exceeds the amount of slack-fill that is required to perform such necessary functions as protecting the product and ensuring proper package closure in the package that contains 3 oz of product. At the same time, the agency notes that both packages of gelatin contain sufficient mix to provide the same amount of finished product. The agency tentatively concludes that, absent a functional effect, the portion of slack-fill within a container resulting from product reformulation (e.g., removal of a macronutrient such as sucrose) that reduces the volume of product in that container constitutes nonfunctional (misleading) slack-fill. The agency invites comment on this tentative conclusion and on the criteria that could be used to distinguish between functional (justifiable) and nonfunctional (misleading) slack-fill in a case such as this.

The agency also invites comment on the appropriateness of establishing an exemption from the definition of nonfunctional slack-fill for packages containing slack-fill that results from an inability to further reduce the size of the package. The agency notes that some food products (e.g., saffron and saccharin) are frequently sold in very small quantities for various reasons, including: Limited shelf-life, high cost per unit volume, or the need to use only a small amount of the product at any one time. To the extent that such foods must be sold in a package of some minimum size to accommodate required food labeling excluding any vignettes or other nonmandatory designs or label information, discourage pilfering, or facilitate handling, the resulting slack-fill may be a function of a minimum package size requirement. Comments on the need for an exemption for such packages should present specific examples of products that have a minimum package size requirement and whose packaging includes slack-fill that should, or should not, be excluded from the proposed definition of nonfunctional slack-fill. Comments should provide substantive arguments for or against such an exclusion and, if appropriate, contain criteria to be used in determining such an exclusion.

The agency invites comment on any other practices or developments that may result in slack-fill and that are not addressed by the language of the proposed definition of nonfunctional slack-fill. Comments should provide specific examples of containers that represent functional slack-fill versus nonfunctional slack-fill or misleading fill. When appropriate, comments should also include suggested wording to be used in this rulemaking to ensure that the examples are adequately covered by any regulation that FDA adopts. The agency also invites comment on the phrase "filled to substantially less than capacity" in proposed § 100.100(a). FDA intends this phrase to mean that any packages containing levels of nonfunctional slack-fill that are significant in proportion to the volume of the container would be misbranded. FDA requests comment on the appropriateness of this standard. The agency also requests comment on how to define "significant" in this context.

Finally, the agency invites comment on whether it makes a difference if a product is packaged in a container that allows consumers to fully view the contents of the container. Specifically, would nonfunctional slack-fill be misleading when consumers can clearly see what they are purchasing?

The agency believes that several factors, such as the cost of packaging materials, space required for storage and transport, and increased national interest in efficient packaging to reduce solid waste, will serve to reduce slack-fill in many commodities.

The agency believes that the proposed regulation will ensure adequate implementation of section 403(d) of the act, thereby, providing additional consumer protection against misleading fill and facilitating value comparisons on the part of consumers. Thus, section 403(d) of the act will become preemptive upon adoption of proposed § 100.100. This regulation, if adopted, will also provide State regulatory agencies, as well as FDA, with a uniform means of taking action against misleading containers. The agency also notes that section 4 of the 1990 amendments (21 U.S.C. 337) provides for State enforcement of section 403(d) of the act in Federal court. Consequently, manufacturers can expect that packaging will be treated uniformly throughout the States with regard to misleading containers.

Therefore, FDA is proposing § 100.100 *Misleading containers* in part 100 (21 CFR part 100) within a newly proposed subpart of part 100 to be entitled "Subpart F—Misbranding for Reasons Other Than Labeling." The proposed regulation states that food is misbranded if its container is so made, formed, or filled as to be misleading. It defines misleading fill as nonfunctional slack-fill. Finally, the proposed regulation includes criteria for use in determining whether slack-fill is functional versus nonfunctional.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Although not a labeling requirement per se, this action is closely related to food labeling and arises out of the misbranding sections of the act. In all other respects, this action comes within the exemption in § 25.24(a)(11). Moreover, although this action is not specifically designated in 21 CFR 25.22(a) and does not fall within the scope of the general provision (21 CFR 25.22(a)(19)), it could not significantly affect the quality of the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Economic Impact

FDA has examined the economic implications of the proposed rule on misleading containers and nonfunctional slack-fill as required by Executive Orders 12291 and 12612 and the Regulatory Flexibility Act. Executive Order 12291 compels agencies to use cost-benefit analysis when making decisions, and Executive Order 12612 requires Federal agencies to ensure that Federal solutions, rather than State or local solutions, are necessary. The Regulatory Flexibility Act requires regulatory relief for small businesses where feasible. The agency finds that this proposed rule is not a major rule as defined by Executive Order 12291. In accordance with the Regulatory Flexibility Act (Pub. L. 96–354), FDA has also determined that this proposed rule will not have a significant adverse impact on a substantial number of small businesses. Finally, any federalism issues that would require an analysis under Executive Order 12612 are resolved as a matter of law by section 6 of the 1990 Amendments.

A. Market Failure

FDA believes the current proposal cannot be justified on the grounds of market failure. Required net weight figures already provide information on package contents. Furthermore, if consumers object to the level of slack-fill in a given package, they can easily identify that product by brand name and refrain from purchasing that particular product in the future. However, FDA believes that the IOM report and comments on whether section 403(d) of the act is being adequately implemented establish that a situation in which rulemaking is required under section 6 of the 1990 amendments exists.

There are three primary alternatives available to FDA with respect to ensuring adequate implementation of section 403(d) of the act.

(1) Adopt a regulation that does not define nonfunctional slack-fill but only repeats the language of section 403(d) of the act.

(2) Define nonfunctional slack-fill as proposed, with possible additional exemptions such as the following: (a) Gift products in nonreusable containers, (b) new products, initially introduced, where appropriate packaging material and equipment are not already available, and (c) small businesses.

(3) Define not only misleading fill but also when a container has been made or formed to be misleading.

B. Costs

1. Repeat the language of section 403(d) of the act

This alternative serves as the benchmark for estimating the costs and benefits of the other alternatives; therefore, no costs or benefits will be estimated for this alternative.

2. Define nonfunctional slack-fill as proposed, with possible additional exemptions

Potential compliance costs to industry include designing and manufacturing new packages. FDA currently has no information on the number of firms that would be affected or on the cost, if any, of required package changes. FDA requests information on compliance costs to firms resulting from this alternative beyond the costs that would occur if FDA promulgates a regulation that repeats the language of section 403(d) of the act.

In addition, consumers may undergo a utility loss from a reduction in the variety of packages currently available. Although the utility loss per product is probably small, FDA believes this utility loss may be significant in the aggregate, compared to the utility loss from the reduction in the variety of packages that would occur if FDA promulgates a regulation that repeats the language of section 403(d) of the act. FDA requests information on consumer valuation of packaging variety.

This alternative includes a possible exemption for gift products in nonreusable containers. The cost of this alternative with this exemption is as above, less the compliance cost to manufacturers of these products and the utility loss to consumers from reducing the current level of variety in the packaging of these products. FDA cannot estimate this cost at this time because FDA has been unable to specify an operational definition of gift product. FDA requests comments on whether it would be appropriate to provide this exemption, on defining gift product, and on consumer dissatisfaction with the fill of these products.

This alternative also includes a possible temporary exemption for new products, initially marketed, where appropriate packaging material and equipment (that is, material and equipment that eliminate nonfunctional slack-fill) are not already available. The cost of this alternative with this exemption is as above, less the compliance cost to manufacturers of these products and the utility loss to consumers from the reduction in the current rate of introduction of new products onto the market. FDA cannot estimate this cost at this time and requests information on the effect of this proposal on the rate of introduction of new products onto the market in the absence of this exemption, and on consumer valuation of any change in the rate at which new products are introduced onto the market. FDA also requests information on whether it would be appropriate to provide this exemption.

In addition, this alternative includes a possible exemption for small businesses. Under the Regulatory Flexibility Act of 1990, FDA is required to consider relief for small businesses from regulation where feasible. The cost of this alternative with this exemption is as above, less the compliance cost to small businesses and the utility loss to consumers from a possible reduction in the competitiveness of small businesses. The fixed cost of developing and introducing new packaging and purchasing new packaging equipment is a significant cost for small businesses. In the absence of this exemption, small businesses will be less able to produce a wide variety of products and product sizes than large businesses. FDA cannot estimate this cost at this time. FDA requests information on the effect of this alternative on small business in the absence of a small business exemption. FDA also requests information on whether it would be appropriate to provide this exemption.

3. Define not only misleading fill but when a producthas been made or formed to be misleading

The costs of this alternative are identical in kind to the costs of defining nonfunctional slack-fill as proposed. FDA cannot estimate these costs without specifying the conditions under which a product has been made or formed to be misleading. However, since this alternative would place

additional restrictions on packaging beyond the restrictions that would occur if FDA promulgates a regulation that repeats the language of section 403(d) of the act or defines nonfunctional slack-fill as proposed, the compliance cost of this alternative will be greater than that of either of these other two alternatives. FDA requests comments on potential specifications of when a product is made or formed to be misleading, as well as on the costs of such specifications to industry, consumers, and society in general.

C. Benefits

1. Repeat the language of section 403(d) of the act

This alternative serves as the benchmark for estimating the costs and benefits of the other alternatives; therefore, no costs or benefits will be estimated for this alternative.

2. Define nonfunctional slack-fill as proposed, withpossible additional exemptions

Potential benefits of this alternative include a reduction in the incidence of differing interpretations of the language of section 403(d) of the act that might occur if FDA promulgated a regulation repeating the language of section 403(d). FDA cannot estimate this benefit at this time and requests information on the likely incidence and cost of differing interpretations of the language of section 403(d) of the act that might occur if FDA promulgated a regulation repeating the language of section 403(d).

Potential benefits of this alternative to consumers will result from the possible reduction in the incidence of consumer dissatisfaction with the fill of food containers. A certain amount of consumer dissatisfaction with slack-fill is likely to remain since the amount of slack-fill in general will continue to vary between packages of the same products (because of settling, product breakage, etc.), between different brands of the same product (because of different packaging technology and product characteristics), and between different products. FDA currently has no information on the level of consumer dissatisfaction with the fill of containers, or on the degree to which current consumer dissatisfaction concerns nonfunctional slack-fill rather than slack-fill in general. Thus, FDA cannot estimate this benefit at this time.

However, since consumers can identify offending packages by brand name and refrain from purchasing that product in the future (even when complaints of slack-fill cannot be addressed by current Federal or State law), it is unlikely that utility losses from this source are significant. The benefit to consumers from changes in the regulations addressing slack-fill should therefore be quite modest.

The benefit of this alternative with any of the three possible additional exemptions will be as above, less the value of the reduction in consumer dissatisfaction with the fill of the products covered in the exemptions. FDA cannot estimate the benefit of this alternative with the possible exemptions at this time and requests information on consumer dissatisfaction with the fill of the products specified in the possible exemptions.

3. Define not only misleading fill but when a producthas been made or formed to be misleading

The benefit of this alternative is a reduction in consumer dissatisfaction with the form or construction of packaging. FDA cannot estimate this benefit without specifying the conditions under which a product has been made or formed to be misleading beyond the current provisions of section 403(d) of the act. FDA requests comments on potential specifications of when a product is made or formed to be misleading, as well as on the benefits of such specifications to consumers.

D. Conclusion

In accordance with Executive Order 12291, the agency has analyzed the economic effects of this proposed rule and has determined that this rule, if promulgated, will not be a major rule as defined by that order.

In accordance with the Regulatory Flexibility Act, the agency has requested information that will allow the agency to consider a small business exemption. FDA requests information on the effect of this proposed rule on packaging costs of small businesses.

Finally, FDA requests information on any other economic functions slack-fill might fulfill other than facilitating the test marketing of new products and the preservation of packaging variety for gift products.

VI. Comments

Interested persons may on or before January 11, 1993, submit to the Dockets Management Branch (address above) written comments regarding this regulation. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 100

Administrative practice and procedures, Food labeling, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 100 be amended as follows:

PART 100—GENERAL

1. The authority citation for 21 CFR part 100 continues to read as follows:

Authority Secs. 201, 301, 307, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 337, 342, 343, 348, 371).

2. New subpart F, consisting of § 100.100, is added to read as follows:

Subpart F—Misbranding for Reasons Other Than Labeling

§ 100.100 Misleading containers.

In accordance with section 403(d) of the act, a food shall be deemed to be misbranded if its container is so made, formed, or filled as to be misleading.

(a) A container shall be considered to be filled as to be misleading if it contains nonfunctional slack-fill. "Slack-fill" is the difference between the actual capacity of a container and the volume of product contained therein. "Nonfunctional slack-fill" is the empty space in a package that is filled to substantially less than its capacity for reasons other than:

(1) Protection of the contents of the package;

(2) The requirements of the machines used for enclosing the contents in such package;

(3) Normal product settling during shipping and handling;

(4) The need for the package to perform a specific function (e.g., where packaging plays a role in the preparation or consumption of a food), where such function is inherent to the nature of the food and is clearly labeled; or

(5) The fact that the product is a gift product consisting of a food or foods combined with a reusable gift container, where the container is intended for further use after the food is consumed.

(b) [Reserved]

Dated: November 5, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

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